UNRAVELLING THE RULE AGAINST THE DISCRIMINATION OF FIELDS OF TECHNOLOGY UNDER THE PATENT RULES OF THE TRIPS AGREEMENT

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This dissertation is submitted for the degree of
Doctor of Philosophy

Jesus College November 2018

PREFACE

This dissertation is the result of my own work and includes nothing which is the outcome of work done in collaboration except as declared in the Preface and specified in the text.

It is not substantially the same as any that I have submitted, or, is being concurrently submitted for a degree or diploma or other qualification at the University of Cambridge or any other University or similar institution except as declared in the Preface and specified in the text. I further state that no substantial part of my dissertation has already been submitted, or, is being concurrently submitted for any such degree, diploma or other qualification at the University of Cambridge or any other University or similar institution except as declared in the Preface and specified in the text.

This thesis, including footnotes, does not exceed the permitted length.

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ABSTRACT

The rule against the 'discrimination' of fields of technology in TRIPS Article 27.1 has the potential to contradict the very technology-specific nature of patent law and to disallow the WTO membership from specifically addressing public interest and right-holder related concerns in a given field of technology. However, in *Canada- Patent Protection of Pharmaceuticals* (DS114), the only report by a WTO tribunal to have substantively dealt with this obligation to date, the Panel indicated that this rule is not absolute by formulating the concept of 'discrimination' in Article 27.1 as the 'unjustified imposition of differentially disadvantageous treatment'.

Nevertheless, this thesis argues that the Panel left some vital elements of its formulation open-ended, thereby making it difficult for a member to comprehend the circumstances in which the 'differential treatment' of field of technology constitutes 'discrimination'. To bring clarity to this ambiguity, this thesis interprets this obligation afresh and identifies some fundamental rationales that should have, and in fact appear to have influenced the Panel in its formulation. To this end, this thesis draws some vital influences from the context relating to WTO's substantive non-discrimination norms (National Treatment and Most-Favoured Nation Treatment) under its covered agreements that deal with goods and services and explores the type and extent of autonomy that has been preserved within TRIPS's Objectives and Principles. Whilst this thesis argues that an ambiguous obligation such the prohibition of 'discrimination' of fields of technology found in TRIPS Article 27.1 should be interpreted in a manner that seeks a balance between the obligation and the autonomy of the WTO membership, it also sheds light on the future of TRIPS's own National Treatment and Most-Favoured Nation treatment obligations for which WTO tribunals have not yet recognized the applicability of any general exceptions or justificatory concepts.

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CHAPTER 1

INTRODUCTION

A. THE BACKGROUND, RESEARCH QUESTION AND THE CONTRIBUTION

The rule against the 'discrimination' of *fields of technology* in TRIPS Article 27.1 applies in the context of availability and enjoyment of patent rights. Given the apparent breadth of the notion of 'discrimination' in this provision that has not been defined in the Agreement, the academic commentary rightly pointed out its potential to impede the ability of the WTO Members to tailor patent protection to address public interest and industry-specific concerns in any given field of technology. However, in *Canada- Patent Protection of Pharmaceutical Products* that is the only Report of a WTO tribunal to have substantively dealt with this non-discrimination obligation to date, the Panel noted that 'discrimination' in the context of Article 27.1 is the 'unjustified imposition of differentially disadvantageous treatment'.[1] Consequently, the academic commentaries recognized that the Panel acknowledged a degree of autonomy on the part of the WTO Members to subject fields of technology to differential treatment in the sphere of their patent laws without violating this obligation.[2]

So far, however, this autonomy has remained unexplored. This thesis argues that any such autonomy on the part of the Member States rests of the concept of *justification* that the Panel introduced into its formulation. The lack of any examination in the Report as to why it created this concept or how it should operate in this context continues to be vital gap in the comprehension of this obligation that has not been scrutinized in the academic literature or elsewhere. Hence, in the process of unravelling the rule against the 'discrimination' of fields of technology in TRIPS Article 27.1, the most vital research question this thesis addresses is as to what constitutes a legitimate justification in the context of this obligation. In order to explore this, the thesis entails a comprehensive analysis of the concept of justification. The practical aim is to provide insights to national policy makers who may wish to tailor patent protection to address important societal interests without violating this obligation. Accordingly, this thesis attempts to provide a comprehensive, comparative and better understanding of the scope of the

[1] Panel Report, *Canada- Patent Protection of Pharmaceutical Products*, WT/DS114/R, para. 7.94.
[2] See for e.g G. Dinwoodie and R. Dreyfuss, 'Diversifying without Discriminating: Complying with the Mandate of the TRIPS Agreement', *Mich. Telecomm. & Tech L. Rev.* vol. 13, no. 2, p. 445.

non-discrimination obligation relating to fields of technology than currently found in the literature.

Further, this thesis offers an important contribution to our understanding of the TRIPS Agreement more generally- as it demonstrates how its obligations can be interpreted and applied in a manner that acknowledges the autonomy of the Member States to pursue other vital public policy interests that have been recognized in its Objectives and Principles. The importance of a balance between TRIPS obligations and such autonomy on the part of the WTO Members has been acknowledged by the WTO Panel in its Report in *Australia- Plain Packaging*.[3] In this dispute, Australia was alleged to have violated, *inter alia*, TRIPS Article 20 by adopting its Tobacco Plain Packaging measures that affected the use of trade marks. Interpreting the notion of 'unjustified' in Article 20, the Panel noted the that the obligation *not* to encumber the use of a trade mark must be balanced against the right of the Members to adopt measures to protect public health that has been recognized in Article 8 (Principles) of the Agreement.[4] The need for such a balance would similarly resurface in an allegation based on the non-discrimination obligation in Article 27.1 as Members are likely to rely on some form of autonomy to defend allegations of inconsistency. Thus, the contribution made in this thesis as to how the concept of justification could be used to achieve an appropriate balance in the context of this non-discrimination obligation adds to the more general understanding of the requisite balance between TRIPS obligations and the autonomy of the Member States.

B. THE RESEARCH METHOD AND ORDER OF ANALYSIS

This thesis adopts a doctrinal approach to scrutinize this concept of justification as it argues that the Panel was influenced by the presence of similar legal concepts in the WTO's substantive non-discrimination obligations (National Treatment and Most-Favoured Nation) under the other covered agreements dealing with *trade* in goods and services that balance those obligations with a degree of autonomy on the part of the Member States. It is this trade context that influenced the Panel to reason that non-discrimination norms are not absolute in the WTO - which it appears to have rightly perceived as vital context when formulating the broad notion of 'discrimination' in TRIPS Article 27.1 as it is in fact a specie of trade.

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[3] Panel Report, *Australia- Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/R, WT/DS441/R, WT/DS456/R and WT/DS467/R.

[4] Ibid., para. 7.2403.

Accordingly, Chapter Two of this thesis scrutinizes the negotiation history specifically relating to this non-discrimination norm to demonstrate how this 'trade concept' was used to achieve a compromise when the negotiations concerning the patent section of TRIPS were at a deadlock, signaling that it is capable of acknowledging some autonomy on the part of the Member States. It also discusses the potential concerns surrounding the ambiguity of this obligation, which is followed by Chapter Three that examines the current lack of understanding in the WTO jurisprudence and the academic literature as to the concept of justification in the context of this obligation. Chapter Four adopts an interpretational approach to rationalize the reasons for the Panel's concept of justification by examining the balance that the substantive non-discrimination obligations under the WTO's covered agreements relating to trade in goods and services and their jurisprudence have sought to achieve with the autonomy of the Member States, and shows that the need for such a balance between the non-discrimination obligation in TRIPS Article 27.1 and the autonomy of the WTO Members preserved under the TRIPS Agreement led the Panel to create this concept in TRIPS Article 27.1. With a detailed analysis of the interplay between the TRIPS's Objectives and Principles, Chapter Four also identifies the constitutive elements of this concept under this provision. Chapter Five discusses the objectives, scope and application of three national measures currently found among the Members of the WTO that explicitly subject pharmaceutical inventions to special treatment in the sphere of patent law, followed by Chapter Six that examines their potential consistency with the developed understanding of the non-discrimination obligation. Chapter Seven entails a discussion of the implications flowing from Chapter Six to highlight the pragmatic lessons that are potentially relevant to policy makers who might intend to tailor patent protection consistently with this obligation and other theoretical implications that this could have on the other grounds of discrimination in Article 27.1 and TRIPS Agreement more generally. It concludes by highlighting the broader implications of this 'unravelling' of the non-discrimination obligation that shows the significance of a balance between WTO obligations and the autonomy of the Member States to protect national interests.

CHAPTER 2

THE ORIGINS OF THE RULE AGAINT DISCRIMINATION AND ITS CONCERNS

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property 1994 (TRIPS) that specifies substantive norms and standards relating to copyrights, trade marks, geographical indications, industrial designs, patents and undisclosed information is undoubtedly an exceptional multilateral agreement in the field of international intellectual property law. For the first time an international treaty specified, *inter alia*, the patent law obligations of the Members of the World Trade Organization (WTO) in relation to matters that were previously left unregulated multilaterally. It even ensured the effectiveness of its obligations by sanctioning trade retaliation through its unique Dispute Settlement mechanism in the event of non-compliance.

Of the many patent rules that TRIPS succeeded in setting-out is the general obligation in Article 27.1 to grant patents to inventions in *all* fields of technology, whether products or processes, provided they are new, inventive and capable of industrial application or utility. The same TRIPS provision also proceeds to state that patent rights *shall be available* and *enjoyable without discrimination as to the place of invention, field of technology, and whether the products are imported or locally produced*. This rule against discrimination was a novel creation by the TRIPS Agreement as such a concept was non-existent in the patent laws of any country at the time TRIPS was being negotiated. Accordingly, this Chapter demonstrates the *trade* origins of this obligation by examining the negotiation history that specifically relates to this obligation in a manner that has not been fully appreciated in the current commentaries of the Agreement. It also examines the concerns that have been raised in relation to this obligation to highlight the need for clarity with regards to its scope.

Thus, Part A begins with an examination of how intellectual property law standards entered the GATT/WTO framework. Part B examines the negotiation history that led to the creation of the rule against discrimination in Article 27.1. Part C discusses the concerns raised in the existing literature relating to the impact that this obligation could have on the TRIPS Agreement, which is followed by a conclusion in Part D that identifies the reasons why this thesis focuses on the particular facet of this obligation that prohibits 'discrimination' of fields of technology.

A. THE 'GATT-ABILITY' OF INTELLECTUAL PROPERTY LAW STANDARDS

TRIPS was not the first treaty that had the ambition of standardizing national intellectual property laws. It was preceded by the *Paris Convention for the Protection of Industrial Property* (1883) and the *Berne Convention for the Protection of Literary and Artistic Works* (1886) that still hold good through their various revisions even to date. This is particularly so as they have been incorporated into TRIPS to a large extent by reference. In fact, Thomas Cottier states that the Paris and Berne conventions were the humble beginnings of the ever-expanding field of international *economic* law.[1] These conventions, together with certain other treaties that had existed up until the GATT Ministerial mandate in Punta del Este, had several drawbacks that were aptly highlighted by the note prepared by the International Bureau of the World Intellectual Property Organization (WIPO) for the TRIPS Negotiation Group.[2] The main concerns for the industrialized nations in the field of patent law were the lack of harmonization relating to patentable subject matter and patentability criteria, the varied durations of patent protection and the broad discretion on the part of the signatory states to grant non-voluntary licences. The only standardization of patent law rules, if any, were between a few signatory states caused by the National Treatment obligations in Paris and Berne that required the *equal treatment* between nationals and foreigners. The lack of patent protection in the pharmaceutical, chemical, food and agricultural sectors and the discrimination of those fields for reasons of public health and nutrition were detrimental to the technology-intensive developed nations. The varying levels protection in the field of patents and other forms of intellectual property affected the market access of these developed nations, causing a loss to the derivable profits. These sentiments were evident in a submission made by Japan, United States and the then European Communities to the TRIPS Negotiation Group.[3] The fear of free-riding on the technologies and products of these developed nations created the *trade-related impact* of intellectual property that was deemed sufficient to bring it within GATT's trade-based framework. Accordingly, the Ministers of GATT declared at Punta del Este in 1986 that the Uruguay trade negotiations

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[1] T. Cottier, 'Working Together Towards TRIPS', in J. Watal and A. Taubman (eds.), *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations*, World Trade Organization, 2015, p. 79.

[2] GATT document MTN.GNG/NG11/W/24, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods- Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property- *Note Prepared by The International Bureau of WIPO*, 5 May 1988.

[3] GATT document MTN.GONG/NE11/W/7, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods- Submissions from Participant on Trade Problems Encountered in Connection with Intellectual Property Rights- *Submission by the European Communities, Japan and the United States*, 29 May 1987.

should include the subject of 'Trade-related aspects of intellectual property rights, including trade in counterfeit goods' that must, *inter alia*, seek to promote effective and adequate protection of intellectual property rights.[4] The contour of this mandate was to reduce the distortions and impediments caused to trade by the *lack of or insufficient* protection of intellectual property on the one hand, and to ensure that the enforcement of intellectual property rights do not by themselves constitute *barriers* to legitimate trade on the other. This was an indication that the minimum standards of intellectual property protection that was to be mandated by the Agreement had to meet this balance.

It took almost two years after the Punta del Este mandate for the TRIPS Negotiation Group to decide if its negotiations were to concern trade in counterfeit goods or if it should also address substantive norms concerning intellectual property law standards. Addressing the latter was the ambition of the United States from the very beginning. Consequent to the mid-term review in 1989, the Negotiation Group decided in favour of this broader mandate. Adrian Otten notes that there was still much disagreement as to whether the *results* of such negotiations should be *implemented* by GATT, which came to be known as the 'GATTability' problem of intellectual property.[5] The developing nations led by the 'Group of 14' that included India, Brazil and Argentina, agreed that GATT could tackle rules concerning counterfeit goods. However, they contended that substantive intellectual property law standards could not fall within the ambit of GATT/WTO as these had a significant impact on the developmental, technological and public interest objectives of those countries that made them more sensitive issues than mere trade. Therefore, they noted that substantive intellectual property law measures should come under the purview of a distinct international organization such as the World Intellectual Property Organization (WIPO). In a move that was to have significant implications for the future of the TRIPS negotiations and the final version of the Agreement itself, the Group of 14 developing countries presented a proposal in 1990 that consisted of two Parts. Part One entitled 'Intellectual Property and International Trade' that dealt with counterfeit goods, which in their opinion could come within the purview of GATT, and Part Two dealing with standards and principles relating to intellectual property, which was *ultra vires* the GATT.[6]

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[4] GATT document MIN.DEC, Multilateral Trade Negotiations- The Uruguay Round- *Ministerial Declaration on the Uruguay Round*, 20 September 1986.

[5] A. Otten, 'The TRIPS Negotiations: An Overview', in Watal and Taubman (eds.), n. 1, p. 55 at p. 64.

[6] GATT document MTN.GNG/NG11/W/71, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Communication from Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay*, 14 May 1990.

Since the presentation of this proposal, this dualistic position of the developing countries continued even beyond the Ministerial Meeting in Brussels in December 1990. However, after a few months following the Brussels Ministerial Meeting, many negotiators representing these developing countries repeatedly complained to the Chair of the Negotiation Group that unilateral pressure was being exerted upon them to agree to the 'GATTabiliy' of intellectual property. This is particularly evident in the GATT Secretarial Notes on the TRIPS Negotiation Group meetings held on the 27th and 28th June 1991.[7] Notwithstanding such complaints, they eventually 'agreed' to the inclusion of substantive intellectual property law norms into the trade discipline that materialized with the Dunkel Draft of the Agreement in late 1991,[8] which continued into the final version of the Agreement.

Much has been written about the pressure exerted by the North in the final phases of the TRIPS negotiations, the discussion of which is beyond the scope of this thesis.[9] However, it is pertinent to note that notwithstanding such pressure to bring substantive intellectual property norms within the ambit of TRIPS and WTO, it is too simplistic and inaccurate to state that the Agreement is purely a device of the North. Conversely, as Antony Taubman notes, the TRIPS Agreement has:

> … proven to be a nuanced and balanced instrument and an expression of sound policy thinking, and it can still today enable fair and balanced public policy and defend against the excessive influence of sectoral interests and specific actors in domestic policy-making.[10]

Taubman states that the reason for this is that for the first time in the history of international intellectual property law, negotiators from the developing nations were able to build *public policy safeguards* into the text of an international treaty.[11] The safeguards that he speaks of are the Objectives and Principles respectively enshrined in Articles 7 and 8 of the Agreement.

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[7] GATT document MTN.GNG/TRIPS/1, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 27 and 28 June 1991*, Note by Secretariat, 25 July 1991, para. 4, 5.

[8] GATT document, MTN.TNC/W/FA, Trade Negotiations Committee, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, 20 December 1991, Annex. 3, [hereinafter referred to as 'Dunkel Draft'].

[9] For a detailed analysis of the North-South and North-North debates relating to TRIPS negotiations see C. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, 2007, pp. 1-18; D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Fourth edition, Sweet & Maxwell/Thomson Reuters, 2012, pp. 3-31; N.P. de Carvalho, *The TRIPS Regime of Patents and Test Data*, Second edition, Kluwer Law International, 2014, pp. 1-29.

[10] A. Taubman, 'Thematic Review: Negotiating "trade-related aspects" of Intellectual Property Rights', in Watal and Taubman (eds.), n. 1, p. 15 at p. 23.

[11] Ibid.

Article 7 provides as follows:

> The protection and enforcement of intellectual property rights should contribute to *the promotion of technological innovation* and to the *transfer and dissemination of technology*, to the *mutual advantage of producers and users of technological knowledge* and in a manner *conducive to social and economic welfare*, and to a *balance of rights and obligations*.[12]

Article 8.1 provides as follows:

> Members may, in formulating or amending their laws and regulations, adopt measures *necessary to protect public health and nutrition*, and to *promote the public interest in sectors of vital importance to their socio-economic and technological development,* provided that such measures are *consistent with* the provisions of this Agreement.[13]

Moreover, the Preamble of TRIPS, *inter alia*, states as follows:

> *Recognizing* the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;
>
> *Emphasizing* the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

The inclusion of these provisions demonstrated a significant accomplishment on the part of the developing world. The very body of the Agreement spells out the objectives of protecting intellectual property rights and preserves the autonomy on the part of the WTO Members to address other vital policies such as public health and nutrition that are potentially affected by intellectual property law rules. The growing significance of these provisions in the interpretation and implementation of the Agreement will be examined later in thesis, but it suffices to note at this juncture that although the 'GATTability' of substantive intellectual property rules were seen apprehensively by the developing world, the inclusion of these provisions alleviated their fears. As Taubman notes, it is probably the presence of these provisions that indicate the balance sought by the Agreement that have, save in the case of the

[12] Emphasis added.
[13] Emphasis added.

HIV/AIDS epidemic and the problem of access to medicine, worked to ensure that the severe consequences that were expected by many opponents of the Agreement have not materialized.

B. INTRODUCING THE NON-DISCRIMINATION OBLIGATION TO THE PATENT LAW RULES

The principal objective of establishing the General Agreement on Tariff and Trade (GATT) in 1947 was to promote global economic prosperity, *inter alia*, by eliminating discriminatory treatment in international trade. The type of discrimination that initially caught the attention of the GATT negotiators was that caused by trade restrictive practices of certain countries that disadvantaged *foreign* products. Such practices came to be referred to as 'distortions and impediments to international trade'. The reason for international intervention to eradicate such practices is succinctly explained by Peter Van der Bossche and Werner Zdouc in the following manner:

> … discrimination in matters relating to trade breeds resentment and poisons the economic and political relations between countries. Moreover, discrimination makes scant economic sense as, generally speaking, it distorts the market in favour of goods and services that are more expensive and/or of lower quality.[14]

With the expansion of GATT/WTO influence to embrace services, investments and intellectual property, the principle of non-discrimination had to operate as one of the basic principles of WTO law that applied to all areas. Thus, it was included to the Preamble to the *Marrakesh Agreement Establishing the World Trade Organization* (WTO Agreement) which identifies 'the elimination of discriminatory treatment in international trade relations' as one of the means by which the WTO is meant to achieve trade liberalization. Accordingly, the substantive non-discrimination norms of National Treatment (NT) and Most-Favoured Nation Treatment (MFN) were adapted to the contexts of all the Agreements annexed to the WTO Agreement, and TRIPS was no exception. While the NT obligation was not novel to international intellectual property law at the time, as the Paris and Berne Conventions contained similar provisions, the introduction of the MFN obligation was a maiden accomplishment. However, these were insufficient in the field of intellectual property in the light of the concerns of the proponents of TRIPS. Firstly, rarely did countries offer preferential treatment to foreigners that

[14] P. Bossche and W. Zdouc, *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, Third edition, Cambridge University Press, 2013, p. 315. Footnote omitted.

triggered the MFN obligation. Secondly and more significantly, many countries did not recognize certain types of intellectual property rights even of their own nationals rendering the NT obligation to be insufficient. These reasons justified the inclusion of substantive intellectual property law standards into TRIPS that must be adhered to by the members of the WTO.

Daniel Gervais observes that the negotiation of the patent section was the most difficult.[15] Detailed commentaries on the negotiations of TRIPS's patent rules have already been presented by many academics,[16] and therefore, this section does not aim to repeat such analyses. However, it attempts to provide a glimpse of the much-tangled context in which the non-discrimination rule in TRIPS Article 27.1 found its legislative footing in the Dunkel Draft of the Agreement, which is still very much an area of the negotiations that has not yet been fully understood.

A sense of how the GATT/WTO proponents perceived the inordinate state of international patent law in the pre-TRIPS era is accurately described by Nuno Pires de Carvalho, who states that the most serious obstacle against *trade in goods* was:

> …the *discriminatory* treatment of certain fields of technology as regards patents and, in particular, non-availability of patent protection in the chemical and pharmaceutical fields.[17]

The TRIPS Negotiation Group encountered the concept of 'discrimination' in *intellectual property law* soon after the Punta del Este mandate when it was assembling factual information concerning the then state of international intellectual property law. According to Adrian Otten,[18] it was during these meetings that the Group first received contributions from the World Intellectual Property Organization (WIPO). Consequent to these meetings, the GATT Secretariat compiled a paper[19] which condensed the WIPO's contributions and the various concerns raised by the delegates. Although this compilation paper was not made available to the public, Otten describes that it had four distinct headings, the second of which was 'Issues in Connection with the Availability and Scope of Intellectual Property Rights'. Sub-section (c)

[15] Gervais, n. 9, p. 428.
[16] See generally Carvalho, n. 9; Correa, n. 9; Gervais, n. 9; Also see J. Malbon, C. Lawson and M. Davison, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary*, Edward Elgar, 2014, pp. 405- 565.
[17] Carvalho, n. 9, p. 245. Emphasis added.
[18] Otten, n. 5, p. 60.
[19] GATT document MTN.GNG/NG11/W/12, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods- *Compilation of Written Submissions and Oral Statements*- Prepared by the Secretariat, 11 August 1987.

of this heading was entitled '*Discrimination* in the Availability and Scope of Intellectual Property Rights'.

With specific regard to the state of international patent law at that time, WIPO indicated to the TRIPS Negotiation Group that certain fields of technology were completely excluded from patent protection in certain national jurisdictions.[20] The most notable of such fields were pharmaceuticals, food and agrochemicals. WIPO also highlighted that there were several divergences between countries with regard to the scope of patent rights and the duration of patent protection. Nevertheless, WIPO did not refer to such exclusions or limitations as being 'discriminatory'. On the contrary, it showed that the signatory states were entitled to make such exclusions and limitations under the Paris Convention that governed international patent law at that time as they had a substantial level of discretion to decide what was patentable, the patentability criteria, the scope of patent rights and their duration. Such a state of international patent law was a serious source of concern to the proponents of TRIPS. As Catherine Field states in her account of the negotiations, TRIPS was aimed to address:

> …the lack of consistency in the level of protection, weak standards and uncertainty over the protection of new technologies.[21]

These concerns were particularly evident in the submissions made to the Negotiation Group by the EC, Japan and US. For example, the EC noted:

> Specific exclusions from patentable subject matter, in particular, those relating to food, chemical and pharmaceutical products have exposed Community firms to unfair competition in certain important export markets. The fact that certain countries grant only process, as opposed to product, patents in the chemical sector can give rise to "counterfeiting" which often cannot be the subject of judicial proceedings.[22]

Further:

> National laws limiting the lifetime of patents to sometimes wholly inadequate periods, such as periods of only five years, have likewise had a negative impact on certain exports.[23]

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[20] Note prepared by the International Bureau of WIPO, n. 2, pp. 2-11.
[21] C. Field, 'Negotiating for the United States', in Watal and Taubman (eds.), n. 1, p. 129 at p. 131.
[22] Submission by the European Communities and Others, n. 3, p. 3.
[23] Ibid.

Similarly, Japan stated that:

> Inventions made by Japanese enterprises are used freely by third parties due to the impossibility of their protection by patents. Problems of "unpatentable subjects" (exceptions from patent protection) are especially serious, as there are many countries which do not grant any patents at all or grant patents only or the manufacturing process in such fields as chemicals, pharmaceuticals, etc. Which require a vast amount of funds for research and development.[24]

Particularly with regard to the scope of patent rights, the US submitted that:

> Many countries put limitations on the rights that are offered. For example, certain countries do not allow:
>
> (i) Patents for new uses of known products or compounds;
>
> (ii) Patents for chemical compounds or compositions. Patents are sometimes issued for the latter but not the former.[25]

Evidently, securing patent protection for pharmaceuticals was of utmost importance to Japan, EC and US. Carlos Correa states that this was so important that the very existence of TRIPS is probably attributable to securing patent protection for pharmaceutical products.[26] These patent law related concerns of these industrialized countries were subsequently addressed by many provisions in the final version of the Agreement, but most notably by Article 27. TRIPS Article 27 substantially limited the discretion that countries had enjoyed under the Paris Convention, which is why Carvalho refers to it as 'the core provision'.[27] The first sentence of Article 27.1 provides as follows:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

The general rule is that patents shall be available to inventions in all fields of technology, provided they are new, inventive and capable of industrial application. The two *provisos* mentioned in this provision relate to certain specific permissible exclusions. Article 27.2

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[24] Ibid., p. 8.
[25] Ibid., p. 18.
[26] Correa, n. 9, p. 271.
[27] Carvalho, n. 9, p. 245

permits exclusions on the ground of *public ordre* or morality, for the protection of human, animal, plant life or health and the preservation of the environment. Article 27.3 allows exclusions for methods of treatment and inventions concerning plants, animals and micro-organisms. Thus, no longer were WTO Members entitled to deny patents for pharmaceuticals or agrochemicals. This was a 'major concession'[28] made by the developing members given that they firmly insisted on preserving their right to exclude certain inventions in the light of vital public interests. This is evident from the very first Anell Draft[29] and up until the Brussels Draft[30] of the Agreement, although they subsequently let go of their position between the Brussels Ministerial meetings and the Dunkel Draft in late 1991. Together with a uniformed patent term mandated by TRIPS Article 33 that requires WTO Members to provide a twenty-year term of patent protection and the standardized scope of rights for patented products and processes in Article 28, the first sentence of Article 27.1 addressed many of the apprehensions of the industrialized countries.

Naturally, this victory on the part of the proponents of TRIPS makes one question the reason for including the rule against 'discrimination' found in the second sentence of Article 27.1 which can now be introduced as follows:

> Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, *patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced*.[31]

Articles 65 and 70 provide for certain transitional arrangements for developing WTO members, and paragraph 3 of Article 27, as explained before, specifies certain permissible patent exclusions for methods of treatment and other animal, plant and micro-organism related inventions. Subject to these specific exceptions, the second sentence of Article 27.1 lays down a unique non-discrimination obligation that requires patent rights to be *available* and *enjoyable* without 'discrimination' on three grounds: place of invention, field of technology and place of production. The 'availability' of patent rights refers to the patent eligibility and patentability

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[28] Correa, n. 9, p. 275.
[29] GATT document MTN.GNG/NG11/W/76, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods- Status of Work in the Negotiating Group- *Chairman's Report to the GNG*, 23 July 1990, Section 5, Article 1.5B, [hereinafter referred to as 'Anell Draft'].
[30] GATT document MTN.TNC/W/35/Rev.1, Trade Negotiations Committee- *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, 3 December 1990, Article 30.3.b, [hereinafter referred to as 'Brussels Draft'].
[31] Emphasis added.

criteria, whereas the 'enjoyment' of patent rights refers to the enforcement and scope of rights that are conferred.

One cannot deny the fact that this seems strange as the patentability criteria, scope of rights and duration of patents have already been standardized by the other provisions of TRIPS. Those provisions already serve to ensure that the patentability criteria, scope of rights and the duration of patent protection cannot be applied differently to different fields of technology. On the other hand, one cannot also ignore the fact that this non-discrimination rule does not only speak of discrimination based on 'fields of technology'. It even prohibits 'discrimination' based on the 'place of invention' and 'place of production'. This signals the fact that this non-discrimination norm in which the concept of 'discrimination' has been left completely undefined in the Agreement was not merely meant to reinforce the other provisions of the Agreement, but to address something that could *not* be resolved by any one of them. This is where the negotiations that specifically relate to the non-discrimination obligation becomes vital to comprehend.

In WIPO's communication to the Negotiation Group it had noted that in addition to the exclusion of certain fields of technology from the patents systems and the limitations imposed on the patent rights of certain fields of technology, several countries at that time had adopted broad mechanisms relating to *compulsory licences* of patented inventions. WIPO had noted that such mechanisms were consistent with the Paris Convention. The Paris Convention in its Stockholm Revision stated that:

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.[32]

Thus, there were no limitations on the right of countries to determine the grounds on which compulsory licences could be issued, save in the case of those issued in the event of 'failure to work or insufficient working'. The Stockholm Revision of the Paris Conventions introduced that in such cases a licence cannot be applied for until the expiration of four years from the filing date, or three years from the grant of a patent, whichever is later, and should not be granted in any event if the patentee could justify his inaction by *legitimate reasons*.[33]

[32] Section 5A(2), The Paris Convention for the Protection of Industrial Property, 1883 (as revised in Stockholm and amended in 1979).
[33] Ibid., Section 5A(4).

Nevertheless, the concept of 'legitimate reasons' had not been defined in the Convention and some countries did not accept technological and commercial obstacles as being sufficient to justify non-working. Accordingly, WIPO highlighted that *non-voluntary* licences for non-working were provided for by the laws of 'a vast majority' of countries that were parties to the Paris Convention with the US being a 'notable exception'.[34] Additionally, WIPO highlighted that several countries permitted such non-voluntary licences for the following reasons:

- In the public interest,
- On grounds such as abuse of monopoly, the satisfaction of the reasonable requirements of the public, economic development, the development of international trade, the needs of export markets, the violation of antitrust laws,
- In the interest of public health, or in the case of inventions relating to food or to medicines,
- In the interest of national defence,
- State use.[35]

Such broad compulsory licences were considered to be akin to 'distortions and impediments' to trade for the more industrialized Members during the TRIPS negotiations. The most pressing concerns for the EC, Japan and US were the grant of non-voluntary licences due to the lack of or insufficient local working, which many developing Members synonymized for *local manufacture,* and the practice of *automatic compulsory licences* in certain jurisdictions that applied to certain types of products. Jayashree Watal, a representative of India, states that a measure that these three industrialized Members repeatedly flaunted as an example of the latter was India's automatic licence of right system that applied to food and pharmaceuticals.[36] These industrialized Members perceived such broad compulsory licencing mechanisms to be detrimental to their pharmaceutical industry. In its submissions to the Negotiation Group together with Japan and US, the EC even included a separate section titled 'Compulsory Licensing of Pharmaceutical Patents', which stated as follows:

> Compulsory licensing of pharmaceutical patents before products have enjoyed the necessary minimum period of exclusivity in the market have also *depressed sales of the patented product and had a negative impact on the recovery of the*

[34] Note prepared by the International Bureau of WIPO, n. 2, p. 10.
[35] Ibid.
[36] J. Watal, 'Patents: An Indian Perspective', in Watal and Taubman (eds.), n. 1, p. 295 at p. 306.

> *considerable investment needed to sustain innovation in the pharmaceutical sector*. In addition in the case of compulsory licensing the level of royalty obtained is often significantly lower than that which would have been negotiated in the context of contractual licensing. In certain countries compulsory licences are granted systematically without having regard to whether the invention is worked or not. [37]

In a similar vein, US submitted:

> Some countries issue compulsory licenses while at the same time excluding the foreign patent holder from importing goods covered by the patent. This can be particularly burdensome when the country also controls investments, so the foreign patentee is unable to establish a subsidiary in the country to produce its products.
>
> Compulsory licensing provisions allow a foreign government to legally revoke the patent holder's exclusive rights to produce the licensed product. *United States pharmaceutical manufactures find that some countries allow compulsory licensing two years after the patent is granted*. Other countries' laws actively foster compulsory licensing agreements and allow for a patent to lapse after two years from issue…
>
> …In at least one country, compulsory licenses are sometimes issued to local nationals despite local working by multinationals.[38]

Given this detrimental impact allegedly caused by compulsory licences particularly to their pharmaceutical industries, limiting the availability of compulsory licences under the TRIPS Agreement became another significant objective for US, Japan and EC. In this context, Watal notes that they initially wanted to ensure that the Members adhere to the Stockholm Revision of the Paris Convention. She states:

> It seems that, for all three, the level of ambition on the working requirements and compulsory licences in 1987-8 was only to get all countries to adhere to the Paris Convention 1967 standard of time limits before issuing a compulsory licence or direct non-revocation of patents on grounds of non-working. Even in later submissions, when the United States wanted to limit the grounds for

[37] Submission by the European Communities and Others, n. 3, p. 4. Emphasis added.
[38] Ibid., pp. 18-19. Emphasis added.

> compulsory licences to declared national emergency and adjudicated violation of antitrust laws, while not accepting such limitations for government use, the only prohibition the United States sought for non-working of patents was against revocation.[39]

Subsequently, they were even more discontented with compulsory licences, perhaps attributable to the active lobbying by the pharmaceutical industry. This persuaded the industrialized Members to attempt to regulate compulsory licences even further than the Paris Convention by proposing provisions to explicitly recognize the ability of patentees to justify non-working due to 'legal, technical or commercial reasons'.[40] However, the more radical proposals came from US. As reflected in one of the alternative texts proposed in the Anell Draft, US sought to limit the *grounds* of issuing compulsory licences to two circumstances: to remedy an adjudicated violation of competition law and to address a declared national emergency.[41]

On the other hand, the developing countries did not want their right to issue compulsory licences to be restricted in any manner and submitted that they should be able to issue licences even in the event of non-working which meant the lack of local manufacture.[42] This stance that was traceable to the original proposal of the Group of 14 developing countries[43] was even reflected in their proposal to the Anell Draft that provided as follows:

> Nothing in this Agreement shall be construed to prevent any PARTY from taking any action necessary: (i) for the working or use of a patent for governmental purposes; or (ii) where a patent has been granted for an invention capable of being used for the preparation or production of food or medicine, for granting to any person applying for the same a licence limited to the use of the invention for the purposes of the preparation or production and distribution of food and medicines.[44]

The conflict in the proposals relating to compulsory licences is a fine example of how TRIPS negotiations did not only concern North-South debates, but also those between North-North. In relation to the endeavor of US in this context, Watal states that after the Anell Draft, the US

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[39] Watal, n. 36, p. 302.
[40] Anell Draft, n. 29, Section 5A.3.2.
[41] Ibid., Section 5A.2.
[42] See for example GATT document MTN.GNG/NG11/27, Negotiating Group on Trade Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods- *Meetings of Negotiating Group, 1 November 1990*- Note by the Secretariat, 14 November 1990, para. 4.
[43] See Communication from Argentina and Others, n. 6, Part II, Article 6.
[44] Anell Draft, n. 29, Section 5B.

managed to secure the support of a number of Commonwealth countries to limit the grounds on which compulsory licences could be issued. She states:

> Almost overnight, India became isolated in its opposition to limiting the grounds for compulsory licences to remedy a declared national emergency or adjudicated cases of anti-competitive practices.[45]

Nevertheless, this setback for countries like India was temporary. Around March 1990 India submitted a room document that renamed the compulsory licensing provision 'Use Without Authorization of the Right Holder', which combined provisions on compulsory licences and government use. The government use provision that influenced this proposal was of the US that recognized a significant level of power on the part of the US government to use a patented invention. By coupling such government use with compulsory licences, this room document recognized a significant level of discretion on the part of the Members to determine the grounds on which such licences could be issued. This proposal gained support from many countries including Japan, EC and Canada, as Watal notes, because the US government use provision was hurting their industries.[46] This resulted in the US delegation failing in its attempt to limit the grounds for the issuance of compulsory licences. This was a major victory for the developing countries. However, it did *not* mean that measures like India's licence of right system were going to survive the TRIPS Agreement as this was when the rule against 'discrimination' in Article 27.1 started to raise its head in the negotiations.

In the days that followed, industrialized country Members continued in their attempt to introduce the time limits in the Stockholm Revision of the Paris Convention and to specify the legitimate reasons for the non-working of patented inventions. This is reflected in the Brussels Draft of December 1990.[47] It was during this period that the concept of *non-discrimination* was first introduced into the draft texts of the Agreement. For the first time in the history of the negotiations, the Brussels Draft included the language of non-discrimination in the following manner:

> Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, *in all fields* of technology, provided that they are new, involve an inventive step and are

[45] Watal, n. 36, p. 304.
[46] Ibid., pp. 304-306.
[47] Brussels Draft, n. 30, Article 34(n).

> capable of industrial application.' [Patents shall be available without discrimination *as to where the inventions were made*.][48]

Non-discrimination based on the *place of invention* at this stage of the negotiations was to ensure that foreign inventors were not discriminated vis-à-vis local inventors. It was *broader* than the National Treatment obligation as it required patents to be available to both locals and foreigners, irrespective of where the 'invention' took place. However, the fact that this was bracketed, together with the comments accompanying the draft, demonstrated that this was not yet finalized. The same draft contained yet another and a more detailed non-discrimination provision in the section on compulsory licences. Although India's successful intervention ensured that the grounds were not limited, one of the conditions for such licences in the Brussels Draft was as follows:

> Laws, regulations and requirements relating to such use may [not] discriminate between fields of technology or activity [in areas of public health, nutrition or environmental protection or where necessary for the purpose of ensuring the availability of a product to the public at the lowest possible price consistent with giving due reward for the research leading to the invention].[49]

The fact that such compulsory licences should *not* be discriminatory was still an active issue, and it is strange that the commentary in the Brussels Draft did not make any mention of this. The second bracketed section is also interesting as it set-out the reasons why some Members might seek to 'discriminate' fields of technology in the issuance of compulsory licences. In the meantime, the negotiations for the more streamlined Stockholm type compulsory licensing mechanism for non-working was at a deadlock as the developing country Members were not willing to make any more compromises at this stage of the negotiations. As Piragibe dos Santos Tarrago, a then negotiator for Brazil explains, preserving the liberty that Brazil enjoyed under the Paris Convention to grant licences for non-working was vital to ensure that patent owners did not justify their patent monopoly by mere importation.[50] As the developing country Members were not agreeable to the inclusion of the Stockholm criteria, nor to the softening of the 'legitimate reasons' to justify non-working, Catherine Field notes that the Chair of the Negotiating Group proposed a compromise that was based on the *trade concept* of non-discrimination. She states:

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[48] Ibid., Article 30.1. Emphasis added.
[49] Ibid., Article 34(k).
[50] P. Tarragô, 'Negotiating for Brazil', in Watal and Taubman (eds.), n.1, p. 239 at p. 247.

> Building on the *trade concept of non-discrimination*, the Chair of the Negotiating Group proposed compromise language that, subject to the transitional provisions in the agreement, "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced". Delegations were asked if they could live with this compromise, taking into account the provisions on limitations and exceptions and compulsory licences. This language now appears in the TRIPS Agreement.[51]

As she states, this trade concept of non-discrimination found in Article 27.1 first manifested itself in the Dunkel Draft of the Agreement[52] to reach a compromise when the negotiations were at a deadlock. However, its wording was such that the concept of 'discrimination' was given a very broad scope. Its manifestation in the Dunkel Draft deleted the previous draft non-discrimination obligations found in two provisions of the Brussels Draft which specified that 'Patents shall be available *without discrimination* as to where the inventions were made' and that compulsory licences should not be '*discriminating* between fields of technology or activity'. Those deleted provisions were subsumed into this non-discrimination norm, which simultaneously widened their scope. Hence, compared to the Brussels Draft, patents should not only be available without discrimination as to the place of invention, but 'available and enjoyable' without 'discrimination' on the grounds of field of technology, place of production and place of invention. The ground of 'place of production' was a completely new addition. More significantly, the prohibition of discrimination of 'fields of technology' went beyond the context of compulsory licences, which was originally intended under the Brussels Draft. Thus, as Watal notes, this wide-ranging norm ended the Indian licence of right system that applied to food and medicine.[53]

It is in this manner that this broad concept of 'discrimination' found its footing in Article 27.1 of the TRIPS Agreement. The preceding discussion shows that while specific forms of non-discrimination were initially introduced during the negotiations to address certain issues concerning compulsory licences and local working requirements, its scope was abruptly widened by a broad concept that prohibits 'discrimination' with regard to the availability and enjoyment patent rights based on three grounds mentioned in Article 27.1. As Catherine Field notes, this *trade* concept was introduced to the field of patent law to serve as a compromise solution when the parties could not agree on certain rules relating to compulsory licences. This

[51] Field, n. 21, p. 142. Emphasis added.
[52] Dunkel Draft, n. 8, Article 27.1.
[53] Watal, n. 36, p. 307.

thesis will later show that in the absence of any similar non-discrimination norm in any other multilateral treaty dealing with patent law, these origins of the obligation have influenced the current formulation of this obligation at the WTO level in the hope of identifying the type of compromise that was meant to be struck by this norm.

C. 'DISCRIMINATION' AND ITS POTENTIAL IMPACT ON THE TRIPS AGREEMENT

- *POTENTIAL EFFECTS OF PROHIBITING 'DISCRIMINATION' BASED ON 'FIELDS OF TECHNOLOGY' AND 'PLACE OF PRODUCTION'*

The prohibited grounds of discrimination in Article 27.1 that have received most attention in the academic literature are 'fields of technology' and 'place of production'. This is because the meaning attributable to the concept of 'discrimination' in these contexts has the potential to impede the ability of the WTO Members to utilize the policy spaces preserved under the Agreement and implement TRIPS's minimum patent law standards in a manner that best fits their individual circumstances. The following paragraphs show that some of those policy spaces threatened in this manner concern a WTO Member's ability to determine the substantive content of the patentability criteria, to grant compulsory licences of patented inventions and to permit limited exceptions to patent rights.

With the patentability criteria being set-out in the first sentence of Article 27.1, the prohibition of 'discrimination' of 'fields of technology' with regard to the 'availability' of patent rights prevents a WTO Member from applying *different* patentability criteria to different fields of technology. Gervais notes that it prohibits the treatment of different inventions in a different manner when examining their patentability.[54] Thus, a WTO Member *cannot*, for example, use different patentability criteria to inventions in the field of biotechnology. However, many academics including Gervais himself notes that this does not prevent a member from *applying* the patentability criteria set-out in Article 27.1 in a way that accords differential treatment to fields of technology as the concepts of novelty, inventive step and industrial application are by themselves left undefined under the Agreement.[55] As Carlos Correa states:

[54] Gervais, n. 9, p. 430.
[55] Ibid.

> …the determination of the ways in which these patentability standards are interpreted and applied is one of the *most important flexibilities left by the TRIPS Agreement*.[56]

Similarly, the UNCTAD- ICTSD Resource Book on TRIPS provides that:

> Members have considerable leeway in *applying* those three criteria.[57]

Hence, although a member cannot add unique patentability conditions for biotech inventions, they are entitled to, for example, construe and apply the requirement of 'industrial application' in a manner that addresses a specific concern in the field of biotechnology.[58] However, requiring patents to be *available* without 'discrimination' implies that there is a *limit* to which this could be done, which in turn depends on the meaning attributable to the concept of 'discrimination'. This is the reason why Graeme Dinwoodie and Rochelle Dreyfuss note that the non-discrimination obligation has the potential to circumscribe this ability of the national courts, legislators and administrators to 'tailor patent protection' in a manner that reflects the differing concerns in different industries.[59]

In relation to the prohibition of 'discrimination' of 'fields of technology' with regard to the 'enjoyment' of patent rights, its impact on the ability of the membership to make limited exceptions (Article 30) and grant compulsory licences (Article 31) was explicitly acknowledged by the Panel in *Canada- Pharmaceuticals*.[60] In this dispute that is more fully discussed in the next Chapter, the European Community alleged that Canada's regulatory review and stockpiling exceptions violated the non-discrimination obligation in TRIPS Article 27.1 as they only applied to pharmaceutical products.[61] In its defence Canada argued, *inter alia*, that the non-discrimination obligation did not apply to limited exceptions as the latter is regulated by a separate provision (Article 30) that makes no reference to this obligation.[62] The Panel noted in its Report that there was nothing in Article 27.1 to show that the non-discrimination obligation was subject to either Article 30 or Article 31. As limited exceptions

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[56] C. Correa, 'Patent Rights', in C. Correa and A. Yusuf (eds.), *Intellectual Property and International Trade: The TRIPs Agreement*, Third edition, Kluwer Law International BV, 2016, p. 263 at p. 281. Emphasis added.
[57] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development and UNCTAD-ICTSD Project on IPRs and Sustainable Development (eds.), *Resource Book on TRIPS and Development*, Cambridge University Press, 2005, p. 348. Emphasis added.
[58] See, for e.g. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on The Legal Protection of Biotechnological Inventions, Article 5(3).
[59] G. Dinwoodie and R. Dreyfuss, 'Diversifying without Discriminating: Complying with the Mandate of the TRIPS Agreement', *Mich. Telecomm. & Tech L. Rev*., vol. 13, no. 2, 2007, p. 445 at p. 447.
[60] Panel Report, *Canada- Patent Protection of Pharmaceutical Products,* WT/DS114/R.
[61] Ibid., para. 4.3-4.5.
[62] Ibid., para. 4.16.

and compulsory licences affect the enjoyment of patent rights as much as any other measure, the Panel noted that such measures should also comply with the non-discrimination obligation.[63]

This scope of the non-discrimination obligation has been heavily criticized. It has been contended that adhering to the non-discrimination obligation prevents an exception from being 'limited' under of Article 30. Therefore, that it intrudes the ability of the WTO Members to make limited exceptions. As Dinwoodie and Dreyfuss state:

> requiring exemptions to be available for all forms of technology as a matter of international law could distort domestic law by inducing national legislators to adopt exemptions that are broader than necessary. This outcome would also conflict with the basic thrust of Article 30, which expressly requires any given exemption to be "limited."…
>
> …In the end then, for these and a series of other reasons that we have written about at length, we think the Panel was wrong to subject exemptions to the technological neutrality condition.[64]

Even in respect of compulsory licences, Correa argues that subjecting Article 31 to the non-discrimination obligation is incorrect as it is only logical to limit certain modalities of compulsory licences to particular fields of technology.[65] These criticisms concerning the scope of the non-discrimination norm have even resulted in the Court of Justice of the European Union to doubt the Panel's opinion,[66] all of which demonstrate the potential of this particular facet of the non-discrimination obligation to affect the ability of the WTO Members to grant limited exceptions and compulsory licences.

In a similar vein, the non-discrimination obligation vis-à-vis the 'place production' has caused much debate as to whether the ability of the Members to grant compulsory licences for the lack of or insufficient 'local manufacture' of inventions has still been preserved under the TRIPS Agreement. Correa states that:

> The interpretation of this part of the provision is perhaps the most controversial. Although this proposition has been understood as prohibiting

[63] Ibid., para. 7.88-7.93.
[64] Dinwoodie and Dreyfuss, n. 59, p. 449.
[65] Correa, n. 9, p. 283
[66] See for example, *Monsanto Technology LLC v. Cefetra BV (2010), Case C-428/08,* 2010 E.C.R 7, in which the European Court of Justice effectively held that 'limited exceptions' to patent rights are not subject to the non-discrimination rule in TRIPS Article 27.1.

> any obligation to locally work a patented invention and the possibility of granting compulsory licences due to lack or insufficient working, this interpretation is *not* based on a literal reading of the text.[67]

In a rather unique reading of this part of the rule, Correa suggests that 'products' in this part of Article 27.1 only a refers to 'infringing products' rather than the patentee's *own* products. Therefore, that the grant of a compulsory licence due to the patentee's failure to work an invention within a given jurisdiction does not fall within the scope of this ground of 'discrimination'. Correa states that in any event, TRIPS Article 7 that identifies the objective of promoting technology transfer foresees the grant of compulsory licences for non-working.[68] Similarly, Justin Malbon, Charles Lawson and Mark Davison state that the broad wording of the TRIPS provision on compulsory licences (Article 31) is a recognition of the broad discretion that members have to grant compulsory licences and that this was confirmed by the Doha Declaration that recognizes the freedom on part of the WTO Members to determine the grounds upon which compulsory licences could be issued.[69]

On the contrary, Gervais relies on TRIPS Article 28 that gives a patentee the exclusive right to prevent third parties from 'importing' the patented product or products obtained by a patented process, and states that TRIPS indicates that importation must be accepted among the membership as a 'legally effective working' of a patent under national law.[70] The most extreme opinion in this regard is that of Carvalho who disagrees with Correa's interpretation of this norm and Bodenhausen's explanation that 'working' in the context of the Paris Convention was the *local manufacture* of an invention. He states that the non-discrimination rule plainly prohibits the grant of compulsory licences based on local working, and that in any event, importation should be sufficient to prevent the grant of such licences. In his words:

> What Article 27.1 does is to prohibit WTO Members to oblige patentees to work patents (in the sense of manufacturing the claimed products and/or using the claimed process) within their territories. In a nutshell, Article 27.1 says that, where patent owners are obliged to work their patents, they may provide evidence of compliance with such an obligation through the importation of the

[67] Correa, n. 9, p. 284. Emphasis added.
[68] Ibid., pp. 285-286.
[69] Malbon et al., n. 16, p. 497.
[70] Gervais, n. 9, p. 433.

patented articles or the importation of products manufactured directly with the patented processes.[71]

There are several other academics who take middle ground between these two extreme perspectives, a notable one of which is that of Thomas Cottier, Shahiza Lalani and Michelangelo Temmerman. They argue that there is no 'discrimination' within the meaning of Article 27.1 if a measure addresses an abusive failure on the part of a patentee to work an invention, which should be determined in the light of the economic factors pertaining to a given Member.[72] The examination of all the other academic commentaries dealing with this issue is beyond the purposes of this section, which was only intended to highlight the potential that TRIPS's non-discrimination norm has to impede the ability of the Members to grant compulsory licences due to non-working which was beyond any agreement during the negotiations.

This concerning potential of the non-discrimination obligation to inhibit these 'flexibilities' in TRIPS potentially prevents the WTO Members from striving to achieve the requisite balance necessitated by the Objectives and Principles of the Agreement. This is the balance that Antony Taubman rightly notes, between the protection intellectual property rights and the ability of the membership to pursue other vital public policies.[73] The following section examines how these potential intrusions could specifically impact *public health* and *technology transfer*, which are two policies that have been explicitly mentioned in the Objectives and Principles highlighting the significance of their protection and promotion for the balance that the Agreement seeks to achieve.

- *PUBLIC HEALTH AND TECHNOLOGY TRANSFER*

In the preceding discussion of the negotiations that crafted the patent section of TRIPS it was highlighted that the Group 14 developing countries presented a proposal to the TRIPS Negotiation Group in May 1990.[74] Part II of this document dealt with substantive norms relating to the protection of intellectual property. Article 2 of this Part entitled 'Principles' contained four sub-articles, which according to Santos Tarragô, highlighted the deep concerns of the

[71] Carvalho, n. 9, p. 294.
[72] T. Cottier, S. Lalani and M. Temmerman, 'Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements', *Journal of International Economic Law*, vol. 17, no. 2, 2014, p. 437.
[73] Taubman, n. 10, p. 17.
[74] See Communication from Argentina and Others, n. 6.

developing countries and formed the genesis of the current Articles 7 (Objectives) and 8 (Principles) of the Agreement.[75] Of the numerous objectives mentioned in Article 7 one that was repeatedly highlighted by the developing countries during the negotiations was *technology transfer*. As the developed countries who demanded high standards of intellectual property protection did *not* have such standards during the periods in which they achieved economic prosperity, the developing countries contended that they would be agreeable to the high standards of protection only if they could be assured of economic and technological development in this process. In the context of patent law, the mechanism that the developing countries repeatedly cited as being vital for such purposes was the local working of patented inventions, the lack of which was considered to be an 'abuse' of the patent system.[76] This was a mechanism that at least *they* believed to be still legitimate under the TRIPS Agreement.

While there is some uncertainty as to whether compulsory licences can be issued under TRIPS for a patentee's 'mere' failure to work an invention, there is considerable agreement that the *abusive* failure to do so should entitle a member to grant such a licence.[77] As Cottier and others have pointed out, whether a patentee abuses his right in this context is necessarily dependent on the *economic factors* of a country that would serve to justify the need for local manufacture to meet the objectives of technology transfer in TRIPS Article 7.[78] In fact, the jurisprudence in India relating to its compulsory licensing scheme shows that patentees could satisfy the local working requirement by importation, *provided* they could adduce sufficient evidence to show why the invention could not be locally manufactured.[79] With the significance that developing country Members continue to give compulsory licences to address the lack of local working of patented inventions with the intention of attaining the objectives of TRIPS, the non-discrimination rule that prohibits 'discrimination' based on the 'place of production' tends to cause discomfort. By preventing 'discrimination', together with the right of importation in Article 28, it has been argued that importation must be sufficient to satisfy any local working

[75] P. Tarragô, n. 51, p. 249.

[76] See, e.g. GATT document MTN.GNG/NG11/21, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 14 to 16 May 1990*, Note by the Secretariat, 22 June 1990, para. 28; GATT document MTN.GNG/NG11/25, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 10 to 21 September 1990*, Note by the Secretariat, 8 October 1990, para. 6.

[77] For example, during TRIPS negotiations, even the industrialized countries admitted that compulsory licences for 'non-working' could be issued when such non-working could not be justified by the patentee, although their proposals tended to give patentees significant leeway in establishing the latter.

[78] Cottier et al., n. 72, p. 444, pp. 452- 460. Also See C. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?', in K. Maskus and J. Reichman (eds.), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, Cambridge University Press, 2005, p. 227.

[79] See *Bayer Corp. v. Union of India and others, Order of the Intellectual Property Appellate Board*, OA/35/2012/PT/MUM, p. 43.

requirements. If such were the case, it effectively undermines the objective of ensuring technology transfer by proscribing a mechanism which the developing countries were insistent in utilizing for this purpose. As highlighted in Part B, the developing countries were clearly not agreeable to any limitations on their ability to grant compulsory licences during the TRIPS negotiations which in fact led to the creation of this 'non-discrimination' obligation.

Public health is another vital public policy that is explicitly mentioned in the TRIPS Agreement. Article 8.1 entitled 'Principles' explicitly recognizes the ability of the Members to adopt measures *necessary* to protect public health, provided such measures are *consistent* with the Agreement. The fact that such a provision proposed by the developing countries survived the entire TRIPS negotiations demonstrates that the negotiators foresaw that overzealous intellectual property protection could impede other equally or even more significant public policies such as public health. Hence, the presence of such provisions in TRIPS support Taubman's vision that TRIPS was not a consequence of trade trumping over human rights, environment or other vital interests, but a specie of an *intricate balance* between such competing interests. Given that the ability of the WTO Members to address vital policies like public health are found in a seperate provision of the Agreement, and therefore, likely to be overlooked in the interpretation of the other provisions of TRIPS, the *Ministerial Declaration on the TRIPS Agreement and Public Health* confirmed their interpretational significance for all the provisions by stating that each provision of TRIPS must be interpreted in the light of the Agreement's Objectives (Article 7) and Principles (Article 8).[80] Particularly in relation to public health, the Ministers also declared that the Agreement 'does not and should not' prevent WTO Members from taking measures to protect public health.[81]

In one of his first works dealing with the TRIPS Agreement and public health, Carlos Correa explained why developing countries should pay greater attention to public health in the process of complying with the minimum standards of the TRIPS Agreement.[82] In a manner that is still relevant today, Correa stated that a large part of the world's population does not have access to essential medicines, that they are poor, cannot afford medication, which altogether result in them having shorter life expectancies and high rates of mortality. Therefore, he identified that the answer lies in well *calibrated* national health, pharmaceutical and patent policies.[83] Before

[80] World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, WT/MIN(01)/DEC/2, Doha, 2001, para. 5(a).
[81] Ibid., para. 4.
[82] C. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre, 2000.
[83] Ibid., p. 7.

he proceeded to explain some general approaches that these countries could use to devise more health-sensitive patent systems, he identified the non-discrimination rule in Article 27.1 as being an obstacle. In his words:

> Article 27.1 of the TRIPs Agreement bans any discrimination, in either the recognition or exercise of patent rights, based on the field of technology. This means that both negative discrimination (e.g., reducing the rights available to pharmaceutical patent holders) and positive discrimination (broadening such rights) may be deemed TRIPs-inconsistent.[84]

On a rather simple premise that *differentiation* does not constitute 'discrimination' under this provision,[85] Correa went on to suggest some pragmatic instruments that members may adopt. The next Chapter of this thesis explains the reasons why Correa's premise that differentiation is not 'discrimination' does not draw a complete picture of the non-discrimination obligation. Therefore, this distinction does not necessarily render the measures suggested by him to be consistent with the non-discrimination obligation. Nonetheless, this section discusses some of the most significant proposals that Correa made to demonstrate that WTO Members have in fact adopted national measures that could be traced to his suggestions and that their consistency with the non-discrimination obligation fundamentally rests on what constitutes 'discrimination' in the context of this obligation relating to fields of technology.

In the context of *patent eligibility*, Correa states that WTO Members are *not* obliged to recognize first and second medical use patents.[86] In fact, India is one such Member that does not recognize patents for medical indications. Section 3(d) of its Patent Act, *inter alia*, provides that a 'new use of known substance' is not an invention. Correa also suggests that countries are entitled to refuse patents that are purely directed at genes, whether isolated or in purified form, by relying on the distinction between discoveries and inventions.[87] This is currently a point of intense debate in the more developed parts of the world where they have made significant progress in the field of biotechnology. After several years of the US Patent Office being in the practice of granting patents for isolated gene sequences, the US Supreme Court decided in 2013 that the *mere* isolation of a gene is not an 'invention' as the subject matter of such alleged invention is no different to that which exists in nature.[88]

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[84] Ibid.
[85] Ibid., p. 8.
[86] Ibid., p. 20-26.
[87] Ibid., p.15-20.
[88] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)

With regard to the 'inventive step' requirement, Correa states that countries may use an 'obvious to try' concept in the pharmaceutical and chemical fields, as there is often:

> … a close structural relationship between a compound which is claimed as new and inventive, and known compounds, such as salts of acids, bases, isomers, and homologues.[89]

In fact, the US Courts utilize a concept known as 'lead compounds' to ascertain the inventiveness of pharmaceutical and chemical inventions in this manner. As Guyan Liang highlights, the US Federal Courts use this concept to draw a presumption of obviousness when the invention is *structurally* similar to a lead compound in the prior art *and* it would have been obvious to a skilled artisan to choose that particular lead compound for modification.[90] However, Liang also states that it is a concept that is applied very cautiously by the Courts and requires a high standard of proof to render an invention 'obvious'. In his words:

> This is a very high standard, which has not been met by any CAFC case challenging the validity of a compound claim. Structural similarity alone does not suffice, according to the CAFC, because the court assumed that properties of chemical compounds are unpredictable and that similar structures do not always lead to similar properties.[91]

A similar concept is legislatively provided for in the Indian Patent Act, although this is done in the context of *patentable* subject matter. Section 3(d) of the Patent Act provides that the mere discovery of a new form of a known substance is not patentable unless there is an 'enhancement of the known efficacy' of the substance. Thus, derivative pharmaceutical inventions that build on compounds belonging to the prior art not patentable without proof of 'enhanced efficacy'.[92]

In relation to the concept of 'industrial application', Correa states that countries may use it to 'avoid the proliferation of patents that may unduly jeopardize innovation and competition in

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[89] Correa, n. 82, p. 46.

[90] G. Liang, 'The Validity Challenge to Compound Claims and the Unpredictability of Chemical Arts', *Wake Forest J. Bus. & Intell. Prop. L.,* vol. 13, no. 1, 2012, p. 38.

[91] Ibid., p. 80-81. Also see A. Trask, '"Obvious to Try": A Proper Patentability Standard in the Pharmaceutical Arts?', *Fordham Law Review*, vol. 76, no. 5, 2008, p. 2625; S. Rollins, 'Isn't It Obvious? How Klein's Definition of Analogous Prior Art Conflicts with the Supreme Court's Vision for Obviousness', *Iowa Law Review*, vol. 98, no. 3, 2013, p. 1377; J. Lief and P. Schuyler, 'Pharmaceutical Patents after KSR: What Is Not Obvious?', *Journal of Commercial Biotechnology*, vol. 15, no. 1, 2009, p. 44.

[92] See S. Basheer and P. Reddy, 'The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)', *SCRIPTed*, vol. 5, no. 2, 2008; E. Oke, 'Exploring the Flexibilities in TRIPS: Lessons from India's Pharmaceutical Patent Law', *Commonwealth Law Bulletin*, vol. 41, no. 1, 2015, p. 82; R. Gabble and J. Kohler, 'To Patent or Not to Patent? The Case of Novartis' Cancer Drug Glivec in India', *Globalization and Health*, vol. 10, no. 1, 2014, p. 1.

the health sector'.[93] He does not explain as to how this could be done, but a practice in Canada that *was* used to ascertain the utility of inventions up until very recently showed the potential of this proposal.[94] Canada used a concept known as the 'promise doctrine' to ascertain the utility of an invention that specifies a specific utility or effect.[95] The literature and case-law suggest that the Canadian Courts were inclined to generate such 'promises' particularly in the case of pharmaceutical inventions. The construction of a promise heightened the standard of utility that must be disclosed in those patent applications as that promise had to be demonstrated or 'soundly predicted' at the time of filing for patent.[96] The impact this was having on pharmaceutical inventions was such that Norman Siebrasse notes that of all the cases in which the 'promise doctrine' was a determinative issue since 2005, only two were *not* pharmaceuticals.[97]

Finally, with respect to compulsory licences, Correa states that WTO Members are entitled to grant compulsory licences for 'essential drugs' given that the *World Health Organization* has signified their importance to developing countries.[98] Although 'essential drugs' falls within the ambit of pharmaceutical technology, Correa claims that this would *not* amount to 'discrimination' of a 'field of technology' as it would be limited to pharmaceuticals that are of *utmost importance to public health*.[99] Although to the author's knowledge there is no WTO Member that has adopted a compulsory licensing scheme that is specifically directed towards a list of drugs categorized as being 'essential' *by the WHO*, many Members currently recognize certain grounds for the grant compulsory licences that mainly affect pharmaceutical patents. For example, the Indian Patent Act provides that a compulsory licence could be issued when 'the patented invention is not available to the public at a reasonably affordable price'.[100] In a much-commended decision, which is also criticized in other parts of the world, the Controller of Patents issued a compulsory licence in 2012 to Natco Pharma for Bayer's Nexavar drug, *inter alia*, on the basis that Bayer's cancer drug that was being sold at Rs. 280,000 a month was 'undoubtedly' not made available to the public at a 'reasonably affordable price'.[101] The

[93] Correa, n. 83, p. 49.
[94] The Canadian Supreme Court recently held denounced this practice in *AstraZeneca Canada Inc. v. Apotex, Inc.*, 2017 SCC 36.
[95] *Eli Lilly Canada Inc. v. Novopharm Ltd.* [2010] FCA 197.
[96] See N. Siebrasse, 'Form and Function in the Law of Utility: A Reply to Gold & Shortt', *Canadian Intellectual Property Review,* vol. 30, no. 2, 2014, p. 110; N. Siebrasse, 'The False Doctrine of False Promise', *Canadian Intellectual Property Review*, vol. 29, no. 1, 2013, p. 3; R. Gold and M. Shortt, 'The Promise of the Patent in Canada and Around the World', *Canadian Intellectual Property Review*, vol. 30, no. 2, 2014, p. 35.
[97] Ibid., Siebrasse, 'The False Doctrine', pp. 36-37.
[98] Correa, n. 83, pp. 93-99.
[99] Ibid.
[100] Patents Act 1970 (India), Section 84(1)(b).
[101] *Natco Pharma Ltd. v. Bayer Corporation, Order of the Controller of Patents*, C.L.A No.1 of 2011, pp. 35-36.

Intellectual Property Appellate Board (IPAB) upheld this decision highlighting the importance of the right to life and health.[102] Similarly, even the French Intellectual Property Law Code entitles the Minister of Industrial Property to issue 'ex officio licences' in the interest of 'public health demands' at the request of the Minister of Health. It specifically states that the provision only applies to *drugs and medical devices*.[103]

As these instruments suggested by Correa are primarily directed towards pharmaceuticals, their compatibility with the wide-ranging rule against the 'discrimination' of fields of technology in TRIPS Article 27.1 rests on the meaning attributable to the concept of 'discrimination' in this context. In fact, several national measures that could be traced to Correa's recommendations have been criticized and even challenged by the pharmaceutical industry for violating the non-discrimination obligation on the basis that they are disadvantageous to the industry. The following Chapters will demonstrate that merely relying on differentiation to defend such measures is not that simple as originally suggested by Correa as the manner in which this non-discrimination norm has been worded gives it an extensive scope of application. At the same time, however, reason suggests that a downright prohibition of measures aimed towards the protection of public health would not only render patent systems of several WTO Members to be inconsistent with TRIPS, but more pressingly, it would destroy the intricate balance that has been craftily knitted into the TRIPS Agreement between intellectual property protection and other public interests. Therefore, identifying the manner in which such measures could comply with this non-discrimination obligation is one of the vital objectives of this thesis.

D. CONCLUSION

This analysis of the negotiations that led to the final version of the non-discrimination obligation in Article 27.1 and the discussion relating to the concerns surrounding this obligation show its potential to affect the delicate balance between intellectual property protection and other societal interests that TRIPS seeks to achieve. While all the *grounds* of discrimination mentioned in Article 27.1 have the potential to affect this balance, its facet relating to 'fields of technology' in particular has the potential to impede the ability of the WTO Members to define and apply the patentability criteria, craft limited exceptions and even to determine the grounds of compulsory licences. This is the ground in which the *trade* concept of non-discrimination affects patent law most deeply and this is why this thesis focuses on the ground of 'fields of

[102] *Bayer Corp. v. Union of India*, n. 80, para. 40-44.
[103] Intellectual Property Law Code of France (Consolidated version of March 17, 2017), Article L613-16.

technology'. Uncertainty as to what constitutes 'discrimination' in this context affects the ability of the Members to comply with TRIPS's patent law obligations in a manner that best fits their domestic circumstances, that could in turn affect the balance that TRIPS mandates between intellectual property protection and other important societal interests.

CHAPTER 3

WTO JURISPRUDENCE AND ACADEMIC COMMENTARY ON THE NON-DISCRIMINATION OBLIGATION

Since the TRIPS Agreement came into force in 1994, only eleven disputes initiated at the Dispute Settlement Body (DSB) relate to the Agreement's patent law obligations. Of the eleven disputes that have been so initiated, only three have generated Panel or Appellate Body Reports. Surprisingly, only one of them has ever substantively dealt with the non-discrimination obligation in Article 27.1. This isolated Report is that of a WTO Panel in *Canada- Protection of Pharmaceutical Patents (2000)*[1] and it entails the only formulation of this obligation at the WTO level. This Chapter examines this Panel Report and its formulation of this obligation to highlight the gaps in the Report and the academic literature that concerning the Panel's concept of 'justification' in relation to the ground of 'fields of technology'.

Accordingly, Part A discusses the facts in *Canada- Pharmaceuticals* pertaining to the non-discrimination obligation in TRIPS Article 27.1, the Panel's formulation of this obligation and its application to the facts in the dispute. Part B highlights the significance of the Panel's concept of 'justification' and scrutinizes the academic literature that followed the Report to highlight that although much has been written about the Panel's recognition of autonomy on the part of the WTO Members to subject fields of technology to differential treatment, the literature has not appreciated that the type of autonomy that the Panel sought to have preserved fundamentally rests on its concept of 'justification'. Finally, Part C entails a brief conclusion highlighting the need for a more detailed analysis of this concept that is undertaken in the following of Chapters of this work.

A. THE WTO PANEL'S FORMULATION OF 'DISCRIMINATION'

To bring its patent law into conformity with its international obligations under the North American Free Trade Agreement (NAFTA) and the TRIPS Agreement, Canada made several amendments to its patent laws in 1992 and 1993. These amendments cumulatively extended the term of patent protection for all inventions to twenty years, allowed product patents for

[1] Panel Report, *Canada- Patent Protection of Pharmaceutical Products*, WT/DS/114/R.

pharmaceutical inventions and introduced exceptions to patent rights in lieu of the laxer compulsory licensing scheme that had been applied to pharmaceuticals since 1923.[2] Two exceptions that were so introduced were the *regulatory review* and *stockpiling* exceptions respectively provided for in Sections 55.2(1) and 55.2(2) of the Canadian Patents Act. The regulatory review exception permitted any person to make, use or sell any invention for a purpose that is 'reasonably related to the development and submission of information required under the law of Canada, a province or a country other than Canada that regulated the manufacture, construction use or sale of any product'. The stockpiling exception went one step further and permitted any person to *manufacture and store* products for which regulatory approval had been sought for a period set by regulations for the purpose of selling the products immediately after the expiration of the patent. The regulations made by the Minister concerned provided for the stockpiling exception to be applicable to pharmaceutical inventions for a period of six months immediately preceding the expiration of the patent.

The European Communities (EC) disputed these provisions and requested consultations with Canada in 1997 alleging that they were inconsistent with the TRIPS Agreement. Consequently, EC requested the DSB to establish a Panel and in its complaint alleged that the stockpiling exception was inconsistent with Article 28.1 and Article 33 as it effectively allowed any person to work the invention during the last six months of the patent term. It claimed that this was contrary to the *exclusive rights* set-out in Article 28.1 and *reduced* the duration of pharmaceutical patents to nineteen years and six months as opposed to the twenty years required for all patents under TRIPS Article 33.[3] As the regulations had only provided for the application of the stockpiling exception for pharmaceuticals, EC further alleged that it violated the rule against the 'discrimination' of fields of technology in Article 27.1 because it treated pharmaceuticals *less favourably* than inventions in other fields of technology.[4]

With reference to the regulatory review exception, EC argued that it was unlimited in duration, quantity, extent and only vaguely regulated with reference to the objective of the permitted activity. It alleged that this violated Article 28.1 by permitting very significant quantities of the patented product to be manufactured, imported and sold without the consent of the patent holder during the entire term of the patent.[5] It also alleged that although this exception was *not*

[2] Ibid., p. 12- 15. Also see M. Goudreau, *Intellectual Property Law in Canada*, Second edition, Kluwer Law International, 2015, p. 64.
[3] Panel Report, *Canada- Pharmaceuticals*, n. 1, para. 4.2.
[4] Ibid., para. 4.3.
[5] Ibid., para. 4.4.

explicitly limited to pharmaceutical inventions, the legislative history and practice showed that it was meant to, and did in fact, apply only to pharmaceutical inventions, thereby violating the non-discrimination obligation in Article 27.1. It noted that this was particularly so as the regulatory review exception did not apply to inventions in other fields of technology such as agricultural chemical products, foodstuff, aircraft, ships, or motor vehicles that were similarly regulated in Canada.[6] Although EC made these allegations based on the non-discrimination obligation in Article 27.1, it did not propose an interpretation of the obligation either in its complaint or subsequent arguments, except for stating on numerous occasions that the measures in question were discriminatory because they treated pharmaceutical inventions *less favourably*.

Canada sought to defend these allegations on a number of grounds. Firstly, it argued that its exceptions constituted 'limited exceptions' in terms of Article 30, and therefore, that the limitation of the rights set-out in Article 28.1 were justified.[7] Secondly, it argued that its exceptions did not violate the *non-discrimination obligation* for *either* of two reasons: the non-discrimination obligation refers to 'patent rights' in Article 28 that can be subject to 'limited exceptions' in Article 30, and therefore, the rule itself is subservient to the 'limited exceptions' provision,[8] *or* the Canadian exceptions were not discriminatory in any event because they were not associated with any particular field of technology.[9] With regard to the first of these sub-arguments, Canada argued that if the non-discrimination rule applies to Article 30 it would require 'across-the-board' derogations of patent rights that would by itself prevent exceptions from being 'limited' within the meaning of Article 30.[10] Further, that such an 'absolute' scope of the obligation as proposed by the EC would deprive the WTO Members of the ability to:

> … *create appropriate solutions for specific problems* on a case-by-case (or product group by product group) basis, and instead obliged them to impose universally applicable measures which could be entirely inappropriate in most contexts.[11]

Finally, with regard to the Article 33 allegations, Canada argued that its exceptions did not impair the rights of patentees to exploit the patent by themselves for the full term of the patent.[12]

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[6] Ibid., para. 4.5.
[7] Ibid., para. 4.10-4.15.
[8] Ibid., para. 4.16.
[9] Ibid., para. 4.18.
[10] Ibid., para. 4.16.
[11] Ibid. Emphasis added.
[12] Ibid. para. 4.19-4.20.

The Panel initiated its analysis by highlighting that EC had the burden of establishing a *prima facie* case that Canada violated any of the TRIPS provisions.[13] With a controversial interpretation of Article 30 that deals with 'limited exceptions' to patent rights, the Panel found that EC had established a *prima facie* case of inconsistency as it had provided sufficient evidence to show that the stockpiling exception was not 'limited'.[14] Hence, the Panel did not even scrutinize the consistency of the stockpiling exception with the non-discrimination obligation as it was inconsistent with the Agreement in any event. However, the Panel found that the regulatory review exception complied with Article 30 and constituted a limited exception, and therefore, proceeded to scrutinize its consistency with the non-discrimination obligation in Article 27.1.[15]

The Panel stated that the primary purpose of the non-discrimination obligation was to eliminate the *restrictions* placed on the availability of patent rights and the practice of *automatic compulsory licensing* that specifically affected pharmaceuticals and certain other products in the pre-TRIPS era.[16] It refused to accept Canada's contention that the non-discrimination obligation was subject to Article 30 by stating that the words 'patent rights' in Article 27.1 is *not* qualified by any term or provision. Therefore, it explained that:

> A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights themselves.[17]

Nor did the Panel agree with Canada that this would necessitate 'across-the-board' exceptions. In an interesting explanation of the co-relation between the non-discrimination obligation and Article 30, the Panel stated that an exception does not necessarily satisfy the condition of being 'limited' by merely being applicable to one field of technology.[18] Thus, potentially 'discriminating' a field of technology with regard to the applicability of an exception does not necessarily make it 'limited' in terms of Article 30. It also noted that Article 27.1 does not always require all exceptions to be applicable to all products. In the words of the Panel:

> … it is not true that Article 27 requires all Article 30 exceptions to be applied to all products. *Article 27 prohibits only discrimination* as to the place of invention, the field of technology, and whether products are imported or

[13] Ibid., para. 7.16.
[14] Ibid., para. 7.24-7.38.
[15] Ibid., para. 7.39-7.84.
[16] Ibid., para. 7.90.
[17] Ibid., para. 7.91.
[18] Ibid., para. 7.92.

> produced locally. *Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas*.[19]

While the Panel's perspective of the relationship between the two provisions is complex to comprehend, which is perhaps the reason why this opinion has been criticized in the academic commentaries as will be demonstrated in the next Part of this Chapter, the above quoted passage highlights that there is a distinction between the 'discrimination' of a field of technology and '*bona fide* exceptions that deal with particular problems in certain product areas'. The upshot of this, technically at least, is that there could be exceptions directed at only one field of technology that would *not* be considered to be 'discriminatory' under Article 27.1. It will be demonstrated in the next Part of this Chapter that it is *this* section of the Report that has been repeatedly cited in the literature as acknowledging some form of autonomy on the part of Members to subject fields of technology to differential treatment without violating the rule against 'discrimination'.

Finding that even 'limited exceptions' should abide by the rule against 'discrimination', the Panel began its analysis as to whether it had been violated by Canada. It began by noting that the concept of 'discrimination' in Article 27.1 is broader than the *specific* types of discrimination addressed by the National Treatment (NT) and Most-Favoured-Nation (MFN) treatment obligations in the TRIPS Agreement.[20] This was quite apparent as Article 27.1 prohibits a broad notion of 'discrimination', unlike the NT and MFN obligations in TRIPS that do not even use the word 'discrimination'. Notwithstanding this wide breadth of the concept, the Panel stated that 'discrimination' in Article 27.1 refers to:

> … a normative term, pejorative in connotation, referring to results of the *unjustified* imposition of differentially disadvantageous treatment.[21]

Most of the literature dealing with the Panel Report have not recognized that this passage of the Panel takes precedence over its statement that the non-discrimination obligation does not prohibit '*bona fide* exceptions'. The Panel made the latter statement only in the context of identifying the *scope* of the obligation, whereas the passage quoted above that is referred to as the 'formulation' of the obligation here onwards, directly concerns the concept of 'discrimination' in Article 27.1. In terms of this formulation, which the Panel appears to have suggested as being relevant for all the grounds of discrimination in Article 27.1, conferring

[19] Ibid. Emphasis added.
[20] Ibid., para. 7.94.
[21] Ibid., Emphasis added.

disadvantageous treatment on a field of technology does not necessarily constitute 'discrimination'. Such treatment would violate this obligation only if it were 'unjustified'. Clearly, the Panel either *introduced* a concept of 'justification' into this substantive obligation *or* noted that it is *inherent* in any such non-discrimination obligation within the WTO's multilateral framework. Whatever the Panel meant to do, it demonstrated that there was a concept of 'justification' that lingered within the notion of 'discrimination' in Article 27.1. The significance of this concept will be more fully addressed in the next Part of this Chapter, but it suffices to note at this juncture that the Report lacked any explanation as to how such a concept found its way into this obligation that facially prohibits any 'discrimination' that affects the availability or enjoyment of patent rights on the three grounds specified in Article 27.1 or as to how such a concept ought to operate at least in the context of 'fields of technology'.

The Panel also stated that such 'discrimination' could be explicit (*de jure*) and implicit (*de facto*):

> Discrimination may arise from explicitly different treatment, sometimes called "*de jure* discrimination", but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called "de facto discrimination".[22]

In fact, EC alleged that the Canadian regulatory review exception 'discriminated' pharmaceuticals explicitly and implicitly. The Panel noted that although these *features* of discrimination have been interpreted and applied in various other GATT (General Agreement on Tariff and Trade) and WTO provisions, that their interpretation in TRIPS Article 27.1 could be more complex. It stated that:

> These rulings have addressed the question whether measures were in conflict with various GATT or WTO provisions prohibiting variously defined forms of discrimination. As the Appellate Body has repeatedly made clear, each of these rulings has necessarily been based on the precise legal text in issue, so that *it is not possible to treat them as applications of a general concept of discrimination*. Given the *very broad range of issues that might be involved in defining the word "discrimination" in Article 27.1 of the TRIPS Agreement,* the Panel decided that it would be better to defer attempting to define that term at the outset, but instead to determine which issues were raised by the record

[22] Ibid.

> before the Panel, and to define the concept of discrimination to the extent necessary to resolve those issues.[23]

Acknowledging such complexity, the Panel proceeded to examine the *de jure* and *de facto* allegations of discrimination. With regard to the *de jure* claim, the Panel found that the legislative history relating to the regulatory review exception showed that it was *not* meant to be limited to pharmaceuticals and that in the absence of any evidence to the contrary:

> … the words of the statute compelled the Panel to accept Canada's assurance that the exception was *legally available to every product that was subject to marketing approval requirements*.[24]

Thus, the Panel found that EC had failed to establish a *de jure* case of discrimination as it was *not* explicitly applicable only to pharmaceuticals. With regard to the *de facto* claim, the Panel noted that such a measure should either have a *discriminatory effect* or a *discriminatory purpose*.[25] It stated that a measure would have a *discriminatory effect* if there was 'some practical reason' as to why it only disadvantaged one field of technology in reality.[26] It found that EC had not produced any evidence to show that the regulatory review exception only served to disadvantage pharmaceutical inventions.[27] In relation to *discriminatory purpose,* the Panel noted that there should be some objective indications relating to the measure from which it could be 'inferred' that the measure had discriminatory objectives.[28] Again, it found that EC had not produced any such evidence.[29] Accordingly, the Panel concluded its scrutiny of Article 27.1 finding that EC had *not* established a *prima facie* case that the Canadian regulatory review exception was 'discriminatory'.

B. THE CONCEPT OF 'JUSTIFICATION' AND THE ACADEMIC COMMENTARY

The examination of the Panel Report in *Canada- Pharmaceuticals* shows how little the Panel revealed about its concept of 'justification'. Its significance, however, should not be underestimated. The Panel appears to have suggested that differential treatment that is

[23] Ibid., para. 7.98. Emphasis added.
[24] Ibid., para. 7.99. Emphasis added.
[25] Ibid., para. 7.101.
[26] Ibid., para. 7.102.
[27] Ibid.
[28] Ibid., para. 7.101.
[29] Ibid., para. 7.104.

disadvantageous constitutes 'discrimination' under Article 27.1 *unless* it is 'justified'. Hence, any autonomy that the Panel sought to have preserved in its formulation, if not wholly, fundamentally rests on its concept of 'justification'. By introducing such a concept into its formulation, it appears to have sensed that this obligation had to be balanced against some form of autonomy on the part of the membership. In other words, that the rule against 'discrimination' in Article 27.1 is *not* absolute. As the facts of the dispute did not permit the Panel to expand on this concept, the Report left much uncertainty as to the type of autonomy that it is meant to preserve or as to how it ought to operate in the context of the ground of 'fields of technology'.

The academic commentary concerning the rule against 'discrimination' of 'fields of technology' that followed the Panel Report rightly identified that the Panel sought to acknowledge some autonomy on the part Members to pursue important policy objectives in the context of this obligation. However, the literature has not appreciated the significance of the Panel's concept of 'justification' in this process. Consequently, the uncertainties that the Panel left in its Report relating to this concept have escaped adequate scrutiny even in the academic literature, leaving a fundamental gap in the understanding of the rule against the 'discrimination' of fields of technology relating to how it must be balanced against such autonomy of the Members.

In his seminal commentary on the TRIPS Agreement, Carlos Correa has criticized the Panel's opinion that Article 30 (limited exceptions) and Article 31(compulsory licenses) should comply with the non-discrimination obligation. He states that it only seems 'logical' to limit certain exceptions or modalities of compulsory licenses to certain fields of technology, which would be prevented by such a scope of this obligation.[30] He also refers to an 'interesting statement' of the Panel in which it *apparently* made a distinction between 'discrimination' and 'differentiation'.[31] The passage of the Report that he cites for this proposition is *not* that which relates to the Panel's formulation of 'discrimination' (that it is the unjustified imposition of differentially disadvantageous treatment), but to the part in which the Panel stated that 'discrimination' does not prohibit '*bona fide* exceptions to deal with problems that may exist only in certain product areas'.[32] Observably, the Panel did not make a distinction between

[30] C. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement,* Oxford University Press, 2009, p. 283.
[31] Ibid., p. 282.
[32] This was the distinction the Panel made after holding that TRIPS Article 30 is subject to the non-discrimination rule in Article 27.1. See Panel Report, *Canada- Pharmaceuticals*, n. 1, para. 7.92.

'discrimination' and 'differential treatment' in *this* part of its Report as it only noted that 'discrimination' *does not prohibit* '*bona fide* exceptions'.

Be that as it may, Correa gives significance to the distinction between the two concepts of 'discrimination' and 'differentiation' to support his argument that exceptions to patent rights and compulsory licences *should never* be subject to the rule against 'discrimination'. Relying on this distinction, he states that:

> … differential treatment (including compulsory licences) could be established, for instance, *to address public health problems*, involving products originating from different technological fields, such as equipment, software, diagnostic kits, medicines, and a large variety of other products required for public health purposes.[33]

He opines that even if limitations and exceptions to patent rights are subject to this obligation, the *differential treatment* of a field of technology (in the context of exceptions and compulsory licences) to address *public health concerns* does not constitute 'discrimination'. Nevertheless, Correa does not explain why addressing public health concerns takes such limitations and exceptions away from the realm of 'discrimination' in Article 27.1.
Similarly, again relying on this distinction between 'discrimination' and differential treatment, Correa has stated elsewhere that the non-discrimination obligation does *not*:

> …prevent a WTO member to *differentiate the treatment of inventions* in various technical fields, for instance by adopting specific regulations or guidelines for the examination and grant of *pharmaceutical or biotechnological* products.[34]

Thus, he specifically notes that WTO Members may subject inventions in the fields of pharmaceuticals and biotechnology to differential treatment when examining their patentability without violating the non-discrimination obligation. As before, however, Correa does not explain why this must be the case in the context of pharmaceuticals and biotechnology. A closer inspection of the Panel Report and Correa's interpretation shows that the reasons for the measures suggested by him to be consistent with the non-discrimination obligation are traceable to the Panel's concept of 'justification' that has not been analyzed by him. Had Correa dealt

[33] Correa, n. 30, p. 284. Emphasis added.
[34] C. Correa, 'Patent Rights', in C. Correa and A. Yusuf (eds.), *Intellectual Property and International Trade: The TRIPs Agreement*, Third edition, Kluwer Law International BV, 2016, p. 263 at p. 285. Emphasis added. Here too, Correa quotes the same passage from the Panel report in para. 7.92.

with the Panel's formulation of the concept of 'discrimination' in Article 27.1, he would have appreciated that the mere distinction between 'discrimination' and 'differentiation' does not by itself explain the consistency of the types of differential treatment suggested by him. This is because differential treatment that is disadvantageous constitutes 'discrimination' unless it satisfies the Panel's concept of 'justification'. Consequently, even though Correa was correct to have opined that the Panel recognized the ability of the membership to subject certain fields of technology to differential treatment without violating the non-discrimination obligation, the contours of such an ability is fundamentally dependent on the concept of 'justification' that has not been scrutinized by him.

Consequent to the Panel Report in *Canada- Pharmaceuticals,* Graeme Dinwoodie and Rochelle Dreyfuss co-authored an article entitled '*Diversifying without Discriminating'* that specifically deals with the non-discrimination obligation in TRIPS Article 27.1.[35] Speaking in the context of US patent law, but clearly relevant to the patent systems of any other country, they state that traditional patent law has expanded to cover new fields of technology and that it is unrealistic to think that the same law applies to all these technologies in equal form. Therefore, they state that:

> …it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive.[36]

They note that patent law is capable of organically expanding in this manner given its inherent capability to respond to various demands of different technological communities.[37] Citing the works of Dan Burk and Mark Lemley,[38] they argue that US courts interpret patent norms to suit the idiosyncratic features of different technologies, but that the ability of the courts, legislature and administrators to 'tailor' patent protection in this manner is potentially circumscribed by the non-discrimination obligation in TRIPS Article 27.1.[39] Accordingly, they deal with the Panel Report in *Canada- Pharmaceuticals* and state that the Panel erred in its finding that TRIPS

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[35] G. Dinwoodie and R. Dreyfuss, 'Diversifying without Discriminating: Complying with the Mandate of the TRIPS Agreement', *Mich. Telecomm. & Tech L. Rev.*, vol. 13, no. 2, p. 445.
[36] Ibid., p. 446.
[37] Ibid.
[38] Dan Burk and Mark Lemely have written extensively to highlight the US Courts' diverse application of the patent law norms such as the person ordinarily skilled in the art and disclosure. In essence, they argue that the concept of the person ordinarily skilled in the art is applied more leniently for biotechnological inventions than for computer software, while the disclosure requirement is applied more leniently for computer software than for biotechnological inventions. See D. Burk and M. Lemley, 'Is Patent Law Technology-Specific?', *Berkeley Tech. L. J.*, vol. 14, no. 4, 2002, p. 1155; D. Burk and M. Lemley, 'Biotechnology's Uncertainty Principle', *Case W. Res. L. Rev.*, vol. 54, 2004, p. 691; D. Burk and M. Lemley, 'Policy Levers in Patent Law', *Virginia Law Review*, vol. 89, 2003, p. 1575.
[39] Dinwoodie and Dreyfuss, n. 35, pp. 447-8.

Article 30 is subject to the 'technological neutrality condition' in Article 27.1.[40] Nevertheless, they note that there is still considerable room for tailoring given the Panel's opinion that 'discrimination' is *not the same as differential treatment*.[41] They too rely on the Panel's statement that 'discrimination' in Article 27.1 does not prohibit '*bona fide* exceptions'. They further argue that members must be able to defend an allegation of *de facto* discrimination under Article 27.1 by demonstrating a legitimate purpose, as this is consistent with TRIPS Article 1.1 that gives countries 'deference' as to the means by which they implement the general purposes of the Agreement.[42] Concludingly, they state that WTO Members still have a great degree of discretion to tailor technology specific patent laws and that:

> … Lemley and Burk's legally neutral rules, applied through adjudication, certainly appear to survive challenge. Legislatively constructed industry-specific rules could also be sustained if they were framed in a similarly neutral manner.[43]

Their interpretation of the Panel Report is given near biblical significance by developing country Members and policy advisory bodies to show that the non-discrimination obligation has preserved a significant level of autonomy on the part of the WTO Members to enable them to calibrate their patent systems to best suit their domestic contexts. It is this philosophy that is reflected even in the commentary on TRIPS by UNCTAD-ICTSD, which provides that WTO Members are entitled to adopt different rules for different product areas provided such rules are adopted for *bona fide* reasons.[44]

While it is correct to recognize that the Panel in *Canada- Pharmaceuticals* sought to preserve some form of autonomy on the part of the membership, the reasons cited by Dinwoodie and Dreyfuss do not draw a complete picture of the Panel Report for the following reasons. Firstly, as mentioned in relation to Correa's opinion on this matter, the significance they attach to the distinction between 'discrimination' and 'differentiation' by relying on the Panel's statement on '*bona fide* exceptions' over-looks the potential of the concept of 'differentiation' to constitute 'discrimination' under Article 27.1. Although they argue that technology specific *bona fide* exceptions are a matter of 'differentiation' as opposed to 'discrimination', not

[40] Ibid., p. 449.
[41] Ibid., p. 450.
[42] Ibid., p. 452.
[43] Ibid., p. 453.
[44] United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development and UNCTAD-ICTSD Project on IPRs and Sustainable Development (eds.), *Resource Book on TRIPS and Development*, Cambridge University Press, 2005, p. 341.

scrutinizing the Panel's formulation prevented them from appreciating that '*bona fide* exceptions' is a potential example of a 'justified' differentially disadvantageous treatment that does not constitute 'discrimination'. Consequently, they deal with a potential justification without addressing the broader concept of 'justification' that the Panel highlighted, which would have identified the traits that a technology specific exception should entail to constitute a *bona fide* exception.

The lack of acknowledgement of this relationship between the Panel's concept of 'justification' and *bona fide* exceptions causes them run into further problem in their reasoning. They argue that there should be some form of 'justification' (not limited to cases of *bona fide* exceptions) that applies to cases *de facto* discrimination by relying on TRIPS Article 1.1. TRIPS Article 1.1 provides in relevant part as follows:

> …Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

This too is problematic for the following reasons. Firstly, a close reading of the Panel Report shows that it is not only *de facto* allegations but that even *de jure* allegations of discrimination are capable of being 'justified'. Secondly, TRIPS Article 1.1 only gives deference to a WTO Member with regard to the 'method of implementing' its TRIPS obligations and *not* with regard to the *substantive* obligations themselves.[45] Hence, TRIPS Article 1.1 does not permit the introduction of a concept of 'justification' even in the limited cases of *de facto* allegations. These issues could have been avoided if Dinwoodie and Dreyfuss had dealt with the more relevant part of the Panel Report that entailed its formulation of 'discrimination', which would have permitted them to acknowledge that their proposition that there is still significant space to tailor patent protection would have been much stronger if they had scrutinized the Panel's concept of 'justification'.

Daniel Gervais also briefly deals with the non-discrimination obligation in Article 27.1 in his commentary on the TRIPS Agreement. He states that it requires patents to be available in all fields of technology according to the three usual criteria of novelty, inventive step and industrial applicability.[46] However, citing the works of Dan Burk and Mark Lemley, Gervais notes that:

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[45] See Correa, n. 30, pp. 22-30. Also see Appellate Body Report, *India- Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, para. 59.

[46] D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Fourth edition, Sweet & Maxwell/Thomson Reuters, 2012, p. 430.

> … the differential treatment of inventions according to the field of activity may be desirable, if not inevitable.[47]

While the differential treatment of a field of technology might be inevitable, Gervais does not examine how this would be compatible with the rule against 'discrimination' in Article 27.1 as he does not deal with the Panel Report in *Canada- Pharmaceuticals*, leaving its concept of 'justification' unexamined.

In his commentary on TRIPS's patent regime, Nuno Pires de Carvalho notes that the main purpose of the Agreement was to address the non-availability of patents in the chemical and pharmaceutical sectors and that this was specifically addressed by the non-discrimination obligation in Article 27.1.[48] Unlike the other commentaries, Carvalho cites the most relevant passage of the Panel Report that formulated 'discrimination' in Article 27.1 as the 'unjustified imposition of differentially disadvantageous treatment'. He states that:

> The Panel noted that discrimination goes beyond the concept of differential treatment. In other words, in the Panel's view, discriminatory treatment is always differential. But there may be differential treatment that is not discriminatory.[49]

Hence, the distinction that Carvalho identifies between 'discrimination' and 'differential treatment' based on the Panel's formulation of 'discrimination' makes better sense than deriving such a distinction from the Panel's statement that 'discrimination' does not prohibit *bona fide* exceptions. It will be recalled that Carlos Correa and even Dinwoodie and Dreyfuss have argued that 'differential treatment' does not constitute 'discrimination' on the basis of the Panel's statement on *bona fide* exceptions. This allowed Carvalho to appreciate that *bona fide* exceptions are just one form of differential treatment that is potentially compatible with the non-discrimination obligation. Carvalho also states that the Panel erred in its finding that 'discrimination' within the whole of TRIPS Article 27.1 is the *disadvantageous* differential treatment as this means that there could never be discrimination that is not disadvantageous.[50] He argues that such an interpretation affects the obligation not to 'discriminate' on the basis of the 'place of production', possibly because the mere differentiation based on the place of production of an invention will not be a sufficient disadvantage to violate this provision.

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[47] Ibid.
[48] N. P. de Carvalho, *The TRIPS Regime of Patents and Test Data*, Fourth edition, Kluwer Law International, 2014, pp. 245-6.
[49] Ibid., p. 250. Footnote omitted.
[50] Ibid.

In relation to the ground of 'field of technology', Carvalho states that 'differentiation', as opposed to 'discrimination', acknowledges the existence of differences between fields of technology.[51] He notes that:

> … a measure that acknowledges that a given situation is different and aims at eliminating such a difference, for the purposes of applying TRIPS standards in an equal manner, is TRIPS consistent. That measure is differential, but not discriminatory.[52]

He perceives differentiation as being necessary to ensure the equality between different fields of technology. However, he immediately qualifies this statement by noting that such 'differentiation' should not be used as a pretext to curtail the availability or enjoyment of patent rights. In his words:

> Differentiation, on the other hand, shall not be a pretext or an excuse for *curtailing or expanding* availability of patents and/or enjoyment of rights, as compared to other fields of technology.[53]

He states that such curtailments or expansions of the availability or enjoyment of patent rights constitute 'discrimination' under Article 27.1 that *cannot* be justified by a WTO Member:

> … a WTO member may not defend a provision of national law containing *discrimination* against the availability or the enjoyment of patent rights, *regardless of any motivation that Member may have taken into account for adopting that provision*.[54]

Carvalho's reading of the Panel Report is in a sense more persuasive than the other commentaries dealing with the non-discrimination obligation as he identifies the most relevant passage of the Report that dealt with the concept of 'discrimination' in Article 27.1. However, his reading that any curtailment or expansion of patent rights necessarily constitutes 'discrimination' in Article 27.1 is problematic as this over-looks the Panel's concept of 'justification'. It will be recalled that the Panel formulated 'discrimination' as the '*unjustified* imposition of differentially disadvantageous treatment'. While Carvalho is *technically* correct to have identified that 'discrimination' in Article 27.1 could never be justified, he has not recognized that the treatment accorded by a measure can be justified that would in turn prevent

[51] Ibid., p. 251.
[52] Ibid.
[53] Ibid. Emphasis added.
[54] Ibid., p. 252. Emphasis added.

the type of 'discrimination' proscribed by this obligation. Hence, this gap in his reading results from not adequately appreciating the significance of the Panel's concept of 'justification'.

Justin Malbon, Charles Lawson and Mark Davison also discuss the Panel's formulation of 'discrimination' to a limited extent in their commentary on the TRIPS Agreement. They state that how 'discrimination' in Article 27.1 would be understood in the future depends on how the Panel's concept of 'differently disadvantageous treatment' is interpreted.[55] They note that this is because the Panel appeared to be reluctant to import interpretations prevalent under the National Treatment and Most-Favoured Nation Treatment obligations in GATT (General Agreement on Tariff and Trade) and the other covered agreements. They also state that there is room for further elaboration of 'discrimination' dependent on which *ground* of discrimination is in issue.[56] It is certainly true that much depends on what is meant by the concept of 'differently disadvantageous treatment' as this is what potentially triggers a violation of this obligation, but they do not discuss the Panel's concept of 'justification' or its significance to preserving any autonomy on the part of the WTO Members.

C. CONCLUSION

The examination of the academic literature dealing with this non-discrimination obligation shows that they give great weight to the distinction that the Panel appeared to have made between 'discrimination' and 'differentiation'. Thereby, they argue that the Panel sought to preserve some form of autonomy on the part of the WTO Members to subject fields of technology to differential treatment without violating this obligation. However, the passage of the Panel Report that most of the literature cite for this purpose relates to the Panel's statement on '*bona fide*' exceptions and *not* its formulation of 'discrimination' as the 'unjustified imposition of differentially disadvantageous treatment'. This has resulted in the commentaries over-looking the Panel's concept of 'justification'. Even the commentaries that have cited the Panel's formulation have not been able to acknowledge the significance of this concept. Consequently, there are some significant loopholes in the current comprehension of the Panel Report and the rule against 'discrimination' in Article 27.1.

[55] J. Malbon, C. Lawson and M. Davison, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary*, Edward Elgar, 2014, p. 426.
[56] Ibid., p. 427.

The preoccupation with the distinction between 'discrimination' and 'differential treatment' that is prevalent in the current literature might have been understandable if the Panel itself had made a clear distinction between 'differential treatment' and *disadvantageous* treatment in the context of the rule relating to fields of technology. This is because differential treatment of a field of technology that is disadvantageous is capable of constituting 'discrimination'. Consequently, clear boundaries between differentiation and disadvantageous treatment would have shown the circumstances in which a member could defend an allegation of 'discrimination' without having to rely on a concept of 'justification'. In the absence of clear boundaries that even the academic commentaries have not been able to decipher between 'differentiation' and disadvantageous treatment in the context of a non-discrimination rule relating to fields of technology, it is submitted that any autonomy that the Panel is claimed to have preserved rests on its concept of 'justification', which has hitherto been left unexamined. Therefore, a greater understanding of the Panel's concept of 'justification' is necessary to appreciate the type and extent of the autonomy that it is claimed to have preserved, which is the gap in the understanding of the non-discrimination obligation that thesis seeks to address from the perspective of the ground of 'fields of technology'.

CHAPTER 4

INTERPRETING 'DISCRIMINATION' OF FIELDS OF TECHNOLOGY

This Chapter adopts an interpretational approach to resolve the ambiguities surrounding the Panel's concept of 'justification' and how it ought to operate in the context of the rule against 'discrimination' of fields of technology in Article 27.1. This is meant to reveal the reasons that appear to have influenced the Panel to recognize the applicability of such a concept in the context of this obligation, which provides firm ground to scrutinize how it could operate and thereby provide a more concrete and developed interpretation of the rule against the 'discrimination' of fields of technology that builds on the Panel's formulation of 'discrimination' in *Canada- Pharmaceuticals*.

An interpretation of 'discrimination' of fields of technology must be guided by Article 31(1) of the *Vienna Convention on the Law of Treaties* (1969) which provides as follows:

> A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

Although the Panel did not refer to the dictionary meaning of 'discrimination' in its Report, it is useful to begin by noting that the Oxford Dictionary provides that 'discriminate' means making an unjust or prejudicial distinction.[1] In the context of 'fields of technology', the ordinary meaning of 'discrimination' in Article 27.1 is the *unjust* or prejudicial treatment of fields of technology with regard to the availability and enjoyment of patent rights. Consequently, some form of 'justification' is somewhat inherent even in the ordinary meaning of the term 'discrimination'. However, this Chapter argues that the need for such a concept of 'justification' in a non-discrimination obligation within the WTO's multilateral framework is commanded by a more fundamental feature prevalent in the WTO's substantive non-discrimination obligations under its covered agreements that constitutes the most relevant 'context' within the meaning of VCLT.

[1] See Oxford Dictionaries Online, https://en.oxforddictionaries.com/definition/discriminate, (accessed 10 December 2017).

Accordingly, Part A of this Chapter demonstrates that it is a fundamental trait of the substantive non-discrimination obligations under the WTO's covered agreements, which are the trade sibling of the non-discrimination obligation in TRIPS Article 27.1, that they are *not* absolute or inflexible so as to disregard the autonomy of the WTO Members to pursue important policy objectives and to ignore their diverse levels of economic development. Part B argues that the 'object and purpose' of TRIPS that have been specified in its Objectives and Principles require Article 27.1 to be interpreted in a manner that acknowledges a similar form of autonomy that has been preserved under the TRIPS Agreement. Part C argues that the broad scope of this obligation is such that it is to acknowledge this autonomy that the Panel recognized its concept of 'justification' and proceeds to identify its constitutive elements to provide a more comprehensive interpretation of the rule against the 'discrimination' of fields of technology that gives a deeper understanding of the Panel's formulation of 'discrimination'.

A. TRADE SIBLINGS: THE NATIONAL TREATMENT AND MOST FAVOURED NATION TREATMENT OBLIGATIONS

It will be recalled that the non-discrimination obligation in Article 27.1 was a novel creation by the TRIPS Agreement as there was no similar rule in any other multilateral treaty dealing with international patent law at the time TRIPS was being negotiated. It will also be recalled that this 'trade concept' was utilized as a compromise solution when the TRIPS negotiators could not agree on certain provisions concerning compulsory licences of patented inventions. The interpretation of the concept of 'discrimination' in TRIPS Article 27.1 should reflect this negotiation context that could be done only by acknowledging the trade origins of this unique obligation. These trade origins could be acknowledged only with a proper understanding of the operation of the National Treatment (NT) and Most-Favoured Nation treatment (MFN) obligations in the WTO.

The NT and MFN obligations that originally formed the basic principles of the *General Agreement on Tariff and Trade* (GATT) 1947 were given the task combatting discrimination in international trade under the WTO's multilateral system. Distinctly, they were not only meant to apply to trade in goods, but also to services, intellectual property, investments, sanitary measures and even technical regulations that were the subject matter of the covered agreements. These non-discrimination norms formed the principal mechanism by which the WTO sought to prevent discrimination in international trade and promote equality. As Thomas Cottier and Lena Schneller highlight, these non-discrimination obligations are not ends by themselves, but only

a *means* by which the WTO seeks to enhance global welfare, full employment and sustainable development in line with the Preamble of the WTO Agreement.[2] Given this broader objective of these norms, the following sections of this Part that scrutinize the NT and MFN obligations in GATT, *General Agreement on Trade in Services* (GATS), *Agreements on the Application of Sanitary and Phytosanitary Measures* (SPS) and on *Technical Barriers to Trade* (TBT) demonstrate that a fundamental feature in these norms is that they are meant to be *balanced* against the autonomy of the WTO Members to pursue important policy objectives. This is achieved in two ways: firstly, they require the demonstration of certain specific standards of comparison between the subject matter before they come into operation; secondly, they recognize the applicability of certain justificatory concepts that enable WTO Members to defend an allegation of inconsistency by demonstrating the legitimate exercise of their autonomy. This constitutes the most vital 'context' within the meaning of VCLT Article 31(1) in the interpretation of 'discrimination' of fields of technology in TRIPS Article 27.1 as it informs an interpreter that a non-discrimination obligation that has trade origins can almost never be an absolute obligation. Subsequent Parts of this Chapter argue this what the Panel in *Canada- Pharmaceuticals* acknowledged by identifying a notion of 'justification' within the concept of 'discrimination' in Article 27.1.

- *THE GENERAL AGREEMENT ON TARIFF AND TRADE 1994*

GATT 1994 that succeeded its 1947 predecessor is the most significant of the thirteen goods-related multilateral agreements annexed to the WTO Agreement. Its Preamble states that its aim is to 'raise the standards of living, ensure full employment and a large and steadily growing volume of real income and effective demand' by reducing tariff barriers and eliminating discriminatory treatment in international commerce. The Most-Favoured Nation Treatment (MFN) and the National Treatment (NT) obligations are the fundamental instruments utilized to eliminate such discrimination, and therefore, are known as the substantive non-discrimination norms in the WTO. The general objective of these non-discrimination norms was succinctly described by the Appellate Body in *EC- Bananas III* as ensuring the 'equal treatment of products, irrespective of their origin'.[3]

[2] T. Cottier and L. Schneller, 'The Philosophy of Non-Discrimination in International Trade Regulation' in A. Sanders (ed.), *The Principle of National Treatment in International Economic Law: Trade, Investment and Intellectual Property*, Edward Elgar, 2014, p. 3 at p. 3.

[3] Appellate Body Report, *European Communities-Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R, para. 190.

Preserving such equality in the treatment of products is so significant to an international trading system dealing with goods that the Appellate Body reiterated in *US- Section 211 Appropriations Act* that these norms have long been the 'cornerstones' of the world trading system and that they are 'central and essential' to assuring the success of a global rules-based system for trade in goods.[4] These obligations that were initially developed in the context of goods were introduced into the new covered agreements that were negotiated under the Punta Del Este Ministerial Mandate. Hence, the Preambles to TRIPS, TBT, SPS and GATS state that the members recognize the need for new rules to apply the *basic principles of GATT* that include the *non-discrimination norms*. To ensure harmonious interpretation of these substantive non-discrimination obligations within the WTO, the WTO tribunals take into consideration the manner in which these norms are interpreted and applied under GATT 1994 when interpreting and applying these norms under the other covered agreements. Thus, the non-discrimination obligations in GATT deserve separate discussion in this Part.

The MFN obligation is considered to have been first used in the international context in the eleventh century in a Charter by the Holy Roman Emperor.[5] It essentially prohibits discrimination *between* trading partners. The MFN obligation in GATT is principally set-out in Article I:1. It requires border or internal measures of a Member that confer 'any advantage' on products from or destined to a Member to be 'immediately and unconditionally' accorded to 'like products' from or destined to other WTO Members.[6] Consequently, any advantage given to products originating from a Member or being exported to a Member should be given to 'like products' originating from, or being exported to, any other WTO Member. Bossche and Zdouc state that by ensuring that WTO Members have the *equality of opportunity*[7] to import from, and export to, other members of the WTO, the MFN obligation prevents favouritism between WTO Members.[8]

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[4] Appellate Body Report, *United States- Section 211 Omnibus Appropriations Act of 1998,* WT/DS176/AB/R, para. 297.

[5] See W. Davey and J. Pauwelyn, 'MFN Unconditionality: A Legal Analysis of the Concept in View of its Evolution in the GATT/WTO Jurisprudence with Particular Reference to the Issue of "Like Product"', in T. Cottier, P. Mavroidis and P. Blatter (eds.), *Regulatory Barriers and The Principle of Non-Discrimination in Worlds Trade Law*, University of Michigan Press, 2000, p. 13.

[6] See P. Bossche and W. Zdouc, *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, Third edition, Cambridge University Press, 2013, pp. 317-330; M. Matsushita, P. Mavroidis and T. Schoenbaum, *The World Trade Organization: Law, Practice, and Policy*, Third edition, Oxford University Press, 2015, pp. 156-177.

[7] Bossche and Zdouc, n. 6, p. 318. Also see Panel Report, *European Communities- Regime for the Importation, Sale and Distribution of Bananas (Ecuador)*, WT/DS27/R/ECU, para. 7.239; Appellate Body Report, *Canada-Certain Measures Affecting the Automotive Industry*, WT/DS139/AB/R, WT/DS142/AB/R, para. 84.

[8] Bossche and Zdouc, n. 6, p. 316.

The National Treatment (NT) obligation addresses a different form of discrimination. It prohibits the favouring of nationals at the expense of foreigners. The key NT provisions in GATT are specified in Article III entitled 'National Treatment on Internal Taxation and Regulation'.[9] The broad and fundamental purpose of GATT Article III is set-out in Article III:1, which, as the Appellate Body has noted, informs the interpretation of the specific NT obligations found in Article III:2 and Article III:4.[10] GATT Article III:1 provides as follows:

> The Members recognize that internal taxes and other internal charges, and laws, regulations … should not be applied to imported or domestic products *so as to afford protection to domestic production*.[11]

Hence, the objective of the NT obligations is to avoid protectionism. The Appellate Body reiterated in *Japan- Alcoholic Beverages II* that the NT obligations avoid protectionism by ensuring 'the equality of competitive conditions for imported products in relation to domestic products'.[12] Article III:2 deals with internal *fiscal* measures, whereas Article III:4 concerns internal *regulatory* measures. Article III:2 subdivides into two provisions that contain two distinct NT obligations. Its first sentence specifies that internal taxes should not be applied to imported products 'in excess of' that which is applied to 'like' domestic products. Its second sentence, read together with its *Ad* note, requires internal taxes not be applied to imported products that are in a 'directly competitive or substitutable' relationship with domestic products so as to 'afford protection to domestic production'. Hence, the applicable sentence of GATT Article III:2 in any given case depends on the degree of the competitive relationship that exists between the imported product and the privileged domestic product. GATT Article III:4, on the other hand, specifies the NT obligation in relation to *non-fiscal* regulatory measures. It requires that internal laws and regulations of a member that affect the internal trade of goods should not subject imported goods to 'less favourable treatment' than that accorded to 'like' domestic goods. Unlike in Article III.2, there is no concept of 'directly competitive or substitutable' products in Article III:4.

Detailed examinations of the substantive scope and application of these obligations have been admirably done by many academics and practitioners, and therefore, such a discussion is not required here. However, the objective of the following sub-sections is to highlight the

[9] See generally Bossche and Zdouc, n. 6, pp. 349-402; Matsushita et al., n. 6, pp. 179-210.
[10] See Appellate Body Report, *European Communities- Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/AB/R, para. 93.
[11] Emphasis added.
[12] Appellate Body Report, *Japan- Taxes on Alcoholic Beverages*, WT/DS8/AB/R, p. 16.

significance of two important mechanisms prevalent in GATT's NT and MFN obligations that serve to acknowledge the autonomy on the part of the WTO Members to pursue vital national interests even in the context of these obligations.

❖ *The Standards of Comparison Between the Subject Matter*

The substantive non-discrimination obligations of GATT only come into play when a specific standard of comparison has been established between the subject matter. For example, to the exception of the NT obligation in the second sentence of Article III:2, GATT's NT/MFN obligations prevent the proscribed types of discrimination only between 'like products'. Therefore, 'likeness' between the disadvantaged and privileged product is a vital prerequisite that must be established by a complainant when demonstrating a violation of these obligations. The Appellate Body has held in the context of the first sentence of Article III:2 that:

> … there are two questions which need to be answered to determine whether there is a violation of Article III:2 of the GATT 1994: (a) *whether the imported and domestic products are like products*; and (b) whether the imported products are taxed in excess of the domestic products. If the answers to both questions are affirmative, there is a violation of Article III:2, first sentence.[13]

Similarly, the Appellate Body has held in the context of Article III:4 that:

> There are three elements that must be demonstrated to establish that a measure is inconsistent with Article III:4: (i) *that the imported and domestic products are "like products"*; (ii) that the measure at issue is a "law, regulation, or requirement affecting the internal sale, offering for sale, purchase, transportation, distribution, or use" of the products at issue; and (iii) that the treatment accorded to imported products is "less favourable" than that accorded to like domestic products.[14]

Consequently, Mitsuo Matsushita, Thomas Schoenbaum, Petros Mavroidis and Michael Hahn note that products that are 'unlike' can be lawfully treated differently even if such treatment falls below the requisite standards mandated by the NT/MFN obligations.[15] Julia Qin opines that

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[13] Appellate Body Report, *Canada- Certain Measures Concerning Periodicals*, WT/DS31/AB/R, p. 468. Emphasis added.
[14] Appellate Body Report, *European Communities- Measures Prohibiting the Importation and Marketing of Seal Products*, WT/DS400/AB/R, para. 5.99.
[15] See Matsushita et al, n. 6, p. 163. Emphasis added.

this is because the general notion of non-discrimination is founded upon the concept of *equality* and the standard of comparison meant to be used to determine the existence or non-existence of such equality in the GATT's substantive non-discrimination obligations is the 'likeness' of the products.[16] Hence, the autonomy of the Members to regulate products that do *not* fall within this 'likeness' criteria is unhindered by the GATT's MFN/NT obligations. In a similar vein, the NT obligation in the second sentence of GATT Article III:2 only comes into play when the products in question are 'directly competitive or substitutable'. While this concept is different to that of 'likeness', it is still a prerequisite that a complainant needs satisfy when demonstrating a violation of this obligation.

Further, even the 'like product' analysis under GATT's NT/MFN obligations is capable of acknowledging certain regulatory concerns of a member to render a product to be 'unlike' and prevent the application of these obligations. The Appellate Body has noted that the 'likeness' of products depends on the nature and extent of the 'competitive relationship' between the products.[17] In making this determination, WTO tribunals often resort to four criteria traceable to the *Working Party Report on Border Tax Adjustments* (1970) and previous GATT practice: (a) the end uses of the products; (b) consumer tastes and habits; (c) product properties, nature and quality; and (d) the tariff classification. However, these criteria have been held only to provide the framework for such an analysis that should be performed on a case-by-case basis.[18] They only constitute guidelines and are in no way exhaustive of the elements that could be taken into consideration when determining 'likeness'.[19] This is facilitated by another feature in the 'likeness' analysis. The Appellate Body has noted that the degree of the 'competitive relationship' that is necessary to render products to be 'alike' *varies* depending on the context in which the concept is used. It explained in *Japan- Alcoholic Beverages II*:

> The concept of 'likeness' is a *relative one that evokes the image of an accordion*. The accordion of 'likeness' *stretches and squeezes in different places as different provisions* of the WTO Agreement are applied. The *width of the accordion in any one of those places must be determined by the particular provision in which the term 'like' is encountered as well as by the*

[16] J. Qin, 'Defining Nondiscrimination under the Law of the World Trade Organization', *Boston University International Law Journal*, vol. 23, no. 2, 2005, p. 221.
[17] Appellate Body Report, *Philippines- Taxes on Distilled Spirits, WT/DS403/AB/R*, para. 170.
[18] Appellate Body Report, *EC- Asbestos*, n. 10, para. 102.
[19] Matsushita et al., n. 6, p. 198.

> *context and the circumstances* that prevail in any given case to which that provision may apply.[20]

The Appellate Body explained that this 'accordion' shrinks in the first sentence of Article III:2 because there is a concept of 'directly competitive or substitutable products' in its second sentence that accommodates a broader competitive relationship between products.[21] Hence, a broad interpretation of 'likeness' in the first sentence of Article III:2 would render its second sentence to be redundant. On the other hand, it explained in *EC- Asbestos* that the 'accordion' stretches in Article III:4 as it does not contain the duality found in Article III:2. In its words:

> … the "general principle" articulated in Article III:1 is expressed in Article III:4, not through two distinct obligations, as in the two sentences in Article III:2, but instead through a single obligation that applies solely to "like products". Therefore, the harmony that we have attributed to the two sentences of Article III:2 need not and, indeed, cannot be replicated in interpreting Article III:4. Thus, we conclude that, given the textual difference between Articles III:2 and III:4, the "accordion" of "likeness" stretches in a different way in Article III:4.[22]

'Stretching' the accordion, however, does not mean that more products are likely to be found 'alike', but that the *analysis* is meant to be broader. Therefore, broader considerations could influence the 'likeness' or 'unlikeness' of the products. This is apparent in the Appellate Body's findings in *EC- Asbestos* itself. Consequent to explaining that the criteria commonly used to examine 'likeness' is not exhaustive and that the considerations in Article III:4 are broader than in Article III:2, it held that asbestos fibre related products were not 'like' other fibre related products *due to the health risks associated with asbestos fibres*. These risks were relevant under the criteria of 'consumer tastes and habits' that served to distinguish asbestos fibres from the other fibre related products, although there were several similarities between them.[23]

As Matsushita and others state, this practice relating to the interpretation of 'like products' gives the WTO tribunals a significant degree of interpretative power to determine the *scope* of GATT's NT/MFN obligations.[24] Preserving such an interpretative power is perhaps necessary in a multilateral system that seeks to eliminate discrimination in goods that take various shapes

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[20] Appellate Body Report, *Japan- Alcoholic Beverages II*, n. 12, p. 114. Emphasis added.
[21] Ibid., pp. 112-113.
[22] Appellate Body Report, *EC- Asbestos*, n. 10, para. 96.
[23] Ibid., para. 121-147.
[24] Matsushita et al., n. 6, p. 196.

and forms. It enables the tribunals and the membership to determine the precise circumstances in which the substantive non-discrimination obligations come into operation. Consequently, relevant for the purposes of this Chapter is to observe that such interpretative power that is preserved within these specific standards of comparison mandated by GATT's NT/MFN obligations set important limitations, or are at least capable of imposing limitations, on the scope of GATT's substantive non-discrimination norms that preserve the autonomy of the WTO Members to regulate products that are 'unlike', the determination of which is also capable of taking into account the regulatory concerns of the products in question.

❖ *The General Exceptions*

An even greater balance between GATT's non-discrimination obligations and the autonomy of the WTO Members is struck by the General Exceptions that have been set-out in GATT Article XX. A Member is entitled to defend a measure that is found to be inconsistent with GATT's substantive non-discrimination obligations, or any other GATT obligation for that matter, by relying on these General Exceptions. Bossche and Zdouc state that the promotion of public health, consumer safety, environment, employment, economic development and national security are the 'core' tasks of local governments. Hence, Members may be politically and/or economically compelled to adopt measures that are inconsistent with the WTO's rules on market access and non-discrimination.[25] They state that it is this that is acknowledged in GATT Article XX, which according to Bossche and Zdouc provide:

> … a set of rules to reconcile trade liberalization, market access and non-discrimination rules with the need to protect and promote other societal values and interests.[26]

Accordingly, they refer to Article XX as a 'balancing provision'[27] that seeks to strike an appropriate balance between GATT obligations and the ability of the WTO Members to pursue such vital policy interests. Peter Stoll and Lutz Strack highlight that the need for such a *balance* is fundamental given that the ability to pursue such vital interests is a matter of national sovereignty.[28] As Article XX is a lengthy provision, only its parts that are most significant for the purposes of this Chapter are quoted below:

[25] Bossche and Zdouc, n. 6, pp. 534-544.
[26] Ibid.
[27] Ibid., p. 547.
[28] P. Stoll and L. Strack, 'GATT Article XX. Lit. B.', in R. Wolfrum, P. Stoll and H. Hestermeyer (eds.), *WTO-Trade in Goods*, Martinus Nijhoff Publishers, 2011, p. 497 at p. 499.

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> (*a*) necessary to protect public morals;
>
> (*b*) necessary to protect human, animal or plant life or health;
>
> (…)
>
> (*d*) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those…
>
> (…)
>
> *(g)* relating to the conservation of exhaustible natural resources …
>
> …

It sets out an exhaustive list of policy objectives that a WTO Member may pursue to justify a GATT inconsistent measure. It is broad in the sense that Members are entitled to pursue those objectives in whichever manner they desire, but it is also limited because the policies that could be pursued have been specified exhaustively. The WTO jurisprudence demonstrates that the availability of an exception under GATT Article XX is dependent on a two-stage analysis: (a) a Member must provisionally justify its measure under one of the sub-paragraphs of Article XX, *and* (b) satisfy the requirements of the introductory paragraph known as the 'chapeau'.[29] The sub-paragraphs of Article XX do not only identify the policy objectives that are to be considered legitimate in the context of this provision, but also specify the degree of connection that must exist between a national measure and the stated policy objective. The parts of Article XX quoted above demonstrate that measures directed for the protection of public morals, human, animal, plant life or health and the compliance with domestic laws and regulations must meet a standard of 'necessity'.

[29] See for example Appellate Body Report, *United States- Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, p. 22; Appellate Body Report, *Brazil- Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R, para. 159.

'Necessity' in this context is considered to be the highest form of nexus that is mandated by Article XX and is distinguished from concepts such as 'relating to' found in certain other sub-paragraphs of Article XX. The Appellate Body has held, however, that it does not mean indispensability and that it should be determined by examining an array of factors and circumstances pertaining to a given measure.[30] The Appellate Body explained in *Korea- Beef* that it always involves:

> … a process of weighing and balancing a series of factors which prominently include the *contribution*… the *importance* of the common interest or values… and the accompanying *impact* of the law or regulation on imports or exports.[31]

In an article that examines the evolution of the test of 'necessity' in WTO law, Ming Du has identified that the importance of the non-trade value, the degree of contribution by a measure, its trade restrictiveness and the availability of reasonable alternatives are meant to be 'weighed and balanced' to ascertain the 'necessity' of a measure.[32] The 'availability of alternatives' requires a tribunal to consider if the Member in question had a GATT consistent measure or a less-inconsistent measure that it could have 'reasonably' adopted instead of its own measure.[33] The use of the term 'reasonable' alternatives has been understood to mean that even a less-inconsistent measure that is identified by a complainant may not be truly an available alternative as it might be unrealistic in the light of the respondent Member's level of economic, social and technological standards. In the context of the General Exceptions in the *General Agreement on Trade in Services* (GATS), the Appellate Body seminally noted in *US- Gambling* that:

> An alternative measure may be found not to be "reasonably available", however, where it is merely theoretical in nature, for instance, where the responding Member is not capable of taking it, or where the measure imposes an undue burden on that Member, such as prohibitive costs or substantial technical difficulties.[34]

In *EC- Asbestos*, Appellate Body highlighted the importance of scrutinizing a range of factors in determining the presence of an available alternative under GATT Article XX. While it noted

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[30] Appellate Body Report, *Korea- Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, para. 161- 163. Emphasis added.
[31] Ibid., para. 164.
[32] M. Du, 'The Necessity Test in World Trade Law: What Now?', *Chinese Journal of International Law*, vol. 15, no. 4, 2016, p. 817 at pp. 826-834.
[33] Appellate Body Report, *Korea- Beef*, n. 30, para. 166.
[34] Appellate Body Report, *United States- Measures Affecting the Cross-Border Gaming and Betting Services*, WT/DS285/AB/R, para. 308; Also see Appellate Body Report, *Brazil- Retreaded Tyres*, n. 29, para. 156

that mere administrative difficulties would not by themselves suffice to show that an alternative is *not* reasonably available, it explained that:

> … in determining whether a suggested alternative measure is "reasonably available", several factors must be taken into account, besides the difficulty of implementation.[35]

Consequently, a range of factors between impossibility and mere administrative difficulties related to the developmental and economic standards of a Member are relevant in determining if an alternative is 'reasonably available'. Stoll and Strack state that even problems relating to the implementation of a suggested alternative are relevant in this determination.[36] Hence, an alternative that is potentially reasonably available to a developed country Member may not be necessarily so to a developing or least developed country Member. This demonstrates that the General Exceptions in GATT do not only provide the WTO Members with the ability to justify measures inconsistent with their non-discrimination obligations, but that they are also capable of acknowledging the diverse levels of development among them. Thereby, Article XX recognizes the fundamental principle in the WTO Agreement's Preamble that requires WTO obligations to be balanced against the domestic interests of WTO Members by, *inter alia*, taking into account their 'different levels of economic development'.[37]

Related to the assessment of available alternatives is the significance that the WTO tribunals attach to the level of protection of a policy objective that a member has sought to achieve. The Appellate Body stated in *EC-Asbestos* in unambiguous terms that a WTO member has the *right* to determine the level of protection of the policy objectives mentioned in Article XX. In its words:

> … we note that it is undisputed that WTO Members *have the right* to determine the level of protection of health that they consider appropriate in a given situation. [38]

The Appellate Body reiterated this in *Brazil- Retreaded Tyres*:

> … the *fundamental principle* is the right that WTO Members have to determine the level of protection that they consider appropriate in a given context.[39]

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[35] Appellate Body Report, *EC- Asbestos*, n. 10, para. 170.
[36] Stoll and Strack, n. 28, p. 512.
[37] See the first sentence of the Preamble to the WTO Agreement.
[38] Appellate Body Report, *EC- Asbestos*, n. 10, para. 168. Emphasis added.
[39] Appellate Body Report, *Brazil- Retreaded Tyres*, n. 29, para. 210. Emphasis in original.

As such, a suggested alternative that does not achieve the same level of protection desired by a respondent Member does not constitute an alternative that is available, as it would violate the right of the WTO Members to determine the importance of a policy and its desired level protection within its jurisdiction. Thus, as Bossche and Zdouc state:

> Other Members *cannot challenge the level of protection chosen*; they can only argue that the measure at issue is not 'necessary' to *achieve that level of protection*.[40]

For this reason, the Appellate Body held in *EC- Asbestos* that the 'controlled use' of asbestos was *not* a reasonable option for France as it did not meet the same level of protection of human life and health as much as a total 'prohibition' of asbestos. Speaking of how these trends relating to the test of necessity have worked to preserve the autonomy on the part of the WTO Members, Ming Du states:

> … the weighing and balancing test, after the AB's constant refinement, tends to give more respect to WTO Members' domestic regulatory autonomy than the GATT/WTO panels did in the earlier years. To begin with, in interpreting "necessary", the AB does not simply endorse an alternative measure with less trade restrictive effects and then impose it on the responding Member. Instead, the AB has repeatedly stressed that a reasonably available alternative must be able to fulfil the responding Member's appropriate level of protection as well as being truly feasible in view of the Member's particular political, cultural and economic situations.[41]

This discussion of GATT's substantive non-discrimination obligations, the most notable trade siblings of the non-discrimination norm in TRIPS Article 27.1, demonstrates that they only come into operation in the presence of certain defined standards of comparison between the subject matter. They do not only prevent the operation of these obligations in the absence of those specific standards of comparison, but the scrutiny of those standards has even served to acknowledge certain regulatory concerns relating to certain products that prevent the operation of these obligations. Further, even when they do come into operation, members have the opportunity to justify an inconsistency by resorting to the General Exceptions. The General Exceptions have also been interpreted in a manner that acknowledges the diverse standards of development among the WTO Members and their right to determine the level of protection that

[40] Bossche and Zdouc, n. 6, p. 558. Footnote omitted. Emphasis added.
[41] Du, n. 32, p. 836. Footnote omitted.

they desire to achieve. These mechanisms that serve to balance these non-discrimination norms against the autonomy of the Members are so vital in the context of the WTO's multilateral system that the next section demonstrates that similar mechanisms are prevalent in the substantive non-discrimination obligations under the other covered agreements of the WTO concerning goods and services.

- *THE GENERAL AGREEMENT ON TRADE IN SERVICES, THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES AND THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE*

The extension of the NT/MFN obligations to international trade in services under the *General Agreement on Trade in Services* (GATS) was a maiden accomplishment by the GATT/WTO trade negotiations that concluded in 1994. As Nicolas Diebold notes, the adoption of these obligations to *intangible* subject matter like services required certain adjustments to be made to the MFN/NT obligations.[42] Particularly, their intangible nature made it difficult to have a clear distinction between border and internal measures. Therefore, the MFN and NT obligations in GATS have been given a broad scope by being applicable to any measure that *affects* trade in services. This has been interpreted by the Appellate Body in *EC- Bananas III* to mean any measure that has an 'effect' on the trade in services.[43] The most fundamental MFN obligation in relation to services is contained in GATS Article II:1. It provides that 'any measure affecting trade in services' of a WTO Member should accord 'immediately and unconditionally' treatment that is 'no less favourable' to 'like services and service suppliers' of other WTO Members than it accords to 'like services and service suppliers' of 'any other country'. Like the MFN obligation in GATT, Bossche and Zdouc note that its main purpose is to ensure that WTO Members have the *equality of opportunities* in the supply of services.[44]

The NT obligation of GATS is set-out in Article XVII:1 and provides as follows:

> In the sectors inscribed in its Schedule, and subject to any conditions and qualifications set out therein, each Member shall accord to services and service suppliers of any other Member, in respect of all measures affecting the supply

[42] See N. Diebold, *Non- Discrimination in International Trade in Services: 'Likeness' in WTO/GATS*, Cambridge University Press, 2010, Ch. 1; Also see G. Muller, 'National Treatment and the GATS: Lessons from Jurisprudence', *Journal of World Trade*, vol. 50, no. 5, 2016, p. 819.
[43] Appellate Body Report, *EC- Bananas III*, n. 4, p. 220.
[44] Bossche and Zdouc, n. 6, p. 335.

of services, treatment no less favourable than that it accords to its own like services and service suppliers.

Accordingly, it requires that 'a measure that affects the supply of services' should accord 'treatment no less favourable' to services or service suppliers of other members than it accords to 'like domestic services or service suppliers'. As in GATT, it too strives to preserve the equality of competitive conditions *between* domestic and foreign services and service suppliers. However, evident in the first words of GATS Article XVII:1 is a vital distinction between its MFN and NT obligations that is not present in GATT. While GATS's MFN obligation is a general obligation that applies to all members, its NT obligation is a 'specific commitment' that is applicable and in fact applies only to the extent that a given member has explicitly committed itself to grant such treatment in respect of a specific service sector.[45] As GATS Article XVII:3 explicitly recognizes the *de facto* application of this NT obligation to *any national measure affecting trade in services*, Gilles Muller and several other writers have argued that GATS's NT obligation has the potential to intrude the national regulatory autonomy more than the parties had intended.[46] Nonetheless, Muller rightly notes that these concerns only materialize if a WTO Member has actually undertaken a specific NT commitment.[47] While this is a pragmatic limitation on GATS's NT obligation, it is also apparent that even when there is such a specific commitment by a Member, the obligation only comes into play when the privileged domestic services/service suppliers are 'like' one of those mentioned in the Member's Schedule. Similarly, even the general MFN obligation in GATS Article II:1 only applies between 'like' services/service suppliers. Consequently, the applicability of both these obligations rest on the concept of 'likeness', which Matsushita and others state, depends on the existence of a competitive relationship between the services/service suppliers in question.[48] Although GATS's concept of 'likeness' has not yet been examined by the Appellate Body, a WTO Panel has acknowledged its similarities with GATT's concept of 'like products' in *China- Electronic Payment Services*. It stated that:

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[45] Ibid., p. 403. Also see Matsushita et al., n. 6, p. 557.

[46] G. Muller, '*De Facto Discrimination Under GATS National Treatment: Has the Genie of Trade Liberalization Been Let Out of the Bottle?*', Legal Issues of Economic Integration, vol. 44, no. 2, 2017, p. 151. Also see M. Crossy, 'Some Thoughts on the Concept of 'Likeness' in the GATS' and J. Pauwelyn, 'The Unbearable Lightness of Likeness in GATS and the Regulation of International Trade in Services', in M. Panizzon, N. Pohl and P. Sauvé (eds.), *GATS and the Regulation of International Trade in Services*, Cambridge University Press, 2008, p. 327 and p. 358 respectively; M. Krajewski and M. Engelke, 'Article XVII GATS', in R. Wolfrum, P. Stoll and C. Feinäugle (eds.), *WTO-Trade in Services*, Martinus Nijhoff Publishers, 2008, p. 396; G. Muller, 'National Treatment and the GATS', n. 44.

[47] Muller, 'De Facto Discrimination', n. 46, p. 166.

[48] Matsushita et al., n. 6, p. 568

> As in goods cases where a panel assesses whether a particular product is a 'like product', the determination must be made on the basis of evidence as a whole. If it is determined that the services in question in a particular case are essentially or generally the same in competitive terms, those services would, in our view, be 'like'.[49]

Accordingly, the *Border Tax Adjustment* criteria that include end uses, consumer tastes and habits, product properties, together with their tariff classification constitute vital indicators of 'likeness' even in the context of GATS.[50] Therefore, as in GATT, the autonomy of the Members to regulate services/service suppliers that are not 'like' is not hindered by the NT/MFN obligations. Moreover, broader regulatory concerns relating to a particular service/service supplier should also be capable of rendering them to be 'unlike' and prevent the application of these norms as the Appellate Body has highlighted in the context of GATT. This autonomy is even greater in relation to GATS's NT obligation as even the determination of 'likeness' comes into play only when there is a specific NT commitment by a WTO Member.

Furthermore, GATS also contains a list of General Exceptions in Article XIV that permit the WTO Members to defend a national measure that has been found to be inconsistent with its NT/MFN obligations. It follows the identical model of GATT Article XX, which Cottier, Delimatsis and Diebold identify as the 'cornerstone' of the multilateral trading system that allows Members to pursue legitimate non-economic policy objectives.[51] Explaining the purpose of GATS Article XIV, they state:

> … the protection of interests such as public health, public order, safety, public morals, environment etc. requires the adoption of trade restrictive measures, technically resulting in a direct conflict with GATS obligations. WTO law seeks to establish a proper balance between different policy goals. Such *balance* is sought and achieved in part by principles of progressive liberalization and inherent limitations. In part it is sought by allowing for general exceptions applicable to all the provisions and existing commitments under an agreement.[52]

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[49] Panel Report, *China- Certain Measures Affecting Electronic Payment Services*, WT/DS413/R, para. 7.701-7.702.
[50] Matsushita et al, n. 6, pp. 568-9.
[51] T. Cottier, P. Delimatis and N. Diebold, 'Article XIV GATS', in Wolfrum et al. (eds.), n. 46, p. 290.
[52] Ibid. Emphasis added.

In order to achieve such a balance, GATS Article XIV recognizes certain policies that a WTO Member may legitimately pursue to justify a measure that is inconsistent with its MFN/NT obligations. Its sub-paragraphs recognize the legitimacy of measures, *inter alia*, 'necessary' to protect public morals, public order, human, animal, plant life and health and the compliance of domestic laws and regulations. To date, however, the Appellate Body has substantively dealt with GATS's General Exceptions only in *US- Gambling* in which it confirmed the relevance of the two-stage analysis found in GATT Article XX.[53] The Appellate Body also imported the 'weighing and balancing' test to determine the 'necessity' of measures that seek to protect public morals and public order under GATS Article XIV's sub-paragraph (a). It is in this context that the Appellate Body noted that mere theoretical or costly alternatives are *not* available alternatives when determining 'necessity', which as highlighted before, now informs the test of 'necessity' in GATT Article XX. Consequently, although there is a lack of jurisprudence dealing with GATS' General Exceptions, it is clear that all the considerations discussed in relation to the test of 'necessity' in GATT Article XX are equally relevant here. Therefore, the General Exceptions of GATS not only provide the membership with the opportunity to justify a measure that is inconsistent with GATS's NT/MFN obligation, but they are also capable of acknowledging the varying developmental standards and the right of the Members to determine the requisite level of protection of a non-economic policy objective. Consequently, the manner in which GATS strives to achieve a balance between its substantive non-discrimination obligations and the autonomy of Members is near identical to that found in GATT.

The mechanisms prevalent in the *Agreements on the Application of Sanitary and Phytosanitary Measures* (SPS) and *Technical Barriers to Trade* (TBT) that seek to achieve a balance between their NT/MFN obligations and the autonomy of the Members are somewhat different to those found in GATT/GATS given that TBT and SPS specifically deal with certain types of non-tariff barriers to trade. These two agreements are a result of a compromise reached by the Members to strike a balance between their *right* to regulate certain aspects of trade against their desire to avoid unnecessary trade obstacles in this process. Thus, Matsushita and others point out that SPS and TBT are a result of an intricate balance that has similar traits to that sought by the General Exceptions of GATT,[54] and even GATS for that matter. This is apparent from the Preamble to SPS which provides that it is meant to '*elaborate* on the application of GATT Article XX(b)' that concerns measures for the protection of human, animal, plant life or health.

[53] Appellate Body Report, *US- Gambling*, n. 34, para. 292.
[54] Matsushita et al., n. 6, p. 434.

The following sections demonstrate that this inherent balancing nature of the SPS and TBT Agreements has resulted in their NT/MFN obligations to be interpreted and applied in a manner that acknowledges the regulatory autonomy of the Members in order to achieve the type of balance that is sought under the NT/MFN obligations in GATT/GATS.

The first recital of the Preamble to the SPS Agreement states as follows:

> … no Member should be prevented from adopting or enforcing measures *necessary to protect human, animal or plant life or health*, subject to the requirement that these measures are *not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination* between Members where the same conditions prevail or a *disguised restriction on international trade*.[55]

This sums up the objective of the SPS Agreement: to balance the right of the Members to adopt SPS measures against the total disregard of the objectives of the WTO. SPS Article 1.1 provides that the Agreement applies to *all* sanitary and phytosanitary measures that *affect* international trade, which has been further defined in its Annexure to include all measures applied to protect human, animal or plant health from food-borne risks, risks from pests and diseases of plants or animals. Therefore, as Dukgeun Ahn rightly notes, the applicability of the SPS Agreement is solely dependent on the objectives of a national measure in issue.[56] This gives the Agreement broad scope of application.

SPS Article 2.1 recognizes the basic *right* of each Member to adopt SPS measures. The Appellate Body has held that this is a recognition of the *prerogative* right of all Members.[57] However, as highlighted in its Preamble, this prerogative right should be exercised responsibly. One of the most significant of those responsibilities have been set-out in Article 2.3 that entail the general NT/MFN obligation of the SPS Agreement. It provides as follows:

> Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of

[55] Emphasis added.
[56] D. Ahn, 'Comparative Analysis of the SPS and the TBT Agreements', *International Law and Regulation*, vol. 8, no. 3, 2002, p. 85.
[57] See Appellate Body Report, *Australia- Measures Affecting Importation of Salmon*, WT/DS18/AB/R, para. 199.

> other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

Accordingly, SPS measures should not arbitrarily or unjustifiably discriminate between members (MFN) or between domestic and foreign territories (NT) with identical or similar SPS conditions. The specifics of the application of this general rule have been elaborated in the jurisprudence concerning SPS Article 5.5 that specifically relates to *distinctions* made with regard to levels of SPS protection. In relevant part, Article 5.5 provides that:

> … each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.

Thus, it prohibits arbitrary or unjustifiable distinctions in the levels of SPS protection in 'different situations' that lead to discrimination or restrictions to international trade. Notwithstanding the apparent broad notion of 'different situations' in this provision, the Appellate Body noted in *Australia- Salmon* that differences in SPS treatment become comparable under the notion of 'different situations' only when the products pose *common* SPS risks.[58] This determination involves the scrutiny of whether the products in question have a common risk of entry, establishment and spread of a particular disease.[59] Hence, in *Australia-Salmon* where certain Australian measures that specifically applied to imported salmon were alleged to violate SPS Article 5.5, the Appellate Body found that the risks associated with the importation of certain types of salmon were *similar* to the risks associated with the importation of any other fish. Therefore, such distinctions with regard to the levels of SPS protection were comparable under Article 5.5.[60] Stoll and Strack have clarified that SPS Article 5.5 applies to products that pose *common* SPS risks in this manner because regulating risks posed by one group of products to the exclusions of others that pose similar risks is a sign of protectionism.[61] Consequently, this prohibited form of protectionism does not come into operation when a member's SPS measures differentiate between groups of products that pose *different* SPS risks.

This jurisprudence now come to influence the scope of SPS's general non-discrimination obligation in Article 2.3. A WTO Panel held in the subsequent compliance dispute in *Australia-Salmon (Article 21.5- Canada)* that even Article 2.3 applies only when the products in question

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[58] Ibid., para. 152.
[59] Ibid.
[60] Ibid., para. 147.
[61] P. Stoll and L. Strack, 'Article 5 SPS', in R. Wolfrum, P. Stoll and A. Seibert-Fohr (eds.), *WTO: Technical Barriers and SPS Measures*, Martinus Nijhoff Publsihers, 2007, p. 435 at p. 452.

could be associated with similar SPS risks.[62] It follows, therefore, that a complainant has the vital burden of demonstrating that the products in question in any given case pose *similar SPS risks* as it is this that triggers the non-discrimination obligations in SPS Article 2.3 and Article 5.5. While this is distinguishable from the market competition-oriented standards of comparison between products/services that trigger similar obligations in GATT/GATS, the objective of preserving 'equality' remains the same. The equality sought to be achieved by the non-discrimination obligations in SPS is the equal treatment of products that pose similar SPS risks. As with products/services that are 'unlike' in the case of GATT/GATS, the flip-side of this coin is that these SPS obligations do *not* obstruct the ability of the WTO Members to regulate SPS risks that do not fall within the ambit of these provisions.

Furthermore, as Article 5.5 only prohibits *arbitrary or unjustifiable* distinctions, a WTO Panel has also noted that different *levels* of risks that are associated with two groups of products that pose similar risks could nonetheless render such risks to be dissimilar and cause such treatment to be incomparable under this provision.[63] Thus, a higher risk in one group of products compared to another group of products with a similar yet less severe risk may not amount to an 'arbitrary or unjustifiable' distinction under this provision. Denise Prévost notes that in addition to such levels of risk, other difficulties associated with controlling such risks and the degree of government intervention necessary to achieve the desired level of protection are relevant in this determination of whether a *distinction* in the context of Article 5.5 is 'arbitrary or unjustified'.[64] Similarly, Joanne Scott notes that while 'higher risks' justify the adoption of higher levels of protection, this determination should involve the scrutiny of the likelihood of a disease being introduced to and being spread in a particular WTO Member, the availability of alternatives and the scale of intervention required for that particular WTO Member.[65] Consequently, a SPS risk posed by one group of products that might not be too severe to a developed country Member might be a high risk for a developing or least developed country Member who does not have the infrastructure to regulate such risks in those products. These factors that are meant to be relevant in the determination of whether Article 5.5 is applicable resemble those relevant under the test of 'necessity' under the General Exceptions of GATT/GATS. Unlike in GATT/GATS,

[62] Panel Report, *Australia- Measures Affecting Importation of Salmon* (Article 21.5- Canada), WT/DS18/RW, para. 7.112.
[63] See Panel Report, *United States- Certain Measures Affecting Imports of Poultry from China*, WT/DS392/R, para. 7.264-7.269.
[64] D. Prévost, 'National treatment in the SPS Agreement: A *sui generis* obligation', in Sanders (ed.), n. 2, p. 125 at p. 149.
[65] J. Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary*, Oxford University Press, 2007, pp. 145-148.

however, these factors serve to ensure that the very *applicability* of SPS's non-discrimination obligations acknowledge the autonomy of the membership to determine the appropriate levels of SPS protection, the vitality of a given SPS risk and the developmental dissimilarities among the WTO Members.

Even when the non-discrimination obligations in SPS Articles 2.3 and 5.5 are triggered in this manner, a measure would be inconsistent only if it results in arbitrary or unjustified *discrimination* as set-out in Article 2.3. Although Article 5.5 only refers to 'discrimination' without referring to the concept of 'arbitrary or unjustified', the Appellate Body noted in *EC-Hormones* that as Article 5.5 is a specific manifestation of the general rule in Article 2.3, the latter constitutes important context to interpret the notion of 'discrimination' in Article 5.5.[66] Therefore, the Appellate Body noted that 'discrimination' in Article 5.5 refers to 'arbitrary or unjustified' discrimination. Examining the negotiation history relating to the non-discrimination obligations in SPS, Denise Prévost states that there was broad consensus among the more developed countries to include a non-discrimination norm that prevented such measures from constituting illegitimate barriers to trade.[67] However, the negotiators foresaw that a strict non-discrimination obligation would not be acceptable given that SPS conditions varied vastly from country to country and the WTO Members should be entitled to adopt SPS measures acknowledging such differences. Hence, the negotiators deemed the concept of 'arbitrary or unjustified discrimination between Members where identical or similar conditions prevail' to be more appropriate in the context of this Agreement.[68]

She states that this concept of 'arbitrary or unjustified discrimination' was meant to strike an intricate balance between the domestic regulatory autonomy of the Members to adopt SPS measures and their obligation not to create illegitimate barriers. While this balance is very similar to that sought by the General Exceptions of GATT/GATS, Prévost identifies a difference between the GATT/GATS and the non-discrimination norms in SPS in the following manner:

> … a crucial difference exists between … the SPS Agreement and the relevant GATT provisions. A rule-exception relationship exists between Article I and III:4 of the GATT, on the one hand, and Article XX of the GATT on the other.

[66] See Appellate Body Report, *European Communities- Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, para. 212.
[67] Prévost, n. 64, pp. 125-131.
[68] Ibid.

> In this GATT framework, discriminatory measures are prohibited in principle by Articles I and III:4, but may be justified under an Article XX exception… *By contrast, the prohibition of… the SPS Agreement itself incorporates flexibility for legitimate SPS measures by expressly limiting the content of its prohibition to cases of arbitrary or unjustifiable discrimination.*[69]

Hence, although there is no rule-exception structure in the SPS Agreement, its non-discriminations obligations inherently only prohibit arbitrary or unjustifiable discrimination between members where identical or similar conditions prevail. The assessment of whether there is such 'arbitrary or unjustifiable discrimination' is broader than the assessment of the presence of 'similar SPS risks' that Prévost argues that differences in the disease status between the territories, the dissimilar climatic conditions and geographical conditions that affect the incidence of pests and diseases, variations in the regulatory controls to minimise such risks and divergent dietary habits are just a few of the multitude of factors that are relevant in this determination.[70]

As Prévost states, this gives the non-discrimination obligations in SPS a *sui generis* character. They have adapted to the exigencies of SPS regulation while bearing vital resemblances to the common balancing concepts found in the non-discrimination norms in GATT/GATS. They are not triggered automatically between products, but only when they pose *similar* SPS risks. Potentially 'similar risks' could also be shown to be 'dissimilar' by demonstrating heightened risks in a given product area in the light of how a WTO Member perceives such risks and its ability to regulate such risks. Moreover, Article 2.3 expressly recognizes the existence of differences in the SPS conditions among the WTO Members that could justify SPS measures that are detrimental to foreign products generally or of a particular Member. Therefore, inherent in the language of the non-discrimination obligations in SPS is the recognition of the sovereign right of the WTO Members to protect their citizens and territories against SPS risks in a manner that is appropriate to their domestic circumstances. This is the reason, Prévost notes, that although SPS's NT/MFN obligations have a broad scope of application, their substantive content is limited compared to similar obligations in GATT/GATS.[71]

The *Agreement on Technical Barriers to Trade* (TBT) is another vital agreement concluded in 1994 that seeks to strike an important balance between the autonomy of the WTO Members to

[69] Ibid., p. 132. Emphasis added.
[70] Ibid., p. 150.
[71] Ibid., p. 157.

regulate products to protect certain public policy objectives and the need to ensure that such an autonomy is not abused to the detriment of international trade. As Bossche and Zdouc highlight, the objectives of such regulatory requirements are often the protection of life, health, environment, consumers, the prevention of deceptive practices and the promotion of other legitimate societal values.[72] They play an important role in fulfilling multiple societal needs.[73] However, the fifth recital of the Preamble to TBT provides that such regulatory requirements should *not* create 'unnecessary obstacles to international trade'. One of the fundamental ways in which TBT seeks to achieve this balance is by adopting the GATT's substantive non-discrimination obligations. The sixth recital of its Preamble states as follows:

> … no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, or for the prevention of deceptive practices, at the levels it considers appropriate…

It then immediately goes on to provide that this right should not be exercised in a manner that:

> … would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade…

Building on this objective, TBT Article 2.1 specifies the substantive non-discrimination obligation in relation to *technical regulations* that encompasses both, the NT and MFN obligations in the following manner:

> Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

Consequently, a member's technical regulations should accord 'no less favourable treatment' to products originating from a WTO Member than it accords to its own 'like' domestic products (NT) or to 'like' products originating from any other country (MFN). Resembling the non-discrimination obligations of GATT/GATS, TBT Article 2.1 applies to 'like products'.[74] The Appellate Body held in *US- Clove Cigarettes* that the 'like product' analysis is identical to that of GATT and involves a determination as to the nature and extent of the 'competitive

[72] Bossche and Zdouc, n. 6, p. 851.
[73] Ibid., p. 852.
[74] Ibid., pp. 865-867. Also see Matsushita et al., n. 6, pp. 448-451.

relationship' between the products in question.[75] Hence, the four common criteria that include the product characteristics, consumer tastes and habits, end-uses and their tariff classification are similarly relevant here.[76] As these criteria still remain only as 'helpful tools' in the assessment of 'likeness', the Appellate Body has reiterated that this does *not* preclude the *regulatory concerns* underlying a technical regulation from being relevant in the 'likeness' determination provided it has a bearing on the competitive relationship between the products.[77] Consequently, although this is not a licence to adopt an 'aims and effect' test, it keeps TBT's 'likeness' analysis sufficiently flexible so as to accommodate situations similar to that of *EC-Asbestos* where regulatory concerns relating to a group of products might be so severe that they could render them to be 'unlike' another group of similar products .

Even when the products in question are 'like' and the non-discrimination obligations in TBT Article 2.1 are triggered, WTO tribunals have sought to achieve an even further balance between these obligations and the autonomy of the WTO Members in the interpretation of the concept of 'treatment no less favourable' under this provision. To begin with, the TBT Agreement does *not* contain any General Exceptions or specific exceptions that apply to its non-discrimination obligations in Article 2.1. Therefore, the demonstration of the products in question being 'alike' and the modification of the conditions of competition to the detriment of a group of products would have sufficed to establish an inconsistency. As Matsushita and others have noted, this would have led to a much stricter regime of non-discrimination than established in GATT.[78] However, in *US- Clove Cigarettes*, which was the first case in which the Appellate Body dealt with this provision of TBT, it compensated this omission by what Matsushita and others claim to be a 'dogmatically tenable contextual and teleological interpretation'.[79] Dealing with the concept of 'treatment no less favourable', the Appellate explained that it covers both, *de jure* and *de facto*, forms of discrimination.[80] However, it held that when an allegation is based on *de facto* discrimination, meaning an origin neutral measure in this context, a tribunal must not only examine if there has been a detrimental modification of the conditions competition, but also examine if it was caused by a *legitimate regulatory distinction*. The Appellate Body

[75] Appellate Body Report, *United States- Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/AB/R, para. 120.
[76] For a criticism of the importation of the competition based 'likeness' see P. Mavroidis, ''Driftin' Too far from the Shore- Why the Test for Compliance with the TBT Agreement Developed by the WTO Appellate Body is Wrong and What should the AB have Done Instead', *World Trade Review*, vol. 12, no. 3, 2013, p. 509.
[77] Appellate Body Report, *US- Clove Cigarettes*, n. 75, para. 119.
[78] Matsushita et al., n. 6, p. 449.
[79] Ibid., p. 451.
[80] Appellate Body Report, *US- Clove Cigarettes*, n. 75, para. 175.

noted that if the answer is affirmative, there would *not* be 'treatment no less favourable' within the meaning of Article 2.1. In the words of the Appellate Body:

> … where the technical regulation at issue does not *de jure* discriminate against imports, the existence of a detrimental impact on competitive opportunities for the group of imported vis-à-vis the group of domestic like products is not dispositive of less favourable treatment under Article 2.1. Instead, a panel must *further analyze whether the detrimental impact on imports stems exclusively from a legitimate regulatory distinction* rather than reflecting discrimination against the group of imported products. In making this determination, a panel must carefully scrutinize the particular circumstances of the case, that is, the design, architecture, revealing structure, operation, and application of the technical regulation at issue, and, in particular, whether that technical regulation is even-handed, in order to determine whether it discriminates against the group of imported products.[81]

However, this concept of a legitimate regulatory distinction is apparently only applicable where the allegation is of *de facto* discrimination.[82] As the Appellate Body appears to suggest, this is because an allegation of *de jure* discrimination is explicitly based on an origin specific national measure that is 'dispositive' of the prohibited type of discrimination. On the other hand, an allegation of *de facto* discrimination requires an additional inquiry as TBT was meant to strike a balance between regulatory autonomy and trade liberalization. Thus, it highlighted that the absence of a recognition of the members' ability to make legitimate regulatory distinctions in the context of *de facto* allegations of discrimination would impede this balance.[83]

Bossche and Zdouc state that the Appellate Body came to this understanding of the meaning of 'no less favourable treatment' in Article 2.1 on the basis of the context of this provision and object and purpose of the TBT Agreement.[84] This is apparent in the reasoning adopted by the Appellate Body. It noted that the objective of avoiding unnecessary obstacles to international trade is qualified by the sixth recital of the Preamble to TBT that recognizes the WTO Members'

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[81] Ibid., para. 182. Emphasis added.
[82] For a criticism of the distinction that the Appellate Body appears to have made between *de facto* and *de jure* discrimination in TBT Article 2.1 see M. Alcover and A. Garces, 'The Interpretation of "Treatment No Less Favourable" under Article III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement: A Comparative Analysis', *Global Trade and Customs Journal*, vol. 11, no. 9, 2016, p. 360.
[83] Appellate Body Report, *US- Clove Cigarettes*, n. 75, para. 174; Also see J. Carlone, 'An Added Exception to the TBT Agreement After Clove, Tuna II and Cool', *B.C. Int'l & Comp. L. Rev.*, vol. 37, no. 1, 2014, p. 103.
[84] Bossche and Zdouc, n. 6, p. 869.

right to regulate products to pursue certain legitimate policies.[85] It highlighted that this recital counterbalances the desire not to create unnecessary obstacles. In the absence of exceptions to the non-discrimination obligation that give effect to this balance, the Appellate Body concluded that:

> … Article 2.1 should *not be interpreted* as prohibiting any detrimental impact on competitive opportunities for imports in cases where such detrimental impact on imports stems exclusively from legitimate regulatory distinctions.[86]

As Matsushita and others point out, the Appellate Body referred to TBT Article 2.2 to support its introduction of the concept of legitimate regulatory distinctions.[87] TBT Article 2.2 requires members to ensure that their technical regulations do not create *unnecessary* obstacles to international trade by providing that they 'shall not be more *trade restrictive* than necessary to fulfill a *legitimate objective*'. The Appellate Body reasoned that as Article 2.2 foresees that *trade restrictive* obstacles *might be necessary* to achieve legitimate objectives, it would be made redundant if Article 2.1 prohibited *all* obstacles to international trade.[88] Reason suggests that the same argument could be made even in relation to *de jure* allegations of discrimination under TBT Article 2.1.

Consequently, the concept of a legitimate regulatory distinction is meant to acknowledge a vital form of regulatory autonomy that is similar to that sought by the General Exceptions of GATT/GATS. Although the purpose of its creation was more or less clear, its substantive content has not yet been fully revealed in the WTO jurisprudence. The Appellate Body noted in *US- Clove Cigarettes* that when assessing if the detrimental treatment is caused by such a legitimate regulatory distinction, a tribunal must examine the design, structure, architecture, revealing structure and the operation of a measure and in particular, whether it has been applied in an even-handed manner.[89] However, it did not clearly address as for what end this should be done or as to what is even meant by a 'legitimate regulatory distinction'.

Jason Houston-Mcmillan examines this creation of the Appellate Body and states that subject to certain conditions such as even-handedness, it effectively recognizes an open list of legitimate policies that a WTO Member may pursue to justify the disadvantageous treatment of

[85] Appellate Body Report, *US- Clove Cigarettes*, n. 75, para. 94.
[86] Ibid., para. 174. Emphasis added.
[87] Matsushita et al., n. 6, p. 449.
[88] Appellate Body Report, *US- Clove Cigarettes*, n. 75, para. 171.
[89] Ibid., para. 182.

foreign products.[90] He states that the policies mentioned in TBT Article 2.2 including the protection of human, animal, plant life or health are instructive as to what may constitute a 'legitimate' policy objective in this context.[91] Consequent to examining the meanings that the subsequent tribunals have attributed to the words 'legitimate', 'regulatory', 'distinctions' and 'even-handedness', Houston-Mcmillan concludes that the concept of regulatory distinctions within the TBT Agreement effectively entitles a Member to differentiate products in the pursuance of a reasonable and justifiable objective in a fair and justifiable manner.[92] Although there is still an appreciable level of uncertainty as to the specifics of this concept and how it must be established before a tribunal, the reason identified by the Appellate Body for its creation is palpably traceable to the balance that the substantive non-discrimination obligations are meant to achieve within the WTO's system.

The foregoing analysis of the substantive non-discrimination obligations in some of the most significant covered agreements of the WTO dealing with goods and services demonstrate a recurring theme that is inherent in the trade concept of non-discrimination. This is the significance of balancing these obligations with the autonomy on the part of the WTO Members to pursue legitimate public policy objectives. Even though the manner in which this balance is sought is not identical under each of the covered agreements that have been discussed in this Part of the Chapter, the need for such a balance is abundantly clear upon the scrutiny of the scope and application of these obligations. This common thread that runs across the substantive non-discrimination norms constitutes important 'context' in the interpretation of the concept of 'discrimination' in TRIPS Article 27.1 and highlights the need to balance this obligation against some form autonomy on the part of the WTO Members. The next Part of this Chapter demonstrates that the need for a similar balance to acknowledge the autonomy on the part of the Members in the context of the rule against the 'discrimination' of fields of technology is reinforced by the 'object and purpose' of the TRIPS Agreement.

[90] J. Houston-Mcmillan, 'The Legitimate Regulatory Distinction Test: Incomplete and Inadequate for the Particular Purposes of the TBT Agreement', *World Trade Review*, vol. 15, no. 4, 2016, p. 543.
[91] Ibid., p. 554.
[92] Ibid.; For a critic of the concept of even-handedness see A. Appleton, 'National Treatment Under the TBT Agreement', in Sanders (ed.), n. 2, p. 92.

- *THE NATIONAL TREATMENT AND MOST-FAVOURED NATION TREATMENT OBLIGATIONS IN THE TRIPS AGREEMENT*

Before proceeding to analyse the 'object and purpose' of the TRIPS Agreement in the next Part of this Chapter, there are some important points to be made in relation to TRIPS's own National Treatment (NT) and Most-Favoured Nation Treatment (MFN) obligations in order to understand why the common thread that is apparent in the interpretation and application of the NT/MFN obligations under the other covered agreements has not manifested in TRIPS. TRIPS Article 3 that specifies its NT obligation requires Members to accord 'treatment no less favourable' to 'nationals of other Members' than it accords to its own nationals with regard to the 'protection of intellectual property'. TRIPS Article 4 that contains its MFN obligation states that 'any advantage, favour, privilege or immunity' given by a Member to the national of any other country with regard to the 'protection of intellectual property' shall be accorded 'immediately and unconditionally' to the nationals of other WTO Members.[93] The concept of 'protection of intellectual property' is defined very broadly in the footnotes to include matters affecting the availability, acquisition, scope, maintenance, enforcement and use of intellectual property rights that have been specifically addressed in the Agreement.

Although these obligations contain the concept of 'less favourable treatment' found in the non-discrimination obligations in the other covered agreements, their scope is very different under the TRIPS Agreement. They apply to 'nationals' as opposed to goods or services. Thus, for example, there is no need to establish the 'likeness' of the products that contain the intellectual property. This is because the Preamble to TRIPS recognizes that intellectual property rights are *private* rights that are owned by *private* individuals.[94] These obligations also encompass a broad range of measures provided they *affect* the types of intellectual property rights addressed in TRIPS. Further and even more fundamentally, TRIPS does not contain any exceptions to these obligations except for the minor exception relating to judicial and administrative processes in Article 3.2 and few other exclusions set out in Article 4. Thus, on their face, its NT and MFN obligations appear to have a greater force than in any of the other covered agreements.

[93] For commentaries on these provisions see, N. de Carvalho, *The TRIPS Regime of Patents and Test Data*, Fourth edition, Kluwer Law International, 2014, pp. 109-135; C. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, 2007, pp. 51-72; J. Malbon, C. Lawson and M. Davison, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights*, Edward Elgar, 2014, pp. 117-163.

[94] See generally A. Sanders, 'National Treatment under the TRIPS Agreement', in Sanders (ed.), n. 2, p. 286.

Nonetheless, the nature of TRIPS is such that this scope does not so readily intrude upon the sort of autonomy that the non-discrimination norms under the other covered agreements have sought to balance. While GATT, GATS, TBT and SPS are trade *liberalizing* agreements, as Susy Frankel rightly notes, TRIPS directly concerns trade barriers given that the protection of intellectual property rights by itself *increases* barriers to trade.[95] The first recital of its Preamble acknowledges this by stating that TRIPS is meant to strike a balance between the *lack of* protection and *over* protection of intellectual property rights. Frankel further points out, however, that WTO Members have agreed that the minimum standards enshrined in TRIPS constitute *acceptable* barriers in this context.[96] In these circumstances, it is those minimum standards and the higher standards that a WTO Member may voluntarily and consistently adopt that are *subject* to TRIPS's NT and MFN obligations.[97] Hence, as Correa notes, TRIPS's non-discrimination obligations do not otherwise by themselves commit WTO Members to provide certain levels of protection.[98] It is only the level of protection that a WTO Member applies consistently with the minimum standards in TRIPS that fall within the scope of its NT/MFN obligations.

These minimum standards in TRIPS by themselves recognize certain exclusions and exceptions to the various forms of intellectual property rights that acknowledge the ability on the part of the Members to pursue important policy objectives to a certain extent in those contexts. For example, Article 13 permits limitations and exceptions to copyrights, Article 17 provides for exceptions to the rights conferred by a trade mark and Article 30 allows for exceptions to rights conferred by patents. Such provisions recognize a level of autonomy on the part of the Members to make exclusions and exceptions and do not trigger the substantive non-discrimination norms in Article 3 and Article 4 provided they do not explicitly or implicitly apply only to 'nationals' of other Members. While this is perhaps the reason why the Panel on *EC- Trademarks and Geographical Indications*[99] did *not* signify the need to adopt any concept to balance TRIPS's NT obligation with the autonomy of the Members, it is submitted that this is not a satisfactory reason to rule out such a need.

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[95] S. Frankel, 'The Applicability of GATT Jurisprudence to the Interpretation of the TRIPS Agreement', in C. Correa (ed.), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules*, Edwar Elgar, 2010, p. 3.
[96] Ibid., pp. 5-6.
[97] Ibid., p. 10. Also see Carvalho, n. 93, p. 110.
[98] Correa., n. 93, p. 52.
[99] Panel Report, *European Communities- Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuff (US)*, WT/DS174/R.

There could be instances when a WTO Member may seek to adopt a measure that renders it more difficult for nationals of another Member to protect their intellectual property rights in order to pursue an important policy objective. For example, as in *EC- Geographical Indications*, a Member may condition the protection of intellectual property rights of nationals of another Member by requiring that Member to adopt a specific system for the protection of such rights. Similarly, a Member may adopt an exception to patent rights that in practice serve to disadvantage nationals of a particular Member. In such instances the autonomy recognized by TRIPS's exceptions and exclusions will not be sufficient to prevent a violation of the NT/MFN obligations. While the WTO tribunals have not yet recognized the applicability of any exceptions or concepts that could balance TRIPS's NT/MFN obligations with the autonomy of the membership to pursue vital policies, the final Chapter of this thesis will revisit this issue to highlight the significance of a more concrete balance in the light of TRIPS's Objectives and Principles because the same 'context' that highlights the need for a balance in the interpretation of the concept 'discrimination' of fields of technology in TRIPS Article 27.1 highlights the need for a similar balance in the interpretation and application of TRIPS's NT/MFN obligations.

B. AUTONOMY UNDER THE TRIPS AGREEMENT: THE PREAMBLE, OBJECTIVES AND PRINCIPLES

In addition to setting out wide ranging minimum standards relating to the protection of intellectual property rights, TRIPS achieved something that had never been done before by a multilateral treaty dealing with intellectual property. In a complex manner, the significance of which was either unforeseen or very tactical, it highlighted the importance of balancing intellectual property law obligations against the WTO Members' need to achieve economic, technological and developmental objectives. Hence, Robert Howse notes that the basic purpose of the TRIPS Agreement is:

> … not protection and enforcement of these private rights as such, but rather in a manner so as to achieve the mutual advantage of both producers and users and a balance of obligations and rights and to contribute to social and economic welfare.[100]

[100] R. Howse, 'The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times', *J. World Intel. Prop.*, vol. 3, no. 4, 2000, p. 493 at p. 497.

In a similar vein, Abdulqawi Yusuf states that in addition to recognizing the need for substantive intellectual property standards to reduce 'distortions and impediments' to international trade, the Preamble to TRIPS acknowledges the significance of underlying public policy objectives in the protection of intellectual property, including developmental and technological objectives. He states that this is an 'explicit' acknowledgement of the role of public policy objectives in the design of national intellectual property systems.[101]

This acknowledgement in the Preamble[102] is manifested in two provisions found in the body of the Agreement entitled Objectives (Article 7) and Principles (Article 8) that were the creations of the 'Group of 14' developing nations. As Peter Yu states, they demonstrate the compromise that was struck between the developed and less-developed countries during the negotiations.[103] It was arguably the best achievement by the developing countries in the negotiations, the benefits of which have not yet been realized to the fullest. This Part argues that the interpretational significance that is meant to be given to TRIPS's Objectives and Principles buttress the 'context' highlighted in Part A by demonstrating the need to acknowledge the autonomy on the part of the WTO Members within the rule against the 'discrimination' of fields of technology in Article 27.1.[104]

The Objectives and Principles are respectively set-out in Articles 7 and 8 in Part I of the Agreement that is entitled 'General Provisions and Basic Principles'. Given the title of this part of the Agreement and their positioning within the substantive parts of the Agreement, Correa states that an interpreter cannot disregard this choice made by the negotiators and must give them a heightened legal status in the implementation and interpretation of the Agreement.[105] One can comprehend the accuracy of this reasoning by appreciating the important sentiments expressed in these provisions. The Objectives (Article 7) provide as follows:

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[101] A. Yusuf, 'TRIPS: Background, Principles and General Provisions', in C. Correa and A. Yusuf (eds.), *Intellectual Property and International Trade: The TRIPs Agreement*, Third edition, Kluwer Law International BV, 2016, p. 3.

[102] Also see United Nations Conference on Trade and Development, International Centre for Trade and Sustainable Development and UNCTAD-ICTSD Project on IPRs and Sustainable Development (eds.), *Resource Book on TRIPS and Development*, Cambridge University Press, 2005, p. 3 and 11 [hereinafter referred to as 'UNCTAD Resource Book']; Correa, n. 93, p. 92.

[103] See P. Yu, 'The Objectives and Principles of the TRIPS Agreement', *Houston Law Review*, vol. 46, no. 4, 2009, p. 979 at p. 1025.

[104] For detailed commentaries on the Objectives and Principles, also see Correa, n. 93, Ch. 4; S. Frankel, 'WTO Application of "The Customary Rules of Interpretation of Public International Law" to Intellectual Property', *Virginia Journal of International Law*, vol. 46, 2005, p. 365; D. Barbosa, M. Chon and A. von Hase, 'Slouching Towards Development in International Intellectual Property', *Mich. St. L. Rev.*, vol. 2007, no. 1, p. 71, 2008, ; H. Ruse-Khan, *The Protection of Intellectual Property in International Law*, Oxford University Press, 2016, Ch. 13.

[105] Correa, n. 93, p. 93. Also see UNCTAD Resource Book, n. 102, p. 124.

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 7 underscores the acknowledgement in TRIPS's Preamble that intellectual property rights are private rights by identifying that the protection of these private rights 'should' contribute to broader national interests. Suggesting the type of compromise that was reached between the negotiators, it acknowledges that the protection of intellectual property is not an end by itself, but only a means to an end.[106] These ends are those identified in Article 7 and include the promotion of technological innovation and the transfer and the dissemination of technology. Hence, the protection of intellectual property rights should contribute to meeting these broader objectives of the Agreement. As Carvalho notes, these ends are to be met with three societal considerations in mind: the mutual advantage of producers and users, conduciveness to social and economic welfare and a balance of rights and obligations.[107] As Article 7 uses the term 'should', many academics have rightly highlighted that the objectives mentioned therein are not achieved automatically by implementing the minimum standards of the Agreement, but that they are *forward* looking and prescribe a sense of responsibility on the part of each Member to ensure that the balance between intellectual property rights and the other public policy interests would be achieved. Henning Grosse Ruse-Khan echoes this academic opinion in the following manner:

> …the use of 'should' in Article 7 suggests that the desired effects are not achieved automatically and do not follow as such from *any* mode of protecting and enforcing IP rights. Neither are these effects necessarily inherent and fully realized in all the individual TRIPS provisions. Had this been the case, Article 7 would be redundant as an operational provision.[108]

The UNCTAD Resource Book on TRIPS also notes that:

> The wording of Article 7 suggests that such a protection *does not automatically lead to the effect described therein*. In introducing IPR protection, countries should frame the applicable rules so as *to promote technological innovation*

[106] Yu, n. 103, p. 1005.
[107] Carvalho, n. 93, p. 166.
[108] Ruse-Khan, n. 104, p. 459. Emphasis in original. Footnotes omitted.

> *and the transfer and dissemination of technology "in a manner conducive to social and economic welfare".*[109]

The Panel on *Canada- Pharmaceuticals* acknowledged this when it stated that the balance between intellectual property protection and other societal interests necessitated by Article 7 has not already taken place in the substantive provisions of TRIPS and that the obligations need certain 'adjustments' by the WTO Members before being able to do so.[110] A WTO Panel reiterated similar sentiments in its report in *Australia- Plain Packaging* by stating that Article 7:

> … reflects the intention of *establishing* and maintaining a balance between the societal objectives mentioned therein'.[111]

This sense of responsibility on the part of the WTO Members that is highlighted by Article 7 indicates the type of autonomy on the part of the Member States to determine the requisite balance between intellectual property rights and other public policy interests that best fits their domestic context in the implementation of the TRIPS obligations. The type of autonomy that Article 7 preserves could hardly be read in isolation of Article 8. Article 8 entitled 'Principles', provides as follows:

> Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

As the Panel on *Australia- Plain Packaging* has highlighted, Article 8.1 serves to ensure that TRIPS does not prevent WTO Members from taking measures to protect vital societal interests.[112] It recognizes the ability of the Members to adopt measures 'necessary' to protect 'public health and nutrition' and to 'promote public interest in sectors of vital importance to their socio-economic and technological development', provided such measures are consistent with the other provisions of TRIPS. Hence, Abdulqawi Yusuf identifies it as the 'public interest principle' of the Agreement.[113] Henning Grosse Ruse-Khan even suggests that Article 8.1 deals

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[109] UNCTAD Resource Book, n. 102, p. 126. Emphasis added.
[110] Panel Report, *Canada- Patent Protection of Pharmaceutical Products*, WT/DS114/R, para. 7.25-7.26.
[111] Panel Report, *Australia- Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/R, WT/DS441/R, WT/DS456/R and WT/DS467/R, para. 7.2403. Emphasis added.
[112] Ibid., para. 7.2403.
[113] See Yusuf, n. 101, p. 16.

with the type of public policy interests that are dealt by the General Exceptions in GATT/GATS.[114] Carlos Correa, who perhaps gives the widest interpretation to this provision, states that Article 8.1 confirms the 'broad and unfettered' discretion that members have to pursue public policy objectives.[115]

Both these provisions have been regarded to be significant in the interpretation and application of the TRIPS Agreement, which was confirmed by the Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration).[116] In this Declaration, that Peter Yu states that 'strongly reinforced' the significance of the Objectives and Principles,[117] the Members declared that:

> … each provision of the TRIPS Agreement *shall* be read in the light of the object and purpose of the Agreement as expressed, in particular, in its *objectives and principles*.[118]

Ruse-Khan notes that this should quash any doubts that anyone continues to have as to the effect of the Objectives and Principles of TRIPS.[119] Even though the Declaration was subsequent to the Panel Report in *Canada- Pharmaceuticals* and could not have influenced its formulation of 'discrimination' in Article 27.1, this Report was the first to have highlighted the significance of TRIPS's Objectives and Principles in the interpretation of the Agreement. The Panel noted that 'the goals and limitations stated in Articles 7 and 8.1 must obviously be borne in mind' in the interpretation of the provisions of the Agreement.[120] The reason for both these provisions to be regarded so significant in the interpretation of the Agreement is because they address two important forms of autonomy on the part of the WTO Members.

The Objectives preserve the ability of the Members to determine the requisite balance between intellectual property rights and other public policy interests that best fits their domestic context. The Principles preserve the ability of the Members to adopt measures to protect public policies in order to give effect to *that* balance. The Objectives and Principles are always read together as Article 8 is a specific manifestation of the balance mandated by Article 7. The ability to adopt measures to protect vital public policies mentioned in Article 8 is one of the ways in

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[114] Ruse-Khan, n. 104, p. 439.
[115] Correa, n. 93, p. 108.
[116] World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, WT/MIN(01)/DEC/2, Doha, 2001 [hereinafter referred to as 'Doha Declaration'].
[117] Yu, n. 103, p. 995.
[118] Doha Declaration, n. 116, para. 5(a).
[119] Ruse-Khan, n. 104, p. 463.
[120] Panel Report, *Canada- Pharmaceuticals*, n. 110, para. 7.26.

which TRIPS acknowledges the significance of the balance articulated in Article 7. This autonomy to determine the proper balance is similar to that found in the jurisprudence relating to GATT Article XX, GATS Article XIV, SPS and TBT Agreements. Just as much as WTO Members have the right to adopt SPS measures and technical regulations to pursue legitimate objectives, they have the autonomy to choose an appropriate balance between intellectual property rights and other public interests that they seek to achieve in relation to each form of intellectual property rights addressed in TRIPS. It is because this autonomy is manifested in Article 8.1 that there is an appreciable level of agreement among the academics that a WTO tribunal cannot question a Member's determination of what constitutes a 'vital public interest' or the level of protection of such an interest that a Member desires to achieve.[121]

This autonomy preserved in the Objectives and Principles comes into operation in the interpretation and application of different types of 'constructive ambiguity' found in the TRIPS Agreement. As Ruse-Khan states, Article 7 comes into play when a TRIPS provision uses broad and vague legal terminology,[122] as is the case with the provisions dealing with exceptions under the TRIPS Agreement. Hence, for example, concepts such as 'limited', 'unreasonableness', 'legitimate interests' and 'normal exploitation' found in TRIPS Article 30 should be interpreted in a manner that acknowledges the balance that a WTO Member is entitled to determine between intellectual property protection and other public policy interests. On the other hand, Article 8 comes into play when a positive obligation itself is left ambiguous, which leads to uncertainty as to what is expected of a WTO Member. In such instances, those obligations must be interpreted in a manner that acknowledges the ability of the WTO Members to pursue vital public policy objectives that have been set out in Article 8 subject to its conditions of 'necessity' and 'consistency'. Disregarding this ability in the interpretation of an ambiguous TRIPS obligation would hinder the autonomy that WTO Members have to determine the requisite balance between intellectual property rights and public interests that best fits their domestic context. This is the reason why Jayashree Watal states that WTO Members are entitled to use the 'constructive ambiguity' found in various parts in TRIPS to observe the Objectives and Principles of the Agreement.[123] Peter Yu further notes:

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[121] See D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Fourth edition, Sweet and Maxwell/ Thomson Reuters, 2012, p. 239; Correa, n. 93, p. 106; Malbon et al., n. 93, p. 216.

[122] Ruse-Khan, n. 104, p. 459.

[123] J. Watal, 'Patents: An Indian Perspective', in J. Watal and A. Taubman (eds.), *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations*, World Trade Organization, 2015, p. 306 at p. 307.

> These constructive ambiguities therefore provide less-developed countries with a bulwark against the continuous expansion of intellectual property rights. If strategically used, they will allow less-developed countries to actively push for interpretations that meet their needs, interests, and goals. They will also preserve the much-needed policy space that has been appropriately reserved to them during the TRIPS negotiations.[124]

This *varying* interpretational significance of the Objectives and Principles has been acknowledged in several academic writings. Denis Barbosa and others state that Article 8 demonstrates a 'retention of sovereignty', which together with Article 7, should be given a 'vectorial' reading.[125] They appear to suggest that the relevance of the Objectives and Principles vary depending on the type of provision at hand. It is submitted that it is dependent on the type of autonomy that is in issue, which in turn depends on the type of TRIPS provision that is in question. Similarly, Ruse-Khan states that the Objectives and Principles must be adhered to when interpreting and implementing *specific* conditions in TRIPS,[126] which he later goes on to elaborate that are ambiguous, indefinite and multi-layered.[127]

In effect, TRIPS preserves a vital yet unique form of autonomy within its Objectives and Principles. The manner in which Articles 7 and 8 are meant to operate demonstrate the vital policy space that has been preserved in TRIPS, which Peter Yu points out in poetic terms, could be a guiding light, a shield for excessive IP demands, a sword to combat overzealous IP standards, a bridge to connect to other areas of international law and a seed for future development.[128] Their interpretational significance demand that even without any reference the WTO's substantive non-discrimination obligations under the other covered agreements discussed in Part A of this Chapter, an open-ended concept such as 'discrimination' must be interpreted in a manner that acknowledges the autonomy on the part of the WTO Members that has been preserved in these two provisions of the Agreement.

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[124] Yu., n. 103, p. 1023.
[125] Barbosa et al., n. 104, pp. 109-111.
[126] Ruse-Khan, n. 104, p. 453
[127] Ibid., p. 465
[128] Yu, n. 103, pp. 1020- 1045.

C. REVEALING THE PANEL'S CONCEPT OF 'JUSTIFICATION'

The 'context' that consists of the substantive non-discrimination obligations in the WTO and the 'object and purpose' of the TRIPS Agreement highlight the need for a balance between the rule against the 'discrimination' of fields of technology and the autonomy of the WTO Members that has been preserved in the Objectives and Principles. This Part shows that the nature of the non-discrimination obligation relating to the ground of fields of technology is such that this balance could be sought only by creating a concept of 'justification', which the Panel appears to have done in its formulation of 'discrimination' in *Canada- Pharmaceuticals*. Thereafter, this Part proceeds to identify the constitutive elements of this concept and provide a more concrete understanding of the Panel's formulation that is specifically applicable to the ground of fields of technology.

- *THE BROAD SCOPE OF THE OBLIGATION*

The discussion in Part A concerning the NT/MFN obligations in GATT, GATS, SPS and TBT showed that they come into operation only in certain defined and comparable circumstances that must established between the subject matter. The 'likeness' of products/services found in GATT/GATS is one such standard. As their NT/MFN obligations seek to preserve the equality in the conditions of competition between products/services, such standards of comparison seek to determine if the privileged and disadvantaged products/services are in fact in a competitive relationship in the first place. Moreover, this determination of 'likeness' has the potential to acknowledge certain regulatory concerns and prevent these obligations from coming into operation when the products in question could be considered to be 'unlike'. However, such standards of comparison are not present in the rule against 'discrimination' of fields of technology in TRIPS Article 27.1. There is nothing in Article 27.1 that suggests that the rule comes into operation only between 'like' fields of technology or upon establishing some similarity between the fields of technology in question. The Panel on *Canada- Pharmaceuticals* acknowledged this when it noted that the obligation in TRIPS Article 27.1 is broader than TRIPS's own NT/MFN obligations found in Article 3 and Article 4. It stated that:

> The primary TRIPS provisions that deal with discrimination, such as the national treatment and most-favoured-nation provisions of Articles 3 and 4, do not use the term "discrimination". They speak in more precise terms. The

ordinary meaning of the word "discriminate" is potentially broader than these more specific definitions. [129]

It is difficult to introduce specific standards of comparison between fields of technology even in the interpretation of this obligation for the following reasons. The Appellate Body seminally cautioned in *India- Patents* that no principle of interpretation entitles 'the imputation into a treaty of words that are not there'.[130] Although there is a link between the substantive non-discrimination obligations and the broader obligation in Article 27.1, an interpreter must acknowledge the wide scope of the latter that results from the lack of any textual reference to a specific standard of comparison that must be established between fields of technology. Hence, the rule must be understood as preventing discrimination between *all* fields of technology, irrespective of whether they are similar or not.

Nicolas Diebold has noted in an article that comprehensively examines the concept of *non-discrimination* in international economic law that where a non-discrimination rule does *not* specify comparators for its application, it is meant to apply to all the subject matter *irrespective* of any standards of comparison.[131] Although Diebold did not specifically identify the non-discrimination rule in TRIPS Article 27.1 to be an example of this, it is submitted that it is so. While NT/MFN obligations are meant to preserve equality in the conditions of *competition*, the rule in TRIPS Article 27.1 does not concern competition at all. It only concerns the *availably* and *enjoyment* of patent rights for fields of technology. Consequently, the existence of competition or of similarities between fields of technology are irrelevant or at most, incidental in the context of this TRIPS's obligation.

Further, there is a pragmatic reason why there could not be a substantive comparison between fields of technology in the context of patent law. Unlike products and services, fields of technology are more complex. There are often a multitude of factors that could render two fields of technology to be different although they may appear to be 'like' or similar at first. The costs involved in research and development, the likelihood of succeeding in the innovation process, market access and consumer demand are just a few factors that vary from technology to technology. Given such idiosyncrasies pertaining to each field of technology, it is almost impossible to specify the factors that must inform a determination of any specific standard of

[129] Panel Report, *Canada- Pharmaceuticals*, n. 110, para. 7.94.
[130] Appellate Body Report, *India- Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R at para. 45.
[131] See N. Diebold, 'Standards of Non-Discrimination in International Economic Law', *International and Comparative Law Quarterly*, vol. 60, 2011, p. 831.

comparison between fields of technology. Thus, the absence of any standard of comparison between fields of technology in TRIPS Article 27.1 gives its non-discrimination obligation a broad scope of application. It does *not* have one of the vital safeguards prevalent in the NT/MFN obligations under the other covered agreements of the WTO. Thereby, Article 27.1 mandates equality between *all* fields of technology with regard to the availability and enjoyment of patent rights.

The broad notion of 'discrimination' and the absence of any specific standards of comparison between fields of technology makes this obligation to be triggered in a wide array of circumstances. As the Panel noted in *Canada- Pharmaceuticals* in its formulation of 'discrimination', it is triggered when a national measure confers disadvantageous treatment to a field of technology in the context of the availability or enjoyment of patent rights. The Panel noted that 'disadvantageous treatment' is something more than mere differential treatment by formulating that 'discrimination' in this context is the unjustified imposition of *differentially disadvantageous* treatment. However, the Panel did not explain what constitutes disadvantageous treatment in this context.

While it is correct that *mere* differential should not constitute *disadvantageous* treatment, it is apparent that they are two extremes of the notion of 'differential treatment'. The notion of mere differential treatment acknowledges the very character of patent law in which every invention is naturally treated differently. As every invention is different from one another, basic patent law concepts need a certain amount of tweaking before being applied to any given invention. Thus, concepts such as novelty, inventive step, industrial application and even the scope of a patent are dependent on the very specifics of the invention in issue. While those forms of differentiation do not trespass the boundaries of disadvantageous treatment, it is also fairly clear as to what should constitute the latter. Restricting, or in the words of Carvalho, 'curtailing' the availability of patents to inventions in a certain field of technology or restricting the scope of rights of patents in a particular field of technology should necessarily constitute *disadvantageous* treatment. Such would evidently constitute 'extra hurdles'.[132] In between these two extremes of differential treatment, the line demarcating the two concepts fluctuates principally in two respects. Firstly, depending on whether the assessment of 'discrimination' is based on the *availability* or *enjoyment* of patent rights. Secondly, and more importantly,

[132] In *EC- Geographical Indications*, a WTO Panel noted that there would 'less favourable treatment' in the context of TRIPS Article 3 if the measure destroyed the effective quality of 'nationals' to protect their intellectual property rights within the jurisdiction of a given WTO member and that it would be so if the thrust and effect of a measure constitutes an 'extra hurdle'. See Panel Report, *EC- Geographical Indications*, n. 99, para. 7. 137.

depending on the *field of technology* in issue. Therefore, it is possible that what amounts to a mere differential treatment in one field of technology could be *disadvantageous* to another, and vice-versa. Moreover, the broad notion of 'discrimination' in Article 27.1 is also such that there is no *de minimis* standard of disadvantageousness that is necessary to trigger a violation of this obligation provided it affects the availability or enjoyment of patent rights.

Consequently, whether a field of technology is *disadvantaged* is dependent on a technology specific fact sensitive assessment. Nevertheless, as TRIPS specifies certain minimum standards that must be adhered to when granting patents (Article 27.1) and the rights that must be given to a patentee (Article 28), it is submitted that there are instances when the *disadvantageousness* of a measure could be presumed. Thus, explicitly imposing *additional* criteria for the patentability of inventions in a particular field of technology and imposing explicit *restrictions* on the patent rights of inventions in a particular field of technology should be so presumptively disadvantageous. This is why it is hardly deniable that the practice of automatic compulsory licences of patented pharmaceutical and food related inventions, which was prevalent in the pre-TRIPS era, was disadvantageous to those fields of technology. However, such a presumption should be capable of being rebutted by a respondent by demonstrating that such treatment falls within its autonomy to define and apply the patentability criteria (Article 27.1), or to grant limited exceptions (Article 30) or compulsory licences (Article 31).

Moreover, a finding of disadvantageous treatment need not be limited to cases where measures explicitly confer such treatment. A tribunal should be entitled to find disadvantageous treatment even in implicit circumstances. The Appellate Body has highlighted the significance of *de facto* application of WTO's non-discrimination norms in *EC- Bananas III*, although this was in the context of the National Treatment and Most-Favoured Nation Treatment obligations. It stated that the application of these rules to *de facto* circumstances serve as an insurance against the circumvention of those obligations by preventing discrimination caused by measures that on their face appear to be non-discriminatory.[133] For the same reason, ensuring the *de facto* application of the rule in TRIPS Article 27.1 is necessary to ensure that WTO Members do not implicitly discriminate fields of technology. Such *de facto* applications of the non-discrimination norms, however, have not been the simplest to comprehend in WTO jurisprudence. Petros Mavroidis notes that although the standard of review is technically the same for *de jure* and *de facto* allegations, the tribunals have begun to require *additional* proof

[133] Appellate Body Report, *European Communities- Regime for the Importation, Sale and Distribution of Bananas*, n. 4, para. 233.

in the case of the latter.[134] The reason for this is that there is a risk of the WTO rules unjustifiably intruding the legitimate regulatory autonomy of its Members if *de facto* allegations are taken too lightly. Hence, a WTO Panel has stated that:

> A complainant, especially in a case of *de facto* discrimination, cannot simply point to the measure at issue and then expect the panel to find a violation where the respondent fails to show that the measure at issue *never could* result in a violation of one or more WTO obligations. In cases of *de facto* discrimination, the complainant must provide evidence and argument sufficient to show why a measure that appears to be non-discriminatory on its face nevertheless in fact provides less favourable treatment to imported products in a way that is repugnant to WTO law.[135]

Consequently, *de facto* allegations require a heightened level of proof. This is also perhaps what the Panel in *Canada- Pharmaceuticals* meant when it stated that although the non-discrimination obligation in TRIPS Article 27.1 applies in *de facto* circumstances, it requires proof of a *discriminatory purpose* or a *discriminatory effect*.[136] An allegation of *de facto* discrimination in the context of Article 27.1 should require the demonstration of the *de facto* disadvantageous treatment of a field of technology with regard to the *availability* and *enjoyment* of patent rights. This should necessarily be supported with satisfactory evidence in order to ensure that it does not unjustly intrude upon the autonomy of the WTO Members preserved under the TRIPS Agreement in relation to their patent law obligations. This autonomy is *distinct* from the type of autonomy discussed in relation to TRIPS's Objectives and Principles. In the context of a *de facto* allegation relating to the *availability* of patent rights, a tribunal must acknowledge the autonomy of the Members to interpret and apply the patentability criteria set out in Article 27.1. Similarly, in the context of such allegations relating to the *enjoyment* of patent rights, tribunals must acknowledge the autonomy of the Members to restrict patent rights by making limited exceptions (Article 30) and granting compulsory licences (Article 31).

For these reasons, demonstrating disadvantageous treatment in *de facto* circumstances would not be an easy task for a complainant. The difficulty that a complainant would face in such circumstances can be observed in the few instances where this non-discrimination obligation in TRIPS Article 27.1 has been in issue. For example, in *Canada- Pharmaceuticals* the Panel was

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[134] P. Mavroidis, *The Regulation of International Trade*, Vol. 1- GATT, MIT Press, 2016, pp. 361-362.
[135] Panel Report, *United States- Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products (Article 21.5 Mexico)*, WT/DS381/RW, para. 7.65.
[136] See Panel Report, *Canada- Pharmaceuticals*, n. 110, para. 7.94 and 7.101.

reluctant to accept that any disadvantageous treatment caused to pharmaceuticals by the Canadian regulatory review exceptions was limited only to pharmaceuticals. It stated that:

> …the critical question was whether there was some practical reason why the regulatory review exception would in reality work *only to the disadvantage of producers of patented pharmaceutical products*.[137]

Notwithstanding the fact that the regulatory review exception was only being applied to pharmaceuticals at that time, the Panel found that there was no *de facto* discrimination of pharmaceuticals. This is also evident in the arbitral award given in the NAFTA dispute initiated by Eli Lilly against the government of Canada. Eli Lilly alleged that Canada's 'promise doctrine' discriminated pharmaceuticals in violation NAFTA Article 1709(7) which similarly prohibits 'discrimination' of fields of technology in relation to the availability and enjoyment of patent rights.[138] The Canadian promise doctrine, which has since been 'over-ruled' by the Canadian Supreme Court[139] *was* used by the Patent Office and the Courts to assess the utility of *all* inventions by examining if an invention is capable of meeting the promise that it makes in its patent specification.[140] Eli Lilly contended that although the doctrine technically applied to all inventions, it was particularly disadvantageous to pharmaceuticals as it had served to invalidate more pharmaceutical patents by heightened proof of 'utility' that is determined vis-à-vis the patent specification. Eli Lilly even highlighted that since 2005, more than twenty four pharmaceutical patents had been invalidated due to the lack of such heightened utility and that the 'promise doctrine' had *not* had any similar impact on other fields of technology.[141] Notwithstanding this, the arbitrators held that Eli Lilly had not sufficiently demonstrated that the doctrine worked to *disadvantage* pharmaceuticals to constitute *de facto* discrimination.[142] Consequently, while the finding of disadvantageous treatment could be made *de jure* or *de facto*, an allegation based on the *de facto* circumstances would necessarily require a significant level of proof than an allegation based on the former.

Consequently, the wide notion of 'discrimination' in Article 27.1 has the potential to proscribe a wide array of patent law measures that disadvantageously affect the availability and/or enjoyment of patent rights of a given field of technology. Although *de facto* allegations would

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[137] Ibid., para. 7.102. Emphasis added.
[138] *Eli Lilly & Co. v. Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Final Award, 16 March 2017.
[139] See *AstraZeneca Canada v. Apotex*, 2017 SCC 36.
[140] See R. Gold and M. Shortt, 'The Promise of the Patent in Canada and Around the World', *Canadian Intellectual Property Review*, vol. 30, no. 1, 2014, p. 35
[141] *Eli Lilly v. Canada,* n. 138, para. 398.
[142] Ibid., para. 439.

require additional proof to ensure that the obligation acknowledges the autonomy of the Members to define the patentability criteria, make limited exceptions and grant compulsory licences, this does not limit the scope of the obligation. Even though the Panel in *Canada-Pharmaceuticals* did not acknowledge, the breadth of the notion of 'discrimination' in Article 27.1 is such that it is even triggered by conferring *preferential treatment* to a field of technology with regard to the availability or enjoyment of patent rights. This is because the general prohibition of 'discrimination' that applies between *all* fields of technology does not specify any particular type or level of treatment that it proscribes. As Catherine Barnard notes, although in a different context, all non-discrimination rules are the legal manifestation of the more general concept of *equality*.[143] Article 27.1 seeks the highest form of equality by prohibiting a broad notion of 'discrimination', which prohibits both, *disadvantageous* and *preferential* treatment. In fact, the WTO is *not* unaccustomed with how preferential treatment could constitute discrimination. For example, the Most-Favoured Nation Treatment (MFN) obligations in GATT, GATS, SPS and TBT scrutinize if a *preference* or *advantage* given to the products/services of one WTO Member are also given to the 'like' products/services of other WTO Members. For these reasons, several academics have highlighted the applicability of the non-discrimination obligation in TRIPS Article 27.1 to cases of preferential treatment. For example, Carlos Correa states:

> Whether the discrimination is positive or negative is, in fact, irrelevant in the light of Article 27.1. An additional period of patent protection for specific categories of products may well be deemed not TRIPS-compliant.[144]

Even Carvalho has noted that the expansion of the availability and enjoyment of patent rights amounts to discrimination in Article 27.1 as much as their curtailment.[145] Similarly, even the UNCTAD-ICTSD Resource Book states that 'discrimination' in this context means the granting of both superior and inferior rights.[146] It is submitted that whether a measure confers preferential treatment, as in the case of disadvantageous treatment, is dependent on a fact sensitive assessment. Nevertheless, such preferential treatment may be presumed where the rights conferred on patents of a particular field of technology go beyond those mandated by TRIPS's minimum obligations. An example of this, as Correa points out, is the extension of patent terms of pharmaceutical patents.[147]

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[143] C. Barnard, 'The Principle of Equality in the Community Context: P, Grant, Kalanke and Marschall: Four Uneasy Bedfellows?', *The Cambridge Law Journal*, vol. 57, no. 2, 1998, p. 352.
[144] Correa, n. 93, p. 26. Footnote omitted.
[145] Carvalho, n. 93, p. 251
[146] UNCTAD Resource Book, n. 102, p. 368.
[147] Correa, n. 93, p. 26.

- *THE CONCEPT OF 'JUSTIFICATION' WITHIN THE RULE AGAINST 'DISCRIMINATION' OF FIELDS OF TECHNOLOGY*

The non-discrimination obligation being applicable to cases of disadvantageous/preferential treatment without a requirement of any specific standard of comparison between the fields of technology gives it a broad scope of application. To the exclusion of a limited form of autonomy that should be acknowledged on the part of the Members to define the patentability criteria, make limited exceptions and grant compulsory licences in determining if there is disadvantageous/preferential treatment in cases of *de facto* allegations of 'discrimination' under this provision, there are no other exceptions to this obligation that entitles a WTO Member to pursue vital public policies by subjecting a field of technology to disadvantageous/preferential treatment. The consequence of this is that unless a respondent could rebut a presumption that an *explicitly* added criteria or restriction that affects the availability or enjoyment of patent rights is disadvantageous or preferential, such a measure would always constitute 'discrimination' without entitling a Member to demonstrate that such treatment was accorded to pursue a vital societal interest.

However, the 'context' and 'object and purpose' under VCLT Article 31(1) highlight the need for some mechanism to balance this non-discrimination obligation against the autonomy on the part of the WTO Members to protect and pursue fundamental public policy interests. The significance of TRIPS's Objectives and Principles demonstrate the type of autonomy that must be acknowledged throughout the TRIPS Agreement. TRIPS Article 8.1 that specifically recognizes the ability of the Members to adopt measures for the protection of certain public policy objectives must be acknowledged in the interpretation of a TRIPS obligation such as the rule against 'discrimination' in Article 27.1 that has been left ambiguous and open-ended. In other words, such an obligation should *not* be interpreted in a manner that impedes the ability of the WTO Members to adopt measures to protect important public policies, as this would impede the autonomy of the Members to determine the requisite balance between intellectual protection and other public policy objectives that has been preserved in TRIPS Article 7. Given the nature of the obligation in Article 27.1, this could be done only by recognizing a concept of 'justification' in its interpretation like the Appellate Body has done through the concept of 'legitimate regulatory distinction' in the context of the TBT Agreement. Such is the purpose of the Panel's notion of 'justification' that it recognized in its formulation of 'discrimination' in Article 27.1. In the light of this rationale that now provides a better understanding of the Panel's formulation, the following sections scrutinize the constitutive elements of such a concept.

To understand how such a concept ought to operate within the non-discrimination obligation in Article 27.1, it is helpful to determine where its burden of proof should lie, which was also an examination that was lacking in the Panel Report in *Canada- Pharmaceuticals*. The Appellate Body has observed in *US- Wool Shirts and Blouses* that the burden of proof generally rests on the party who asserts the existence of a particular claim or defence.[148] Hence, it is the complainant who bears the initial burden of demonstrating a *prima facie* case against a respondent. The WTO Panel reiterated in *Australia- Plain Packaging* that this requires a complainant to demonstrate a *prima facie* case in relation *each element* of the substantive obligation in question.[149] Thus, as the Panel on *Canada- Pharmaceuticals* formulated 'discrimination' as the '*unjustified* imposition of differentially disadvantageous treatment', it *may* have suggested that the requirement of 'unjustified' falls within the ambit of the substantive obligation itself. Therefore, it is the complainant who should initially demonstrate that the treatment is 'unjustified'. This would be consistent with the WTO Panel's opinion in *Australia- Plain Packaging* in which the Panel noted that the complainant bears the initial burden of showing that an encumbrance on the use of a trade mark is unjustified as TRIPS Article 20 does *not* entail a general prohibition of encumbrances.[150]

However, the allocation of the burden of proof of a concept of 'justification' in TRIPS Article 27.1 might not be so straightforward. In the context of the General Exceptions in GATT/GATS, the Appellate Body has explained that once a *prima facie* case of inconsistency with one of their obligations has been established by a complainant, it is the respondent who bears the burden of showing that it is entitled to benefit from the General Exceptions.[151] This is because there is a clear rule-exception structure between the General Exceptions and the substantive obligations of GATT/GATS. Even in the absence of a clear rule-exception structure, there have been instances when the Appellate Body has adopted a similar allocation of the burden of proof. This can be observed in the context of the National Treatment obligation under the TBT Agreement. As the Appellate Body noted in *US- Clove Cigarettes,* there is no violation of TBT Article 2.1 if the *de facto* detrimental impact on imports is caused by a legitimate regulatory distinction. Dealing with the burden of proof of this concept in *US- Tuna II*, the Appellate Body reiterated the significance of the basic principle that the party who avers the existence of a

[148] Appellate Body Report, *United States- Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS/33/AB/R, p. 335.
[149] See Panel Report, *Australia- Plain Packaging*, n. 111, para. 7.2164.
[150] Ibid., para. 7.2167.
[151] See Appellate Body Report, *United States- Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, pp. 20-21.

particular fact bears the burden of proving it.[152] It held that after a complainant establishes a *prima facie* case by showing a detrimental impact on imported goods, the burden *shifts* to the *respondent* to show that such a detriment is caused by a legitimate regulatory distinction. The relevant part of its Report stated as follows:

> In the context of Article 2.1 of the TBT Agreement, the complainant must prove its claim by showing that the treatment accorded to imported products is "less favourable" than that accorded to like domestic products or like products originating in any other country. If it has succeeded in doing so, for example, by adducing evidence and arguments sufficient to show that the measure is not even-handed, this would suggest that the measure is inconsistent with Article 2.1. If, however, *the respondent shows that the detrimental impact on imported products stems exclusively from a legitimate regulatory distinction, it follows that the challenged measure is not inconsistent with Article 2.1*.[153]

In the light of these conflicting allocations of the burden of proof of similar justificatory concepts, it is not easy to determine where the burden relating to a concept of justification should lie in TRIPS Article 27.1. As recognizing a concept of 'justification' in the interpretation of 'discrimination' makes it part of the substantive obligation itself, *Australia- Plain Packaging* suggests that the complainant should at least have the initial burden of demonstrating the absence of a justification. However, more in line with the jurisprudence relating to TBT Article 2.1, the more convincing placement of the burden is on the respondent. This is because the concept of 'justification' introduced into TRIPS Article 27.1 can be distinguished from concepts such as 'unjustified' found in TRIPS Article 20 given that TRIPS Article 27.1 entails a *general* prohibition of discrimination between fields of technology. It applies between all fields of technology without specifying any level of disadvantageous/preferential treatment that violates this obligation. The concept of 'justification' is extraneously introduced like the 'legitimate regulatory distinction' concept in TBT to acknowledge a form of autonomy on the part of the membership to prevent this obligation being applied in any absolute manner. This generality of the obligation shows that there is a greater case for the respondent to establish a 'justification' after a complainant demonstrates a *prima facie* case of inconsistency.

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[152] Appellate Body Report, *United States–Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WT/DS382/AB/R, para. 261.
[153] Ibid. Emphasis added. Footnotes omitted.

In order to understand how a respondent may demonstrate a legitimate justification in this context, it is important to identify the structure that it should entail. Part A of this Chapter examined how the substantive non-discrimination obligations under the other covered agreements are sought to be balanced against the autonomy of the WTO Members to pursue vital policy objectives by recognizing the applicability of certain justificatory concepts. These justificatory concepts like the General Exceptions in GATT/GATS and 'legitimate regulatory distinctions' in TBT permit a Member to defend a violation of the NT/MFN obligations under those agreements by demonstrating the legitimate exercise of its regulatory autonomy. It is submitted that the structure of those justificatory concepts should inform the substantive content of a concept of 'justification' in TRIPS Article 27.1. Consequently, three fundamental features can be observed in such concepts:

- They require a national measure to pursue a legitimate policy objective.
- There should be a sufficient connection between the national measure and the stated objective.
- There should be safeguards to ensure that this autonomy is not abused.

As the specific objective of the concept of 'justification' is to acknowledge the ability of the WTO Members to adopt measures to protect other vital societal interests that have been set out in TRIPS Article 8.1 (Principles), it is submitted that Article 8.1 should inform the above-mentioned features of the concept of 'justification' in Article 27.1. The following sub-sections examine how they could be adapted to the context of the concept of 'justification' in Article 27.1 and demonstrate the substantive burden on the part of a respondent to defend an allegation of 'discrimination' under this provision.

❖ *Legitimate Policy Objectives*

A prominent feature of the justificatory concepts is that they require the pursuance of a *legitimate* policy objective. The General Exceptions of GATT/GATS exhaustively specify the types of policies that are deemed to be legitimate. As highlighted in Part A, they recognize the legitimacy of measures that are necessary to protect, *inter alia*, public morals and human, animal plant life or health. Because they are 'exhaustively' set out, a Member cannot claim the legitimacy of a policy that has not been so identified. However, this need not always be the case. When the Appellate Body introduced the concept of 'legitimate regulatory distinction' to TBT Article 2.1, it did not exhaustively specify what policies would be legitimate in that

context. It did, however, implicitly acknowledge the legitimacy of the policies set out in TBT Article 2.2 that provides in relevant part as follows:

> …such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.

However, as Houston-Mcmillan has noted, Members have a broad discretion to pursue a host of other policies given that TBT Article 2.2 is not exhaustive as to what may constitute a *legitimate* policy in the context of a 'legitimate regulatory distinction' under Article 2.1.[154] This would similarly be the case under the concept of 'justification' in TRIPS Article 27.1 as TRIPS Article 8.1 does *not* exhaustively specify the types of policy objectives that a WTO Member may legitimately pursue. While it specifically recognizes the ability of the Members to adopt measures for the protection of 'public health and nutrition', it recognizes a significant level of discretion on the part of the Members to pursue other policies in the context of the TRIPS Agreement by providing that they have the ability to adopt measures to promote public interest in 'sectors of vital importance to *their* socio-economic and technological development'.

Although TRIPS Article 8.1 appears to be as open-ended as the notion of legitimate regulatory distinctions under the TBT Agreement, TRIPS Article 8.1 is more instructive as it recognizes the traits of a policy interest that might be legitimate: it should be *vital* to *that Member's* socio-economic and technological development. Consequently, this is a determination to be made by each WTO Member. As Correa has noted:

> Although the adjective 'vital importance' would seem to limit the scope of the provision to specifically significant sectors, which sector is important or not is also *subject to determination by the concerned Member in the light of its 'socio-economic and technological development'*.[155]

Many commentators including Correa, Gervais and Malbon have noted that this is a determination that cannot be questioned by a WTO tribunal.[156] It is the sole right of a Member to determine which policy is vital to its socio-economic and technological development *and* the level of protection of such a policy that it desires to achieve. Consequently, much like the jurisprudence relating to the General Exceptions in GATT/GATS and 'legitimate regulatory

[154] See Houston-Mcmillan, n. 90, p. 555.
[155] Correa, n. 93, p. 106. Emphasis Added.
[156] Ibid. Also see, Gervais, n. 121, p. 239; Malbon et al., n. 93, p. 216

distinctions' in TBT, such is a prerogative of a WTO Member. A WTO Panel appeared to acknowledge this prerogative right of a WTO Member in *Australia- Plain Packaging*. In the course of explaining that TRIPS Article 8.1 should be instructive when interpreting the term 'unjustified' encumbrances to the use of trade marks under TRIPS Article 20, the Panel noted that:

> … the balance intended by the drafters of the TRIPS Agreement between the existence of a legitimate interest of trademark owners in using their trademarks in the marketplace, and *the right of WTO Members to adopt measures for the protection of certain societal interests* that may adversely affect such use.[157]

It deserves to be mentioned that Article 8.1 requires this right on the part of the Members to be exercised 'consistently' with the other provisions of the TRIPS Agreement. Nevertheless, this right is restricted *only* to the extent that it has been so limited by the TRIPS obligations. As highlighted in Part B, this right *cannot* be disregarded when a TRIPS obligation itself is ambiguous and open-ended as this would disregard the autonomy of the Members that has been preserved in TRIPS Article 7 (Objectives). Such ambiguous TRIPS obligations should be interpreted in a manner that acknowledges this right of the Members, and therefore, the 'consistency' requirement in Article 8.1 does not constitute an obstacle to the interpretation of the concept of 'discrimination' or the elements of a legitimate 'justification' in TRIPS Article 27.1.

❖ *Necessity*

It is not sufficient for a Member to simply assert that its measure pursues a legitimate policy objective. The justificatory concepts also require a requisite level of connection to exist between the national measure and the policy objective in question. While a WTO Member may have a significant level of discretion to pursue a wide range of policy objectives in this context, whether its measure is in fact capable of contributing towards that objective to the extent that is required is an entirely different question. The latter is often objectively scrutinized by the WTO tribunals.

The General Exceptions of GATT/GATS often contain the requirement of 'necessity'. The SPS and TBT Agreements that build on the General Exceptions of GATT also recognize the

[157] Panel Report, *Australia- Plain Packaging*, n. 111, para. 7.2429. Emphasis added.

prerogative right of the Members to adopt SPS and TBT measures to the extent that they are 'necessary' to achieve vital public policy objectives. As the sixth Recital of the Preamble to TBT states:

> … no country should be prevented from *taking measures necessary* to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate…[158]

Similarly, the first Recital of the Preamble to the SPS Agreement recognizes the right of the Members to adopt SPS measures that are 'necessary' for the protection of human, animal, plant life or health. It was noted that in the context of the General Exceptions in GATT/GATS, the 'necessity' of a measure is scrutinized by weighing and balancing several factors that include the importance of the non-trade value, the degree of contribution, its trade restrictiveness and the availability of alternatives.

The requisite level of connection between a national measure and a policy objective in the context of a 'justification' in TRIPS Article 27.1 is once again informed by TRIPS Article 8.1. Article 8.1 encompasses a test of 'necessity' as it explicitly provides that Members may adopt measures '*necessary* to protect public health and nutrition…'. Given that the concept of 'justification' is supposed to preserve the type of autonomy mentioned in Article 8.1, it is submitted that this level of connection that it specifies cannot be overlooked. Hence, Daniel Gervais states that although a WTO tribunal cannot challenge a Member's determination of its public interest, it is entitled to:

> …consider the adequacy of the measure in terms of the stated objective and its compatibility with TRIPS- and perhaps whether there were less inconsistent (compliant) measures available to achieve the same objective.[159]

He states that this must be examined similar to the way 'necessity' is examined under GATT's General Exceptions. Commenting on this 'necessity' requirement in Article 8.1, Carlos Correa states that the scrutiny should be more flexible than under GATT because it deals with broad concepts such as 'public interest' and 'socio-economic and technological development'. He states that it would be unreasonable to give a restrictive interpretation to this concept under the

[158] Emphasis added.
[159] Gervais, n. 121, p. 239.

TRIPS Agreement as is done under the other covered agreements.[160] It is correct that Article 8.1 uses the broad concepts pointed out by Correa, but in practice a Member is likely to identify a *specific* policy objective. In such circumstances, the use of broad terms such as 'public interest' in Article 8.1 would not by themselves justify any greater level of flexibility in the assessment of 'necessity' than that already found in the GATT jurisprudence. Nevertheless, it is submitted that there are *other* reasons why 'necessity' in TRIPS Article 8.1 should be understood to be a more flexible concept than in the context of GATT/GATS, and these reasons are addressed in the following paragraphs.

The WTO jurisprudence shows that the following factors should be weighed and balanced in determining whether a measure is 'necessary':

- The *importance* of the public interest,
- The level of *contribution* towards the said interest, and
- The availability of compliant or less inconsistent *alternatives*.

In relation to the first of these factors, the Appellate Body has been noted that the more vital or important the policy objective is, the easier it should be to establish that a measure is 'necessary'.[161] By giving them textual recognition, TRIPS Article 8.1 explicitly acknowledges the added significance of protecting of 'public health and nutrition'. The Panel in *Australia- Plain Packaging* stated that Article 8.1 shows that the protection of public health is 'unquestionably' a vital societal interest.[162]

The scrutiny of the level of contribution of a measure must be dependent on the design, architecture and application of a measure. It has been noted that it requires a *genuine relationship* of ends and means between the objective and the measure in issue,[163] which is to be demonstrated with proof of 'material contribution' towards the stated policy objective.[164] However, the Appellate Body noted that it may be difficult to demonstrate such material contribution where a measure pursues the protection of a policy such as public health, as the effects of such measures can only be evaluated with the 'benefit of time'. Therefore, such measures have been regarded to satisfy the requisite level of contribution and show the genuine

[160] Correa, n. 93, p. 106.
[161] Appellate Body Report, *Korea- Beef*, n. 30, para. 164.
[162] Panel Report, *Australia- Plain Packaging*, n. 111, para. 7.2406.
[163] See Appellate Body Report, *Brazil- Retreaded Tyres*, n. 29, para. 151.
[164] Ibid.

connection that is required provided they are 'apt' to make a material contribution towards the stated policy objective.[165]

It is submitted that this is the type of contribution that is required under TRIPS Article 8.1 for a reason that is almost unique to the TRIPS Agreement and intellectual property law measures. Article 8.1 is a manifestation of the balance mandated by TRIPS Article 7 between the protection of intellectual property rights and other vital societal interests. The use of the word 'should' in Article 7 shows that this requisite balance is a forward-looking objective that is not necessarily achieved by implementing TRIPS's minimum standards. This forward-looking balance acknowledges that vital societal interests could be affected by the protection of intellectual property rights. However, it also acknowledges the opposite: that measures adopted in the context of the intellectual property protection *can* have an impact on those societal interests. This potential could be acknowledged in the context of 'necessity' in Article 8.1 only if a measure's *capability to contribute* towards those societal interests to achieve the balance mandated by Article 7 could be recognized. This capability should also recognize the fact that a measure relating to intellectual property protection may not by itself be sufficient to address a particular public interest and may need to form part of a host of national measures. Hence, the level of contribution required to demonstrate a measure's 'necessity' in the context of a 'justification' in TRIPS Article 27.1 should consider a wide array of factors pertaining to the *capability* of a measure to protect a legitimate policy objective with the jurisdiction of a given member in the light of its design, structure and application.

The final element of this 'necessity' analysis should entail the determination of whether there are other alternatives to the respondent's measure. In this context, it involves an examination as to whether an alternative measure that is not 'discriminatory' or *less* 'discriminatory' is available to a respondent. As discussed in relation to the test of 'necessity' under the covered agreements in Part A of this Chapter, such alternatives should meet the respondent's desired level of protection of the stated policy objective and acknowledge the varying degrees of economic, social and technological standards among the membership. In the context of TRIPS Article 27.1, this specifically requires the scrutiny of whether there are measures that would pursue the same policy objective to the respondent's desired level of protection without conferring any disadvantageous/preferential treatment or conferred disadvantageous/preferential treatment to a lesser degree. Fundamentally, and particularly in

[165] Ibid.

the context of patent law, such alternatives should be 'reasonably' available to the respondent member to achieve the stated policy objective in the light of its technological, social and economic standards of development.

With regard to patent law rules, much could be said about the varying legislative, administrative and judicial capabilities among the WTO Members to protect other societal interests that are potentially affected by patents. There are many Members that are still fighting poverty and have not been able to utilize the policy space preserved in the TRIPS Agreement. Carlos Correa has written extensively demonstrating how such Members could enact TRIPS consistent measures to ensure that patents do not adversely affect access to medicine, which is one of the more glaring issues caused by patent systems.[166] Several academic articles have been written and resource books authored to identify these policy spaces.[167] Still, it cannot be conscionably stated that these Members are capable of administering patent law in the same way as the developed country Members. They lack the expertise necessary in the patent offices, the legislature and the judiciary to strike out unwarranted patent applications and monopolies. This does not mean that a WTO tribunal pitted to examine the inconsistency of a national measure should always examine these factors, but that the scrutiny of alternatives should acknowledge that there can be instances when such factors could indicate that certain Members should be given more teeth to prevent abuses of the patent system.

For these reasons, the test of 'necessity' in TRIPS Article 8.1 and the concept 'justification' in Article 27.1 is more flexible than in GATT/GATS. The manner in which a measure's contribution towards a policy is meant to be assessed and the determination of the availability of alternatives show that it sits in between the GATT/GATS notion of 'necessity' and the threshold of merely 'relating to'. This is because a concept of 'necessity' in TRIPS that concerns broader societal interests that have been addressed in its Objectives and Principles is meant to give sufficient regard to the deep and sensitive divergences among the WTO Members.

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[166] See for example C. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, Geneva, South Centre, 2000; C. Correa, 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?', in K. Maskus and J. Reichman (eds.), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, Cambridge University Press, 2005, pp. 227-256.

[167] S. Sterck, 'Patents and Access to Drugs in Developing Countries: An Ethical Analysis', *Developing World Bioethics*, vol. 4, no. 1, 2004, p. 58; E. Oke, 'Exploring the Flexibilities in TRIPS: Lessons from India's Pharmaceutical Patent Law', *Commonwealth Law Bulletin*, vol. 41, no. 1, 2015, p. 82; F. Scherer and J. Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Nations', Journal of International Economic Law, vol. 5, no. 4, 2002, p. 913; M. Lamping et al., 'Declaration on Patent Protection - Regulatory Sovereignty under TRIPS', in *IIC – Int'l Rev. Intell. Prop. & Competition L.*, vol. 45, no. 6, 2014, p. 679.

In effect, the 'necessity' threshold will be satisfied by a respondent if it could show that the measure's design, architecture and application is such that it has the capability to contribute towards the stated policy objective within its jurisdiction and the complainant has not been able to identify an 'available' alternative.

❖ *Even-Handedness*

Another vital feature prevalent in the justificatory concepts that recognize the autonomy of the Member States in the context of the substantive non-discrimination obligations is the presence of safeguards to ensure that Members do not abuse their right. The finest example is the 'chapeau' of the General Exceptions in GATT/GATS. It provides that its exceptions are only available if 'such measures are *not applied* in a manner which would constitute a means of *arbitrary or unjustifiable discrimination* between countries where the same conditions prevail, or a *disguised restriction on international trade*'. Hence, even when the conditions of one of the sub-paragraphs of the General Exceptions are met, a respondent needs to demonstrate that its measure has not been applied in a manner that constitutes 'arbitrary or unjustifiable' discrimination or as a 'disguised restriction' on trade. While the precise meaning of these 'chapeau' conditions have attracted much academic debate and still remain somewhat unclear in WTO jurisprudence, its *purpose* has been clearly identified by the Appellate Body in *US-Shrimp* in the following manner:

> Turning then to the chapeau of Article XX, we consider that it embodies the recognition on the part of WTO Members of the *need to maintain a balance of rights and obligations between the right of a Member to invoke one or another of the exceptions* of Article XX, …and *the substantive rights of the other Members under the GATT 1994*, on the other hand. Exercise by one Member of its right to invoke an exception, such as Article XX(g), *if abused or misused, will, to that extent, erode or render naught the substantive treaty rights* in, for example, Article XI:1, of other Members … The same concept may be expressed from a slightly different angle of vision, thus a *balance must be struck between the right of a Member to invoke an exception under Article XX and the duty of that same Member to respect the treaty rights of the other Members*. To permit one Member to abuse or misuse its right to invoke an

> exception would be effectively to allow that Member to degrade its own treaty obligations as well as to devalue the treaty rights of other Members.[168]

Accordingly, it aims to ensure that a *further* balance is struck between a WTO Member's right to exercise the type of autotomy recognized under the General Exceptions vis-à-vis the obligation not to make the treaty redundant in that process. The concept of 'even-handedness' prevalent in the jurisprudence relating to the TBT Agreement also has similar objectives. It was first coined by the Appellate Body in *US- Clove Cigarettes* when explaining its 'legitimate regulatory distinction' exception to TBT Article 2.1. Although subsequent reports tended to interpret the concept of 'even-handedness' along the lines of the 'chapeau' standards of the General Exceptions, the more fitting comprehension is that it requires *fairness and calibration* on the part of a national measure. Thus, Houston-Mcmillan states:

> …'what exactly is even-handedness'? Employing the language of the three disputes, it can be seen that a valuation of a measure's 'even-handedness' *involves examining whether the measure is 'fair', 'non-discriminatory', and 'calibrated' to its purpose*.[169]

'Calibration' in this context means that a Member must have addressed similar concerns in a similar manner. Hence, in *US – Clove Cigarettes*, the Appellate Body held that reducing the smoking of clove cigarettes without regulating menthol cigarettes was *not* fair as both the types of cigarettes were injurious to health. This is also why the Appellate Body held that measures aimed at protecting dolphins while fishing for tuna in the Eastern Tropical Pacific (ETP) was not fair in *US- Tuna II* because those measures did not consider the risks to dolphins caused by fishing practices in other parts of the ocean outside the ETP. Addressing some concerns to the exclusion of other similar concerns is considered to be 'unfair' as it is an indication of the lack of good faith. A similar safeguard is found in Article 5.5 of the SPS Agreement. The prohibition of 'arbitrary or unjustifiable distinctions' in the levels of protection in SPS Article 5.5 applies where the groups of products in question have *similar* SPS concerns. Therefore, regulating the SPS risks in one group of products to the exclusion of another group with similar SPS concerns is sign of *protectionism* that SPS was meant to tackle.

It is submitted that such a concept of 'even-handedness' that examines if a Member has addressed similar public interests or right-holder oriented concerns in other fields of technology

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[168] Appellate Body Report, *United States- Import Prohibition on Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, para. 156. Emphasis added.
[169] Houston-Mcmillan, n. 90, p. 557. Emphasis added.

should serve to ensure that the autonomy that the concept of 'justification' seeks to preserve is not abused. Hence, the disadvantageous/preferential treatment accorded to a particular field of technology to pursue a vital interest traceable to TRIPS Article 8.1 should be accorded to all other fields of technology with the same or similar public interest and right-holder related concerns. This is the reason that the Panel in *Canada- Pharmaceuticals* appears to have suggested that the non-discrimination obligation in Article 27.1 does *not* prohibit *bona fide* exceptions directed at only one field of technology.[170] It would *not* be *bona fide* if there are other fields of technology with similar concerns that have *not* been similarly addressed by a Member. Nonetheless, it should be acknowledged that although the concerns meant to be addressed in one field of technology may be technically prevalent in other fields of technology, the gravity of the problem in one field of technology might be so grave that it may justify a Member's preoccupation with that field of technology. This explains why only pharmaceutical patents tend to benefit from patent term extension schemes around the world. Many inventions in several other fields including automobiles, building systems and telecommunications similarly face regulatory delays, but its impact is considered to be incomparable to that faced by the field of pharmaceuticals given the nature of the industry. The flipside of this reasoning is that particular types of patent abuses in fields like pharmaceuticals could be so detrimental to a given Member's public health that it may justify the adoption of measures that only address such abuses in the field of pharmaceuticals.

- *AN INTERPRETATION OF THE RULE AGAINST 'DISCRIMINATION' OF FIELDS OF TECHNOLOGY*

The interpretational approach to the rule against the 'discrimination' of fields of technology adopted in this Chapter highlights the need for a concept of 'justification' in the context of this obligation. Consequent to identifying this rationale, this Chapter identified the constitutive elements that such a concept should entail in the context of this obligation. In this process, it also addressed some fundamental features of this obligation that were not adequately addressed by the Panel that demonstrate the wide scope of the rule against the 'discrimination' of fields of technology. Consequently, an interpretation of the rule against the 'discrimination' of *fields of technology* that builds on the Panel's formulation of 'discrimination' in Article 27.1 can be presented as follows:

[170] Panel Report, *Canada- Pharmaceuticals*, n. 110, para. 7.92.

The rule against the 'discrimination' of fields of technology in TRIPS Article 27.1 prohibits a national measure from according disadvantageous or preferential treatment to a field of technology that affects the availability and enjoyment of patent rights, unless it is necessary to pursue a legitimate policy objective and such treatment is applied in an even-handed manner by addressing similar concerns even in other fields of technology.

This interpretation gives a deeper understanding of the Panel's formulation of 'discrimination' in relation to the specific ground of 'fields of technology'. The precise implications that would flow from this interpretation will become evident by testing its operation, which would also provide a better comprehension of its elements that have been discussed in this Chapter. As such, the subsequent Chapters of this thesis apply this interpretation to examine the *potential* consistency of selected national measures that are currently found in the patent systems of certain WTO Members that may trigger a violation of this obligation.

- *TECHNOLOGY SPECIFIC EXCEPTIONS AND COMPULSORY LICENCES*

One of the most criticized aspects of the Panel Report in *Canada-Pharmaceuticals* was its finding that TRIPS Article 30 (limited exceptions) and Article 31 (compulsory licences) are subject to the rule against 'discrimination' in Article 27.1. Academics have opined that this is problematic as it prevents the WTO Members from crafting *technology specific* exceptions and compulsory licences that address specific concerns in certain fields of technology which would have been possible if not for the non-discrimination obligation. It has been argued that this is because Articles 30 and 31 are simply incompatible with the non-discrimination obligation. For example, it has been stated that adhering to the non-discrimination obligation in Article 27.1 prevents an exception from being 'limited' in terms Article 30.

However, it is submitted that these fears have been exaggerated. While the Panel held that Article 30 and Article 31 should abide by the non-discrimination obligation, it also noted that this does *not* mean that exceptions and compulsory licences should always apply to all the fields of technology.[171] In the context of limited exceptions, the Panel noted that it does *not* prevent *bona fide* exceptions that deal with problems in certain product areas.[172] The actual issue was that the Panel did not identify that *such* was the realm of its notion of 'justification', which was

[171] See Panel Report, *Canada- Pharmaceuticals*, n. 110, para. 7.92.
[172] Ibid.

not examined its Report. Given that the foregoing Parts of this Chapter substantively identified the concept of 'justification', the relationship between the non-discrimination obligation and technology specific limited exceptions and compulsory licences deserve a fresh clarification.

As explained by the Panel, both Articles 30 and 31 affect the *enjoyment* of patent rights. Therefore, they should adhere to the non-discrimination obligation in Article 27.1. A technology specific limited exception or compulsory licence that *explicitly* applies only to one field of technology would trigger a presumption of disadvantageous treatment and a *prima facie* case of inconsistency with this obligation. In the light of the concept of 'justification', this does not mean that they would always constitute 'discrimination'. A respondent should be entitled to 'justify' its preoccupation with one field of technology as the Panel rightly acknowledged in its Report. As discussed in the previous Parts, a 'justification' in this context would require the demonstration of a legitimate policy objective, necessity and even-handedness. Given the type of autonomy recognized in Articles 30 and 31, it is submitted that a respondent who could demonstrate that its technology specific exception or compulsory licence satisfies the conditions of Articles 30 or 31 automatically satisfies the existence of a legitimate policy objective *and* the requirement of 'necessity'. The only additional condition that a respondent would need to establish is that such treatment is applied *even-handedly* by addressing similar concerns in other fields of technology. This is what the Panel appears to have meant when it stated that the non-discrimination obligation does not prevent '*bona fide*' exceptions. Whether it is *bona fide* is scrutinized by the concept of 'even-handedness' that has been explained in this Chapter. This understanding that flows from a better understanding of the concept of 'justification' gives better sense to the Panel's perspective of the inter-play between the non-discrimination obligation and Articles 30 and 31. It is submitted that this reconciliation between these two sides of TRIPS's patent rules meet the requisite balance between the non-discrimination obligation and the ability of the WTO Members to make to make limited exceptions and grant compulsory licences.

CHAPTER 5

CASE STUDY: THREE NATIONAL MEASURES THAT POTENTIALLY TRIGGER A VIOLATION OF THE RULE AGAINST DISCRIMINATION

With the introduction of the TRIPS Agreement, subject to certain transitional periods that were provided for developing and least-developed country Members, all WTO Members were required to bring their patent laws into conformity with its patent law standards. This was a major step for those who had not previously provided or only provided limited forms of patent protection for pharmaceuticals for reasons of public health and accessibility. As most of these transitional periods have now come to an end,[1] almost all WTO Members are now required to grant process and product patents to all inventions in all fields of technology without any 'discrimination' as to the availability and enjoyment of patent rights.

However, TRIPS did not specify how precisely these minimum standards should be implemented in the national systems, except by providing in Article 1.1 that:

> Members shall be free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.

This deference on the part of the Members was clear in the manner in which they changed their patent laws to recognize the patentability of pharmaceutical inventions, while simultaneously striving to ensure that other vital public policies are not disregarded in this process. As will be demonstrated in this Chapter, the manner in which India and Brazil chose to do this provide fertile ground to test TRIPS's rule against the 'discrimination' of fields of technology and the concept of 'justification' that has been revealed in the previous Chapter. Moreover, other Members like Australia who had recognized the patentability of pharmaceutical inventions even at the time TRIPS was being negotiated had begun to provide a form of preferential treatment to pharmaceuticals to address the industry's concerns that the *effective* life of their patents were being impeded by regulatory processes. Such measures that have continued beyond the TRIPS Agreement also provide a good opportunity to test the concept of 'discrimination' in TRIPS Article 27.1.

[1] The TRIPS Council extended the transition period for least-developed countries until 1 July 2021.

To enable the subsequent Chapters to apply the more developed understanding of the rule against the 'discrimination' of fields of technology and identify the implications that this would have on the Members of the WTO, this Chapter examines three selected national measures that explicitly subject pharmaceutical inventions to differential treatment. They are dealt in three distinct Parts and concern Section 3(d) of the Indian Patent Act, the Brazilian requirement of 'prior consent' and the Australian scheme of patent term extensions. The aim of each of these Parts is to provide a comprehensive understanding of the objectives, nature, scope and application of these mechanisms that is necessary to scrutinize their potential consistency with the rule against 'discrimination' in TRIPS Article 27.1.

A. INDIA'S REQUIREMENT OF EHNANCED EFFICACY

- *INDIA'S HISTORY WITH PHARMACEUTICAL INVENTIONS: DENYING PRODUCT PATENTS ON CHEMICAL SUBSTANCES AND MEDICINE*

India inherited its patent law from the British during the colonial rule by *Act No. VI of 1856*.[2] Parameswaran Narayanan states that unlike in Great Britain, the concept of patents in India did not originate from any royal prerogative but by the statutes of the Indian legislature.[3] The 1856 Act was re-enacted with modifications in 1859, which was succeeded by the *Patterns and Designs Protection Act of 1872* and the *Protection of Inventions Act of 1883*. These Acts were consolidated by the *Inventions and Designs Act of 1888*, which was subsequently replaced by the *Patents and Designs Act of 1911* which was in force till 1970.[4] All these statutory instruments were based on the British law at the time and recognized the patentability of pharmaceuticals, which were overwhelmingly used by British corporations.[5] Aradhna Aggarwal states that between 1947 and 1957, 99% of the 1704 drug and pharmaceutical patents were held by foreign corporations and that they held over 80% of the market-share in India.[6] With little or no indigenous pharmaceutical industry at that time, Janice Mueller notes that patents seemed as mere tools used by British patentees to control the Indian market.[7] This had a disastrous

[2] See P. Narayanan, *Narayanan on Patent Law*, Eastern Law House, 1975, pp. 1-22.
[3] Ibid., p. 4.
[4] Ibid., p. 5.
[5] W. Bennett, 'Indian Pharmaceutical Patent Law and the Effect of Novartis Ag v. Union of India', *Wash. U. Global. L. Rev.*, vol. 13, no. 3, 2014, p. 535.
[6] A. Aggarwal, *Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry*, Research and Information System for the Non-Aligned and Other Developing Countries, 2004, RIS-DP # 80/2004.
[7] J. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation', *U. Pitt. L. Rev.*, vol. 68, no. 3, 2007, p. 491 at p. 508.

impact on India. By the time it gained its independence in 1947, India was home to one fifth of the world's population, it was the poorest nation, its pharmaceutical industry was dominated by multi-national corporations and was one of the countries with the highest prices on drugs.[8]

Unsurprisingly, immediately upon gaining independence, the Indian legislator gave prime importance to making medicine more affordable to its poverty-stricken population. The revamping of its patent law began in 1948 with the Government appointing Dr. Bakshi Tek Chand, a retired Judge of the High Court of Lahore, to review Indian patent law in order to make the system 'more conducive to national interests'.[9] The Chand Committee submitted an interim report in August 1949 that suggested the immediate amendment of the 1911 Act to counteract the misuse or abuse of patent monopolies.[10] These amendments that brought Indian law in line with the *UK Patents Act of 1949* were aimed at expanding the grounds for compulsory licences by the including the non-working of patents and the failure to meet the requirements of the public on reasonable terms.[11] The Chand Committee submitted its final report in April 1950, the recommendations of which resulted in *Bill No. 59 of 1953* being presented to the Parliament. However, this Bill lapsed before being enacted with the first *Lok Sabha* (the lower house of the Indian Parliament) being dissolved in 1953.

Fresh efforts were made by the Government in 1957 by appointing Shri Justice N. Rajagopala Ayyangar to advise on the revision of patent law. The Final Report of this committee was submitted in 1959 and formed the catalyst for radical changes in Indian patent law. The Ayyangar Report is still biblically cited by the Indian judiciary as it was its recommendations that instigated the first indigenous *Patents Act (1970)* that is currently in force in India. Borrowing the same language and findings from the Chand Committee Report, Justice Ayyangar noted that 'the Indian Patent system has failed in its main purpose, namely, to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public'.[12] The Report made certain observations about patent systems generally that makes it one of the finest national patent reviews that would be relevant to many countries for many years to come. It observed that a patent system should be designed with special

[8] Ibid.
[9] See Patents Enquiry Committee, *Report on the Revision of the Patents Law*, 1959, para. 2, [hereinafter referred to as 'Ayyangar Report'].
[10] Ibid.
[11] See V. Mani, D. Srivasta, M. Chakrapani and J. Erstling, 'The India Patent System: A Decade in Review', *Cybaris*, vol. 8, no.1, Article 2, 2017 at p. 4.
[12] Ayyangar Report, n. 9, para. 25.

reference to the economic conditions of a country, the state of its scientific and technological advancement, its future needs and other relevant factors in order to reduce the abuses to which a system of patent monopoly is capable of being put.[13] It noted that the failure to suit the patent system to such domestic needs could retard the industrial progress of a country.[14]

Accordingly, the Report suggested several changes to the law, almost all of which were adopted by the *Patents Act of 1970*. The most significant of its recommendations relating to patent exclusions had a significant impact on pharmaceutical inventions. The Report called for a clear identification of what is patentable and what is not, and in the case of the latter, whether it is because it is not an 'invention' in the eyes of the law or because it is excluded for competing policy reasons such as national economy or national health.[15] It recommended severe restrictions on the patenting of inventions relating to chemical substances, food and medicine. Recommending only *process* claims for chemical substances, it noted that such a restriction is necessary to advance the chemical and pharmaceutical industries in India and to encourage research in those fields.[16] Similarly, the Report recommended the denial of product claims for food and medicine noting that these were articles of daily use, vital for the health of the community, and should therefore, be available at reasonable prices and beyond any monopoly.[17] The Indian legislature adopted these recommendations by virtue of Section 5 of the 1970 Act that originally provided as follows:

> In the case of inventions- (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds) no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

Even the process patents in these fields were of limited duration. In terms of the then Section 53 of the 1970 Act, such patents only lasted for five years from the date of sealing or seven years from the date of patent, whichever period that was shorter.[18] Vitally, such patents were

[13] Ibid., para. 44.
[14] Ibid., para. 16.
[15] Ibid., para. 46-55.
[16] Ibid., para. 92.
[17] Ibid., para. 101.
[18] See Narayanan, n. 2, p. 179.

subject to automatic licences of right that were available from three years after their grant.[19] Thus, Mueller notes that the 1970 Act was the finest example of how domestic patent systems were structured to achieve national priorities.[20]

The economic, social and political impact of Section 5 was enormous. There was a dramatic increase in domestic generic manufacture of pharmaceutical products, and hence, a sharp decline in the prices of medicine. The reason was because pharmaceuticals patented elsewhere could be freely copied in India. Amy Kapczynski points out that the 68% market-share that foreign pharmaceutical firms held in India gradually reduced to around 60% by the late 1970s, to 55% by 1980, to 40% by 1990 and just over 20% by the early 21st century.[21] Sudip Chauduhri notes that this market-share that was at around 23% in 2004, reduced to 20% in 2008.[22] Moreover, Chan Park observes that by 1999, 70% of bulk drugs and 80% of formulations in the country were supplied by the domestic Industry.[23] Consequently, India, along with Japan, became the only countries in which the pharmaceutical companies of the US and Europe did *not* dominate.[24]

These changes did not only reduce the prices of drugs for the Indian populace, they also built a thriving generic industry that began to focus on foreign markets. As the Supreme Court of India noted in *Novartis v. Union of India*, India became a net exporter of pharmaceuticals by 1988/89 and almost 75% of its net exports were pharmaceuticals by the early 21st century, the majority of which were bulk drugs.[25] The domestic industry became capable of producing bulk drugs (also known as Active Pharmaceutical Ingredients) and formulations and saw the formation of numerous generic corporations who sought to exploit this patent free environment. Cipla, Ranbaxy, Dr. Reddy's, Lupin, Sun Pharmaceuticals, Piramal Healthcare and Cadila Healthcare are a few of such generic companies that developed during this time and some of which are still found in the list of the 20 largest pharmaceutical companies in India.[26]

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[19] Competitors were entitled to obtain an automatic licence to practice the patent three years after grant on terms as agreed by the parties, or failing such agreement, on terms set by the Patent Controller in terms of Sections 87 and 88 of the 1970 Act.

[20] Mueller, n. 7, p. 514.

[21] A. Kapczynski, 'Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector', *Calif. L. Rev.*, vol. 97, 2009, p. 1571 at p. 1578.

[22] S. Chaudhuri, 'The Indian Pharmaceutical Industry After TRIPS', in S. Chaudhuri, C. Park and K. Gopakumar (eds.), *Five Years into the Product Patent Regime: India's Response*, United Nations Development Programme, 2010, p. 19 at p. 21

[23] C. Park, 'Implementation of India's Patent Law: A review of patents granted by the Indian Patent Office', in Chaudhuri et al., n. 23, p. 73 at p. 76.

[24] Chaudhuri, n. 22, p. 21.

[25] *Novartis AG v. Union of India and Others*, 6 SCC 1 (2013), para. 57, [hereinafter referred to as 'Novartis v. UOI (SC)'].

[26] See Chaudhuri, n. 22, p. 21.

- *IMPLEMENTING TRIPS STANDARDS*

The successes of the Ayyangar recommendations were being threatened by the GATT/WTO negotiations which commenced at Punta del Este in 1984, as it clearly signalled the culmination of the TRIPS Agreement that was to set-out minimum standards for the protection of intellectual property rights. With India being one of the founding members of the World Trade Organization (WTO), it had no other option but to implement TRIPS's minimum standards given the 'single undertaking' nature of the WTO and its covered agreements. Nevertheless, as India was a developing country which did not grant product patents for pharmaceuticals at the time TRIPS came into force, it did not have to comply with TRIPS Article 27 immediately. It was entitled to benefit from the ten-year transition period in terms of TRIPS Article 65. Hence, TRIPS Article 27 came into full force in India only on 1st January 2005. Up until then, however, India made certain amendments to its laws in 1999 and 2002 to comply with other TRIPS standards such as the 'mailbox' of patent applications, Exclusive Marketing Rights and to comply with the mandated twenty-year term of patent protection.

During this transition period the tension between pharmaceutical patents and access to affordable medicine came to the international limelight. With certain developed country Members of the WTO opposing the grant of compulsory licences by the less developed country Members for the manufacture and/or importation of less expensive anti-retroviral medicine for the treatment of HIV/AIDS, the 'access to medicine' movement was formed. As Swaraj Barooah notes, this movement gave birth to a well-coordinated network of scholars, activists and community-based organizations who were highly motivated, increasingly sophisticated and remarkably aware of how patents affected public health.[27] This movement culminated with the WTO Ministerial Declaration in 2001 which declared that TRIPS cannot prevent Members from taking measures to protect public health and that the Agreement can and should be interpreted in a manner supportive of the Members' right to protect public health and promote access to medicine for all.[28] These developments highlighted the need for the Indian legislators to tackle some fundamental issues in the process of recognizing product patents for pharmaceuticals, and this served to ensure that the influence of the Ayyangar recommendations did not come to an end even with TRIPS.

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[27] S. Barooah, 'India's Pharmaceutical Innovation Policy: Developing Strategies for Developing Country Needs', *Trade L. & Dev.*, vol. 5, no. 1, 2013, p. 150 at p. 156. Also see Kapczynski, n. 21, p. 1585.

[28] World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, WT/MIN(01)/DEC/2, Doha, 2001, para. 4.

By the end of 2004, India had to decide as to how it was to confer product patents for pharmaceuticals, reversing a conscious decision that it had made in 1970. The final round of amendments to bring its patent laws into alignment with TRIPS standards initially came by way of an Executive Ordinance known as the *Patents (Amendment) Ordinance No. 7 of 2004* that was promulgated by the President. This Executive Order was subsequently presented as a Bill to the Indian Parliament on 18th December 2004. This Bill essentially called for the deletion of the original Section 5 of the 1970 Act that denied product patents for chemical and pharmaceutical products. It attracted three days of Parliamentary debate in which members of the opposition voiced their concerns over public health and access to drugs. The Supreme Court aptly described the essence of this debate in *Novartis v. Union of India* in the following manner:

> To anyone going through the debate on the Bill, Parliament would appear keenly alive to national interests, human- rights considerations and the role of India as the producer and supplier of drugs to different parts of the world where impoverished humanity is critically in need of those drugs at cheap and affordable prices. Cutting across party lines, member after member from the Opposition benches *highlighted the grave risk in creating private monopolies in an area like pharmaceuticals, the abuses to which product patents in pharmaceutical products were vulnerable, and the ploys used by big companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high*.[29]

The main focus of the debates concerned the abusive practice of patenting minor modifications of already existing substances and its potential to detrimentally affect the public health of its citizens. This type of abuse that is commonly referred to as the practice of 'ever-greening' was explained by the Supreme Court as the 'ploy used to artificially extend the period of a patent' to keep competitors out and prices high.[30] To highlight the gravity of such abuse, several members of the legislature specifically referred to Novartis's patent application concerning Glivec, an anti-cancer drug. Shri Suresh Kurup (MP) highlighted that the mere grant of exclusive marketing rights for Glivec had by itself resulted in the cost of monthly treatment increasing from Rs. 10,000 to Rs. 120,000:

> One major area where all of us have raised our criticism was the provision which helps the patent holder multinational companies for evergreening of

[29] *Novartis v. UOI (SC)*, n. 25, para. 79. Emphasis added.
[30] Ibid.

> patents. Sir, a company which obtains a patent by changing their chemicals, before the expiry of the patent, they will again apply for a patent and again get a patent. So, in this way, they will continue to get a patent for the same medicine. For example, the drug called 'Glevic", is used for the treatment of Leukaemia. It is patented by Novartis. This was originally patented in 1993. The cost of the drug for the treatment of this disease comes to about Rs. 1,20,000 per month in India. At the same time, the generic versions are available in the country which cost only Rs. 8000 to Rs. 10,000.[31]

The public outcry regarding Novartis's Glivec drug neatly substantiated these fears against 'ever-greening'.[32] Hence, the lack of any rules in the Bill that identified which inventions *genuinely* deserved patent protection in the chemical/pharmaceutical sector was considered to be a serious issue. For this reason, the Bill was even criticized for bearing a 'heavy footprint' of multinational pharmaceutical companies who wanted to sell high priced drugs only to India's growing middle-class population.[33] Acknowledging these concerns, the Government introduced a new Section 3(d) that provided as follows:

> Section 3. What are not inventions- The following are not inventions within the meaning of this Act-
>
> .
>
> (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> Explanation- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

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[31] See Lok Sabha Debates, Fourteenth Session, Vol. VIII, 4th Session, 22 March 2005, pp. 605-607, [hereinafter referred to as 'Lok Sabha Debates'].

[32] Also see S. Ghoshray, '3(d) View of India's Patent Law: Social Justice Aspiration Meets Property Rights in Novartis v. Union of India & Others', *J. Marshall Rev. Intell. Prop. L.*, vol. 13, 2014, p. 719.

[33] Lok Sabha Debates, n. 31, pp. 553-558.

This new version of Section 3(d) added a new rule to the previous Section 3(d) by providing that the mere discovery of a new form of a known substance shall not be regarded as an invention unless there is an enhancement of the known efficacy of that substance. The Explanation that accompanied it also set out a list of derivatives that shall be considered to be the same as the previous known substance 'unless they differ significantly in properties with regard to efficacy'. The then Minister of Commerce and Industry, Shri Kamal Nath, assured that the new Section 3(d) that encompasses this rule would tackle the ever-greening concerns raised in Parliament.[34] With this assurance and without any discussion about the specifics of the new rule that was introduced to Section 3(d), the Amendment Bill was passed in the Lok Sabha on the 22nd of March 2005, in the Rajya Sabha (Secondary Chamber) on the very next day and received Presidential assent on the 4th of April 2005. Accordingly, the deletion of the then Section 5 removed the bar on product patents in the chemical, food and medicine sectors that existed since 1970. However, this did not mean that India was going to face the kind of turmoil that it faced did during the colonial era because it had utilized a number of flexibilities provided for under the TRIPS Agreement to ensure that its patent system accommodates its national interests.[35] The new rule in Section 3(d) that was introduced by the 2005 amendments was one such tool, and its interpretation and application by the Indian Courts and Patent Offices is examined below to reveal how it is meant to do so.

- *GETTING ACQUAINTED WITH SECTION 3(D): INTERPRETATION AND APPLICATION*

It should be noted that unless stated otherwise, any reference to 'Section 3(d)' here onwards is a reference to the rule that was specifically introduced into Section 3(d) by the 2005 amendments relating to new forms of known substances. Recalling the words used in this part of the provision is vital to appreciate the subsequent role played by the judiciary and the Patent Offices in revealing the specificities of this rule. It provides that '*the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance*' shall not be treated as an invention. It is followed by an *Explanation* which provides that derivatives of a known substance, such as salts, ester and so on, shall be treated as the same substance '*unless they differ significantly in properties with regard to efficacy*'. The upshot of this is that an invention that is a derivative of a known substance would be

[34] Lok Sabha Debates, n. 31, pp. 639-650.
[35] See V. Unni, 'Indian Patent Law and TRIPS: Redrawing the Felxibility Framework in the Context of Public Policy and Health', *Pac. McGeorge Global Bus. & Dev. L. J.*, vol. 25, no. 1, 2012, p. 323.

patentable only if there is a significant enhancement of the known efficacy. Neither did the Amendment Bill of 2004 nor the Act explain what constitutes a 'known substance', 'efficacy' or 'significant enhancement' of properties with regard to efficacy. The following sub-sections discuss how the Courts and Patent Offices in India have resolved these ambiguities surrounding this rule in the light of its intended objective of tackling 'ever-greening'.

❖ *'Enhanced Efficacy'*

As Mueller rightly envisioned back in 2007, the extent to which Section 3(d) could achieve its objective is fundamentally dependent on the meaning of 'efficacy' and the extent of its enhancement that is necessary to render a derivative invention to be patentable.[36] These issues were addressed by the Supreme Court of India in *Novartis AG v. Union of India and Others*.[37] This was the first dispute that instigated a steady comprehension of the scope and effect of Section 3(d), from the Patent Office up until the apex Supreme Court.[38] This section scrutinizes the Supreme Court's interpretation of the term 'efficacy' in Section 3(d) with regard to pharmaceutical inventions as it is the most authoritative interpretation of this concept that raises the brows of the non-discrimination obligation in TRIPS Article 27.1.

The scrutiny of the Supreme Court's interpretation of Section 3(d) would not be complete without an adequate understanding of the facts and history concerning the dispute in *Novartis*. Novartis's patent application for Glivec concerned the *beta crystalline* form of an active ingredient known as *imatinib mesylate*. In 1993 Novartis had applied for a patent in the US in for imatinib in *freebase* form. At that time, however, India did not recognize product patents for pharmaceuticals, and therefore, foreign patent applications that preceded the TRIPS Agreement became part of the prior art in India. Novartis filed its Indian patent application relating to the *beta crystalline form of imatinib mesylate* in 1998 after TRIPS came into force, on the basis that it had significant improvements compared to imatinib in freebase form that

[36] Mueller, n. 7, p. 553

[37] See *Novartis v. UOI (SC)*, n. 25.

[38] In addition to the literature cited above relating to Section 3(d), see S. Thambisetty, 'Novartis v Union of India and the Person Skilled in the Art: A Missed Opportunity', *Queen Mary Journal of Intellectual Property*, vol. 4, no.1, 2014, p. 79; P. Kinge, 'The Supreme Court of India on the protection of incremental inventions', *J. Intell. Prop. L. & Pract.*, vol. 8, no. 8, p. 581; S. Barazza, 'Incremental pharmaceutical innovation in India: The Supreme Court's judgment in the Novartis Gleevec case', *J. Intell. Prop. L. & Pract.*, vol. 8, no. 10, 2013, p. 776; E. Oke, 'Exploring the Flexibilities in TRIPS: Lessons from India's Pharmaceutical Patent Law', *Commonwealth Law Bulletin*, vol. 41, no. 1, 2015, p. 82; B. Sampat and T. Amin, 'How do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice?', *J. Health Pol., Pol'y & L.*, vol. 38, no. 4, 2013, p. 735; R. Gabble and J. Koehler, 'To Patent or Not to Patent? The Case of Novartis's Cancer Drug Glivec in India', *Globalization and Health*, vol. 10, no. 3, 2014; J. Patel, 'India's Crack Down on the Practice of Pharmaceutical Evergreening: The 2013 Novartis Decision', *UMKC L. Rev.*, vol. 85, no. 1, 2016, p. 503.

was part of the prior art in India. As the 'mailbox' system was in place until the end of 2004, Novartis's patent application for beta crystalline form of imatinib mesylate was taken up for examination only after the final patent law amendments in 2005 that introduced the new rule to Section 3(d).

The Assistant Controller of Patents and Designs in Chennai initially denied the patent on the basis that Novartis's application lacked novelty, inventive step and a significant improvement of efficacy mandated by Section 3(d). The decision, *inter alia*, noted that Novartis's assertions relating to the 30% increase in bioavailability of the beta crystalline form of imatinib mesylate compared to imatinib in freebase form and its improved physio-chemical properties were not sufficient to demonstrate an enhancement of efficacy as the prior art consisted of imatinib in freebase *and* mesylate forms.[39] Hence, the data that Novartis had submitted demonstrating enhancements in the beta crystalline form of imatinib compared *only* to its freebase form were insufficient. Citing this deficiency, the Assistant Controller did not think that it was even necessary to define the term 'efficacy' in Section 3(d).

Aggrieved by the Controller's decision, Novartis filed two distinct appeals. A substantive appeal was made to the Intellectual Property Appellate Board (IPAB), while an appeal challenging the constitutionality of Section 3(d) was made to the High Court of Madras. In the latter appeal that was decided first, Novartis claimed that the interpretation of 'efficacy' results in arbitrariness, and thus, violates the Indian Constitution. Disagreeing with Novartis, the High Court explained that the term 'efficacy' is particularly well known to everyone in the field of pharmaceuticals and that the enhancement of such efficacy could in fact be clinically proven in the field of pharmacology.[40] After examining how the new Section 3(d) was proposed by the Government to allay the fears concerning ever-greening, the Court stated that its objective is:

> … to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.[41]

[39] Decision of the Assistant Controller of Patents and Designs for Patent Application No. 168/MAS/1998 on 25/01/2006.
[40] *Novartis AG v. Union of India and Others*, High Court of Judicature of Madras, 2007 (4) MLJ 1153 (W.P. No. 24759 and 24760 of 2006), para. 4.
[41] Ibid., para. 19.

Referring to the Darland's Medical Dictionary, the High Court was the first judicial tribunal to state that 'efficacy' in the context of pharmaceutical products means *therapeutic* efficacy. In its words:

> Darland's Medical Dictionary defines the expression "efficacy" in the field of Pharmacology as "the ability of a drug to produce the desired therapeutic effect" and "efficacy" is independent of potency of the drug. Dictionary meaning of "Therapeutic", is healing of disease- having a good effect on the body". Going by the meaning for the word "efficacy" and "therapeutic" extracted above, that the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/having a good effect on the body?[42]

Accordingly, stating that the pharmaceutical industry in particular was not entitled to claim that the interpretation of 'efficacy' could lead to arbitrariness, the High Court dismissed Novartis's appeal.

The substantive appeal was thereafter taken up by the IPAB. In a detailed order, the IPAB upheld the Controller's decision to deny the patent on the basis of Section 3(d), but over-turned the Controller's findings that the beta crystalline form of imatinib mesylate was neither new nor inventive.[43] Citing the High Court's interpretation of 'efficacy', the IPAB noted that Novartis had failed to show the enhanced efficacy of the beta crystalline form vis-à-vis either imatinib in freebase form or mesylate form.[44] Stating that whether there is a 'significant' enhancement of efficacy should be decided on a case-by-case basis,[45] it noted that neither did the advantageous properties of imatinib in beta crystalline form, nor its increased bioavailability enhanced the *therapeutic* efficacy of imatinib.[46] It also stated that Section 3(d) constitutes a heightened *inventive step* requirement for 'drug and pharmaceutical inventions', and therefore, is a part of the patentability criteria together with novelty and industrial applicability in terms of Section 2(1)(j) of the Patents Act.[47]

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[42] Ibid., para. 13.
[43] *Novartis AG v. Union of India*, Order of the Intellectual Property Appellate Board, M.P No.1 to 5/2007 in TA/1 to 5/2007/PT/CH.
[44] Ibid., pp. 186-190.
[45] Ibid., p. 188.
[46] Ibid., p. 189.
[47] Ibid., p. 190.

Dissatisfied with the IPAB Order, Novartis made its final substantive appeal to the Supreme Court. Refusing to interfere with the Order, the Court availed itself of the opportunity to revisit the issues that were dealt by the High Court and the IPAB and to provide judicial guidance from the apex Court in India. It exhaustively examined how the 1993 patent in the US for imatinib in *freebase* form contained the teachings for the making of imatinib in *mesylate* form.[48] The Court explained that the substance that is 'known' to have the effect of treating a disease should be considered as the 'known substance' for the purposes of Section 3(d). As imatinib in mesylate form, in addition to its freebase form, was known particularly to Novartis to be effective in the treatment of cancer, the Court stated that imatinib in *mesylate* form was the correct 'known' substance for the purposes of Section 3(d).[49] Prior to examining if the *beta crystalline* version of imatinib mesylate had enhanced the efficacy compared its mesylate form, the Court delved into the history of Indian patent law. Concurring with the High Court's observations, the Supreme Court stated that Section 3(d)'s legislative purpose is to tackle the problem of ever-greening:

> The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.[50]

However, the Supreme Court did not think that it had to decide as to where Section 3(d) exactly fits in the process of patent scrutiny.[51] It was of the opinion that it could *either* belong to the patentability criteria, *or* be a patent eligibility standard that identifies patentable inventions.[52] The Court stated, however, that the application for the beta crystalline form of imatinib mesylate 'directly runs into' Section 3(d) of the Act.[53] The Court referred to the New Oxford Dictionary of English to interpret the term 'efficacy'. It noted that 'efficacy' is the ability to produce the desired result that varies depending on the product in question.[54] Stating that this depends on the 'function, utility and the purpose of the product under consideration',[55] the Court

[48] *Novartis v. UOI (SC)*, n. 25, para. 131-157.
[49] Ibid., para. 159-161.
[50] Ibid., para. 103.
[51] See Thambisetty, n. 38.
[52] *Novartis v. UOI (SC)*, n. 25, para. 104.
[53] Ibid., para. 158.
[54] Ibid., para. 180.
[55] Ibid.

noted that 'efficacy' in the case of medicine could *only* mean *therapeutic* efficacy that must be judged 'strictly and narrowly'.[56]

With these general observations in mind, the Court dealt with the enhancements referred to by Novartis. Novartis claimed that the beta crystalline form of imatinib mesylate had more beneficial flow properties, better thermodynamic stability and lower hygroscopicity compared to *imiatinib in freebase form*. It also claimed that the beta crystalline form increased the bioavailability of imatinib by 30% which increased the bodily absorption rate of the drug, again however, only compared to the *freebase form*. The Court noted that there were essentially two problems with these enhancements. Firstly, the data submitted were only with reference to imatinib in freebase form, whereas what was actually needed were enhancements vis-à-vis *imatinib in mesylate form*. Secondly, as efficacy in relation to medicine had to be examined strictly and narrowly, the improved physio-chemical properties and the increased bioavailability of the beta crystalline form were in any event insufficient. The Court categorically stated that beneficial properties relating to a substance cannot be taken into account for the purpose of Section 3(d) as they did not relate to the therapeutic effect of a drug.[57] With regard to increased bioavailability, however, the Court was less severe. It opined that while bioavailability *could* enhance the therapeutic efficacy of a drug, it was not so in this case as no evidence was produced to show that the increased bioavailability resulted in better a therapeutic effect. The Court noted that such an assertion should be 'specifically claimed and established by research data'.[58] As such, the Court agreed with the Controller and the IPAB that Novartis had failed to establish 'enhanced efficacy' of the beta crystalline form of imatinib mesylate.

Consequently, Section 3(d) prevented Novartis from patenting its 'new' version of imatinib, which effectively permitted generic versions of the drug to be sold in the market for lesser prices. The following subsections examine how subsequent Patent Office and judicial rulings have applied and even developed this interpretation of Section 3(d) in the hope of providing greater clarity to this rule.

[56] Ibid.
[57] Ibid., para. 187.
[58] Ibid., para. 189.

❖ *Applying 'Therapeutic Efficacy'*

The interpretation of 'efficacy' of pharmaceutical substances as 'therapeutic efficacy' was a bold move by the Indian judiciary as it was this that made Section 3(d) a truly a unique mechanism to address the problem of ever-greening. With the endorsement of the Supreme Court, this interpretation that 'efficacy' with regard to pharmaceuticals is *therapeutic* efficacy, gradually entered the Patent Office manuals and guidelines in India.[59] The Courts and Patent Offices situated in Mumbai, Chennai, Delhi and Kolkatta have since reiterated the significance of 'therapeutic efficacy' and have provided greater insights relating to this notion in a series of decisions. The most significant of these decisions are discussed in this sub-section to understand how Section 3(d) operates in practice to prevent ever-greening. Some of these decisions were made after the High Court's decision in *Novartis*, but before the Supreme Court decision. This difference in timing does not really matter as the High Court's interpretation of Section 3(d) was nearly identical to the subsequent reading by the Supreme Court.

The decision of the Delhi Patent Office relating to Boehringer Ingelheim Pharmaceuticals' patent application for nevirapine hemihydrate[60] was one of the most significant Patent Office decisions on Section 3(d) after *Novartis*. The application concerned a pediatric HIV drug. Nevirapine was the active ingredient of the invention and was already known to be effective in the treatment of HIV. The Network for People Living with HIV/AIDs and the Positive Women Network filed pre-grant oppositions, *inter alia,* claiming that the hemihydrate form of nevirapine did *not* significantly enhance the therapeutic efficacy of nevirapine. They alleged that the only advancement asserted by Boehringer related to improved particle size stability. The Controller cited the objective of Section 3(d) as explained by the Madras High Court in *Novartis* (as the Supreme Court had not dealt with the matter by then). After citing the High Court's definition of 'efficacy' as 'therapeutic efficacy' in relation to pharmaceuticals, the Controller stated that:

> … what the patent applicant is expected to show is, how effective the new discovery made would be *in healing a disease/having a good effect on the body*.[61]

[59] See the Office of Controller General of Patents, Designs and Trademarks, *Manual of Patent Office Practice and Procedure* 2011, pp. 84- 85; The Office of Controller General of Patents, Designs and Trademarks, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals,* 2014, pp. 28-33.
[60] *In the Matter of Patent Application* No. 2485/DEL/1998.
[61] Ibid., p. 13. Emphasis added.

The Controller stated that even though the improved particle size of the hemihydrate form of nevirapine could provide better storability of the drug, this did *not* enhance the therapeutic efficacy of nevirapine in healing or curing HIV. Therefore, the Controller denied the patent on the basis of Section 3(d).

Another significant pre-Supreme Court (*Novartis*) Patent Office decision was that of the Delhi Patent Office relating to Gilead Science's much litigated drug, Tenofovir. The application concerned particular ester forms (carbamate and carbonate) of a prodrug known as *adenine* that is used in the treatment of HIV/AIDS.[62] As the patent was directed to a particular ester form of a substance that was already known in the prior art, Section 3(d) required Gilead to prove 'enhanced efficacy'. Explaining that 'efficacy' according to the High Court in *Novartis* is therapeutic efficacy, the Controller noted that:

> The intention of the legislation encompassed in section 3(d) of the Patent Act is very clear, product patents particularly of pharmaceutical products in India should be granted with utmost care and should be granted only to very genuine cases. Therefore, a clear bar of showing efficacy has been imposed to Patent the products particularly the Pharma products.[63]

Gilead had submitted data demonstrating the efficacy of its invention, but it had not produced data demonstrating the *enhancement* of efficacy vis-à-vis the prior art that included the base prodrug. The Controller stated:

> The Data provided by the applicants is related to the improved properties of the compound of the present invention. *There is no evidence and data in specification to prove the improved clinical efficacy of the claimed pharmaceutical substance as compared to its own base drug moiety PMPA.*[64]

In the absence of such comparative data, the Controller noted that there could not be an examination of an 'enhancement', which is fatal to the demonstration of 'enhanced' efficacy. Therefore, the Controller denied the patent, emphasizing the significance of producing comparative data to demonstrate the 'enhancement' of the clinical efficacy of substances that fall within the scope of Section 3(d).

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[62] *In the Matter of Patent Application* No. 2076/DEL/1997.
[63] Ibid., p. 22.
[64] Ibid. Emphasis added.

A final Patent Office decision that deserves mentioning is that of the Mumbai Patent Office concerning the patent application of the German pharmaceutical firm, Takeda, that claimed an *isotopically substituted pantoprazole derivative*.[65] The invention was meant to serve as a proton pump inhibitor, effective in the reduction of gastric acid and the treatment of other gastrointestinal diseases. This was one of the first Patent Office decisions *after* the Supreme Court judgment in *Novartis*. The active compound of Takeda's invention was *pantoprazole*, which was already a known substance. However, the invention related to a deuterated form of this compound. Takeda had provided comparative data that compared the clinical data of the invention vis-à-vis the prior art substance and claimed that it demonstrated that its deuterated form metabolized to a lower extent indicating higher stability and exposure. It asserted that these higher exposure levels enhanced the efficacy of the *deuterated* pantoprazole compared to the non-deuterated form.

Takeda had also produced data to show the *enhancement* of the efficacy of their invention compared to a structurally close compound known as *omeprazole*, which had similar proton pump inhibiting capabilities. In the process of dealing with this data, the Controller made an important observation with regard to Section 3(d). The Controller noted that the data comparing the invention with the omeprazole compound was *not* relevant as the enhancement of efficacy should be vis-à-vis the *closest known compound*, which in this case was pantoprazole. In the words of the Controller:

> The question of Section 3(d), vis-à-vis the *significantly improved therapeutic efficacy* is to be adjudicated against the closest compound known, in this case, pantoprazole and not omeprazole. Therefore, the question to be answered is, whether the applicant's counter argument and experimental details meet the requirement of *significantly improved therapeutic efficacy against* pantoprazole.[66]

This explains why the Courts dealing with the Novartis dispute insisted on the enhancement of efficacy of the beta crystalline form of imatinib vis-à-vis its mesylate form rather than its freebase form. It was because the mesylate form of imatinib that had been disclosed was the 'closest' to the beta crystalline form of imatinib mesylate. Dealing with the increased metabolic stability and intrinsic clearance values of Takeda's invention, the Controller held that these experimental details only showed how the human body reacted to the drug, whereas what was

[65] *In the Matter of Patent Application* No. 293/MUMNP/2008.
[66] Ibid., para. 20. Emphasis in Original.

necessary was evidence relating to how the *drug worked in the human body*.[67] As such evidence was missing, the Controller denied the patent on the ground of Section 3(d).

These decisions that followed the *Novartis* dispute clarified some fundamental aspects relating to 'therapeutic efficacy'. A decision of the IPAB demonstrating this developed understanding of Section 3(d) is *Fresenius Kabi Oncology Ltd. v. Glaxo Group Ltd (No. 1)*.[68] In this case, Fresenius had obtained a patent relating to *quinazoline ditosylate* salt compounds that served as protein tyrosine kinase inhibitors (PTK), effective in the treatment of a variety of disorders such as psoriasis and cancer that show inappropriate or uncontrolled cell growth. The prior art had consisted of a previous patent which was also owned by Fresenius that related to bicyclic heteroaromatic compounds of quinazoline that also served as a PTK inhibitor. The disadvantage of the prior invention, however, was that it absorbed large amounts of water that affected its stability as a medicament. Fresenius's patent for the *ditosylate* form of quinazoline alleged that it made the quinazoline compound less hygroscopic, more crystalline and more stable. Glaxo subsequently challenged this patent, *inter alia*, on the basis that Fresenius's patent application had not satisfied Section 3(d). The IPAB noted that the alleged enhancements vis-à-vis the prior art compounds related to the moisture absorption property and the increase in stability, which affected the potency of the drug. Citing the decisions of the High Court and the Supreme Court in the *Novartis* dispute, it stated that the improvement of the potency of a drug did not enhance its 'therapeutic efficacy'. It held that:

> The word 'therapeutic' is linked with h*ealing of disease which means healing that disease*. In fact this decision holds that better potency does not mean better therapeutic efficacy.[69]

Therefore, noting that advantages unrelated to the therapeutic effect of a drug are not relevant in the assessment of the 'enhancement of the known efficacy', the IPAB revoked Fresenius's patent on the ditosylate form of quinazoline.

As such, the meaning of *therapeutic* efficacy is almost well settled. Where the patent application relates to a derivative of a substance that is known to have a medicinal effect, the patent applicant should establish the enhancement of the therapeutic efficacy of that derivative vis-à-vis the closest previous version of that substance. This is to be interpreted narrowly, both by the Courts and the Patent Offices, given the legislative intention to prevent ever-greening

[67] Ibid., para. 21.
[68] IPAB Order No. 161 of 2013 in ORA/22/2011/PT/KOL.
[69] Ibid., para. 49. Emphasis added.

and the Supreme Court's guidance that it should be determined 'strictly and narrowly'. Consequently, a patentee should adduce comparative data to establish the enhancement of such efficacy against the closest version of that substance in the prior art. Moreover, such data must not relate to the pharmacokinetics, but to the pharmacodynamics of the drug that demonstrate the healing or curing effect of a drug *in* the body.

❖ *A Patent Eligibility Standard*

An issue that lingered ever since the creation of Section 3(d) was as to where exactly it fits in the process of patent scrutiny. It was noted in relation to the IPAB ruling in *Novartis*, that the IPAB was of the opinion that Section 3(d) was a heightened standard of the *inventive step* requirement for pharmaceutical inventions. This was doubted because the Supreme Court subsequently held that it could *either* be a patent eligibility or a patentability standard. This uncertainty was finally laid to rest in the latter part of 2015 by the High Court of Delhi in *F. Hoffmann La Roche Ltd. & Anr. v. Cipla Ltd.*[70] Roche owned a patent for *erlotinib hydrochloride* in mixed polymorphic forms of A and B. The product that Roche marketed encompassing the patented invention was Terceva, but only utilized the B polymorphic form of erlotinib hydrochloride as it had a better thermodynamic stability. Consequently, Roche had applied for a new patent directed only at the B polymorphic form of erlotinib hydrochloride. This had been denied by the Patent Office on the basis of Section 3(d) as the improved thermodynamic stability did not increase the therapeutic efficacy of erlotinib. Cipla began marketing an anti-cancer drug called Erlocip in 2006 that also only used the B polymorphic form of erlotinib hydrochloride. Based on its previous patent for the mixed polymorphic forms, Roche sued Cipla in 2008 for infringement. The trial judge initially held that Roche had failed to establish infringement, and being aggrieved with the said judgment, Roche appealed to the High Court.

One of Cipla's rather novel defences was that the fact that Roche had *applied* for a new patent for the B polymorphic form and its denial by the Patent Office by itself showed that a product based purely on the B polymorphic form was beyond the scope of the original patent owned by Roche. The Court stated that Section 3(d) is a patent eligibility standard, because a subject matter that does not satisfy this standard does not even require the assessment of novelty, inventive step and industrial applicability.[71] It further stated that Section 3(d) assumes that

[70] 2016 (65) PTC 1 (Del).
[71] Ibid., para. 61.

structurally similar derivatives are functionally similar, and therefore, unpatentable.[72] Where an invention is structurally similar to a previous substance, it demands better functionality to be patentable by virtue of its requirement of 'enhanced efficacy'. Nevertheless, the Court dismissed Cipla's unique defence noting that Section 3(d) is not meant to penalize an innovator twice.[73] In other words, Section 3(d) is not meant to bar the patenting of a new form of an existing invention and also prevent such a patentee from enforcing his or her rights under an original patent. It stated that Section 3(d) is meant to recognize incremental innovation, but that it also acknowledges that:

> … the incremental steps may sometimes be so little that the product is no different from the original.[74]

Stating that in 'no stretch of imagination' could it be understood as constituting a defence for infringement, the Court allowed Roches's appeal.[75]

❖ *Triggering Section 3(d) as an Objection and Ground for Invalidity*

The preceding discussion concerning Section 3(d) demonstrates that the burden of proving the enhancement of the efficacy of a derivative substance is clearly on the patent applicant. The Patent Office has the power to deny patents in the absence of such evidence. Chan Park observes, however, that the Indian Patent Offices still rarely demand such information *on their own* in the absence of third-party oppositions.[76] After reviewing 2060 pharmaceutical product patents granted between 2005 and 2008, Park observes that there are still instances when patents are granted for polymorphic forms of known substances without any evidence of enhanced efficacy.[77] While these oversights are attributable to the institutional capabilities of the Patent Offices in India, a more pragmatic issue concerned what an objector should establish in order to place the burden on the patent applicant to show 'enhanced efficacy' before the Patent Office.

This issue received the attention of the IPAB in *Fresenius Kabi Oncology Ltd. v. Glaxo Group Ltd (No. 2)*.[78] In Fresenius owned a patent in relation to bicyclic heteroaromatic compounds of *quinazoline* that was used in the treatment of cancer. In addition to seeking the revocation of

[72] Ibid., para. 62.
[73] Ibid., para. 72.
[74] Ibid., para. 73.
[75] Ibid.
[76] Park, n. 23, p. 101.
[77] Ibid.
[78] IPAB Order No. 162 of 2013 in ORA/17/2012/PT/KOL.

Fresenius's new patent concerning a derivative of this substance, Glaxo alleged that Fresenius's original patent for *bicyclic heteroaromatic compounds of quinazoline* should be revoked on the basis of Section 3(d). It argued that the bicyclic heteroaromatic compounds of quinazoline were also derived from a prior art compound and that Fresenius had not provided any comparative data to show any enhancement of efficacy.[79] Fresenius, on the other hand, insisted that its invention was a new chemical entity and did not attract the higher standards of Section 3(d).The IPAB stated in its decision that it is the patentee who must ordinarily demonstrate the enhanced efficacy of an invention in terms Section 3(d). However, it noted that in revocation proceedings, it is the applicant seeking revocation who must plead and prove that the invention is *caught* by Section 3(d). It stated:

> … in a revocation the applicant must *plead and prove that it is hit by S.3(d)* and that is has the *same therapeutic efficacy* as the known substance.[80]

When an applicant seeking revocation establishes this, the IPAB noted that the patentee has the ability to:

> … counter it either by proving that it is *not a derivative of a known substance* or by *proving that though it is only a new form of a known substance he has shown that it has enhanced therapeutic efficacy*.[81]

Noting that Glaxo had only provided vague evidence to show that the bicyclic heteroaromatic compounds of quinazoline were derivatives of a prior art substance, the IPAB thought it was insufficient to trigger Section 3(d) and refused to revoke the patent. These observations made by the IPAB have great practical relevance for the triggering of Section 3(d) and although they were set-out in the context of a revocation proceeding, it could be, and in fact has been adopted even in the context of opposition proceedings. Consequently, a mere allegation that an invention is a derivative is insufficient to either deny or revoke a patent on the basis of Section 3(d). The opposition must establish a *prima facie* case that the *invention is a derivative of a known substance* and that *their therapeutic effectiveness remains the same*. It is only then that the burden shifts to the patent applicant or patentee, as the case may be, to either prove that their invention is new, or that although it is a derivative, its therapeutic efficacy has been enhanced. The significance of this is evident in a decision of the Mumbai Patent Office relating to Eli Lilly's patent application relating to a novel chemical compound.[82] The Patent Office examiner

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[79] Ibid., para. 53.
[80] Ibid., para. 56. Emphasis added.
[81] Ibid. Emphasis added.
[82] *In the Matter of Patent Application* No.1901/MUMNP/2009.

had initially raised an objection based on Section 3(d), subsequent to which Eli Lilly had adduced evidence to demonstrate that the prior art compound suggested by the examiner was structurally different to Eli Lilly's invention. Noting that these structural differences were so significant, the Controller eventually held that Eli Lilly's invention was a 'new' compound and did not attract the higher standards of Section 3(d).

- *CONCLUSION*

The foregoing discussion demonstrates that Section 3(d) evidently adds an extra layer in the patent examination of pharmaceutical inventions. It is meant to deal with the issue of 'ever-greening' by scrutinizing the therapeutic efficacy of inventions that concern new forms of already known pharmaceutical substances. However, it is also apparent that it is *not* a complete bar on the patentability of such inventions. As highlighted by T.C. James who has examined the scope of Section 3(d), nearly 86 patents have been granted for inventions that fell within the scope of Section 3(d) between 2005 and 2009.[83] He states that this would not have been possible if Section 3(d) totally denied patents for incremental pharmaceutical inventions:

> …the fact remains that Section 3(d) had not come in the way of patenting incremental inventions which *meet the criteria* of patentability.[84]

Whether the criteria specified by Section 3(d), as interpreted and applied by the Patent Offices and the Courts, would potentially constitute 'discrimination' of a field of technology under TRIPS Article 27.1 will be examined in the next Chapter of this thesis.

B. THE BRAZILIAN REQUIREMENT OF 'PRIOR CONSENT'

- *BRAZIL'S HISTORY WITH PHARMACEUTICAL INVENTIONS*

Brazil started granting patent protection in 1809 after it gained independence from Portuguese rule. It is considered to be the first Latin American country and the fourth in the world to recognize patent monopolies.[85] Brazil even granted patents for pharmaceutical inventions until 1945 when industrial development in the post-World War II period was considered to

[83] T. James, *Patent Protection and Innovation: Section 3(d) of the Patents Act and Indian Pharmaceutical Industry*, Department of Industrial Policy and Performance, 2009, p. 11.
[84] Ibid. Emphasis added.
[85] J. Sundaram, 'Brazil's Implementation of "TRIPS Flexibilities": Ambitious Missions, Early Implementation and Plans for Reform', *Info. & Comm. Tech. L.*, vol. 23, no. 2, 2014, p. 81 at p. 94.

necessitate the restriction of intellectual property rights in technology-intensive industries.[86] Hence, the then Industrial Property Law was amended to deny patent protection for medicines and chemical products in 1945 with the objective of encouraging the national production of pharmaceuticals.[87] This policy was even reflected in Article 9 'C' of the *Industrial Property Law No. 5772/1971*, which was the immediate predecessor of the current *Industrial Property Law No. 9.279/1996*.[88] However, unlike India, the exclusion of pharmaceutical and chemical inventions from the patent system did not produce the intended result of creating a developed domestic pharmaceutical industry. In fact, Brazil had to import generic antiretroviral medicines to tackle the AIDS crisis that it faced in the latter part of the twentieth century.[89]

Although the domestic pharmaceutical industry did not develop, the right to health achieved great prominence in Brazil in the period between 1971 and 1996. The new Brazilian Constitution that was introduced in 1988 and is still in force today, recognized the right to health as a fundamental right of every Brazilian citizen. Article 196 of the Constitution provides that:

> Health is a right of all and the responsibility of the State, to be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards, and all the universal and equal access to actions and services for its promotion, protection and recovery.

As Jae Sundaram opines, the placement of the right to health in the Constitution in this manner showed that it was not meant to highlight a State aspiration, but that it should be of instant application for the benefit of the Brazilian citizens.[90] This constitutional provision soon began to play a vital role in enhancing the access to medicines debate, particularly in the context of HIV/AIDS given that Brazil was having the highest absolute number of HIV cases in all Latin American countries at that time.[91] In addition to several programmes initiated by the Brazilian Health Ministry to provide non-patented antiretroviral medication, Brazil established its Public Healthcare System in 1990 known as *Sistema Único de Saúde* (SUS). Its objective was to deliver universal healthcare to all Brazilian citizens.[92] Article 6(I) of *Health Act No. 8080/90*,

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[86] B. Salama and D. Benoliel, 'Pharmaceutical Patent Bargains: The Brazilian Experience', *Cardozo J. Int'l & Comp. L.*, vol. 18, no. 1, 2010, p. 633 at p. 640.
[87] Ibid; Also see M. Azam, 'The Experiences of TRIPS-Compliant Patent Law Reforms in Brazil, India and South Africa and Lessons for Bangladesh', *Akron Intell. Prop. J.*, vol. 7, 2015, p. 61 at p. 67.
[88] E. Camara Jr., 'Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA', *IP Litigator*, March/April 2013, p. 13.
[89] See K. Shadlen, 'The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies', *Comparative Politics*, vol. 42, no. 1, 2009, p. 41.
[90] Sundaram, n. 85, p. 91.
[91] A. Nunn, *The Politics and History of AIDS Treatment in Brazil*, Springer, 2009, p. 21.
[92] The SUS was created by two Health Acts Nos. 8080/90 and 8.142/90.

which was one of the legislative enactments that created the SUS, converted the constitutional provision relating to the right to health into an enforceable constitutional right by providing that the SUS 'must' be responsible for promoting full medical assistance including pharmaceutical assistance. Sundaram explains the distinctiveness of the Brazilian SUS scheme in the following manner:

> … the SUS is a publicly funded rights-based universal health system, which does not restrict access to medical care and medicines to its citizens, but one that empowers them to seek access to health care and medicines.[93]

The creation of the SUS transformed the Brazilian health-care system to guarantee the constitutionally recognized right to health. Together with the absence of patent protection for pharmaceutical inventions, the Brazilian legal environment was considered to be one of the most sensitive to public health. However, this environment was not to last long as this was also the time when technology-intensive countries who demanded higher standards of patent protection began to triumph in the GATT/WTO trade negotiations that culminated with the TRIPS Agreement. In fact, Brazil began amending its patent laws several years before TRIPS negotiations actually concluded. The current Brazilian Industrial Property Law that implemented TRIPS's standards was tabled to the Brazilian Congress in 1991, whereas TRIPS was concluded only in 1994. The similarities between the Brazilian Draft Act presented in 1991 and the TRIPS Agreement was a clear sign of the forces behind the Brazilian Law. Hence, by the time Brazil signed TRIPS in 1994, it had already debated its TRIPS compliant Industrial Property Law, and with TRIPS being institutionalized by the legislature in that year, Brazil's new *Industrial Property Law No. 9.279/1996* was passed in May 1996 and came into full force in May 1997. Consequently, Article 8 of Law No. 9.279/1996 (here onwards referred to as the 'Brazilian IP Act') recognized the patentability of *any* invention that is novel, inventive and capable of industrial application, thereby lifting the bar on pharmaceutical and chemical inventions that had existed since 1945.

- *THE 'PRIOR CONSENT' REQUIREMENT AND ITS OBJECTIVES*

In the haste to introduce its new intellectual property legislation and comply with TRIPS standards, Brazil oversaw the flexibilities enshrined in the TRIPS Agreement. It did not avail itself of any of the transitional arrangements and was prepared to grant patents for

[93] Sundaram, n. 85, p. 92.

pharmaceuticals within a year or two of the conclusion of TRIPS negotiations. Consequently, with the new Brazilian IP Act coming into full force in May 1997 that removed the bar on pharmaceutical and chemical inventions, the number of patent applications filed in Brazil increased from 8,057 in 1996 to 16,235 in 1997, reaching 21,825 in the year 2007.[94] 75% to 80% of these applications were made by foreigners.[95] Official data published by the Brazilian Patents and Trademark Office (INPI) also show that there were only 200 patent applications relating to chemical compounds in 1996, but that this number almost doubled each year after the new legislation came into effect, only to the exclusion of 1998.[96] These applications were dominated by applicants from the developed parts of the world. Maria Oliveira, Gabriela Chavez and Ruth Epsztein note that from 1996 to 2002, the domestic pharmaceutical industry was responsible for a mere 3.1% of the total chemical based pharmaceutical patent applications in Brazil.[97] This was similarly the case with patent applications relating to biotechnological inventions.[98]

A pressing concern after the new Brazilian IP Act was the rise in the prices of medicine that placed a significant weight on Brazil's Public Healthcare System (SUS). This was aggravated by the fact that Brazil had decided to examine patent applications that they referred to as 'pipe-line' applications. As opposed to the 'mail box' system which countries benefiting from the transitional arrangements had to implement, the 'pipe-line' system was meant to examine applications that were *already pending* in the patent offices in other countries at the time the new Brazilian IP Act came in to effect.[99] However, the pipe-line system only applied when the product encompassing the invention had *not* been placed in any market. Additionally, the system only applied for one year between May 1996 and May 1997. Notwithstanding these restrictions, almost 63% of these 'pipe-line' applications related to medicine.[100] Inclusive of 'pipe-line' applications, there were an estimated 3000- 4000 medicine related patent applications pending before the Brazilian Patents Office by 1999.[101] The impact that the patent system was already having on the Public Healthcare System (SUS), the further impact that it would have if all those pharmaceutical patents were granted and the consequential impact that

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[94] Centre for Strategic Studies and Debates, *Brazil's Patent Reform: Innovation Towards National Competitiveness*, 2013, p. 42, [hereinafter referred to as 'Brazil's Patent Reform'].
[95] Ibid.
[96] See M. Oliveira, G. Chavez and R. Epsztejn, 'Brazilian Intellectual Property Legislation' in J. Bermudez and M. Oliveira (eds.), *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health*, WHO/PAHO Collaborating Center for Pharmaceutical Policies, 2004, p. 153.
[97] Ibid., p. 167.
[98] Ibid., p. 168.
[99] *Brazil's Patent Reform*, n. 94, pp. 101-103.
[100] Ibid.
[101] *Statement by Minister José Serra to CPI on Prices of Medicines in Brazil*, Basilia, 2 December 1999, Revised Transcript, p. 17, http://www.farmacia.ufrj.br/consumo/leituras/lm_serra_cpi.pdf, (accessed 2 February 2018).

this would in turn have on the Constitutional right to health of the Brazilian citizens sent chills down the spine of the Brazilian Government.

Therefore, Brazil's National Congress set up a Parliamentary Inquest Committee (CPI) in 1999 to examine the reasons behind the exorbitant rise in the prices of drugs and as to what measures could be taken to prevent any further impact on its Public Healthcare System (SUS).[102] The then Brazilian Health Minister, José Serra, submitted to Congress at this inquiry that the new patent system had contributed to this problem.[103] Noting that this had been the impact of having a mere twenty patented medicines at that time, José Serra highlighted that more patents will cause even more chaos and that therefore, the grant of pharmaceutical patents should be strictly scrutinized.[104] To address this risk that José Serra had pointed out, the Ministry of Health together with the Ministry of External Relations, Industry and Management proposed a mechanism to involve Brazil's national sanitary agency, Agência Nacional de Vigilância Sanitária (hereinafter referred to as 'ANVISA') in the process of granting patents for pharmaceuticals.

The rationale was that the Brazilian Patents and Trade Mark Office (hereinafter referred to as 'INPI') did not have sufficient technical expertise to examine pharmaceutical patent applications as such inventions had been excluded from the patent system since 1945, and that this would lead to the grant of *undue* patents in this field. ANVISA, on the other hand, being the drug regulatory authority, was considered to be in a better position to do this or at least to assist the INPI in this process, as its expertise in the field of pharmaceuticals would serve to ensure the adherence to better technical standards in the patentability assessment of pharmaceutical inventions.[105] This is evident in the Inter-Ministerial explanatory statement that made this recommendation:

> As for … the granting of patents – of both process and product – by the Brazilian Patent Office *will only be granted with the prior consent of the National Sanitary Agency* (ANVISA). This joint work by the Brazilian Patent Office and ANVISA will *ensure better technical standards in the decision process for pharmaceutical patents*, similar to procedures employed by the

[102] See M. Tamagno and E. Rodrigues Jr., *Intellectual Property Law in Brazil*, Kluwer Law International, 2010, p. 78.
[103] See Statement by José Serra, n. 101.
[104] Ibid.
[105] See V. Kunisawa, 'Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil', *The Journal of World Intellectual Property*, vol. 12, no. 4, 2009, p. 297 at p. 300.

> most advanced systems of patent control and sanitary surveillance in force in more developed countries.[106]

Satisfied with this proposal, President Cardoso issued an Executive Decree in 1999 known as *Provisional Measure No. 2006/1999* introducing the requirement of 'prior consent' for pharmaceutical inventions. It was formally legislatively introduced into the Brazilian IP Act in 2001 as Article 229-C by *Law No. 10.196/2001*. Accordingly, Article 229-C of the Brazilian IP Act currently provides as follows:

> The granting of patents for pharmaceutical products and processes shall depend on the prior consent of the National Sanitary Agency – ANVISA.

This mechanism that was introduced by Brazil was hailed by many commentators and human rights organizations for defending the constitutional right to health of the Brazilian citizens.[107] Simultaneously, however, it created an opposition which alleged that this mechanism is unconstitutional and inconsistent with Brazil's obligations under the TRIPS Agreement.[108]

- *ITS IMPLEMENTATION*

Article 229-C merely stated that the grant of pharmaceutical patents 'shall depend' on the 'prior consent' of ANVISA. It was completely silent as to what aspects of a patent application ANVISA should examine in giving its consent. This became one of the most pressing issues relating to this mechanism as *Law No. 9782/99* that established the ANVISA identified its institutional purpose as to:

> … promote public health protection by carrying out a sanitary control of the products submitted for sanitary surveillance'.[109]

Hence, it was an agency responsible for sanitary control that was not foreseen to be involved in the patent system. Although the Ministries that recommended this 'prior consent' mechanism suggested that similar measures were used in the developed countries to prevent undue patents in the field of pharmaceuticals, none of these countries had used a health regulatory authority in this manner. This made Brazil the only country in the world to have allowed a regulatory

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[106] Inter-Ministerial Explanatory Statement No. 92/99 for Provisional Act No. 2006/99, para. 8. Emphasis added.
[107] See M. Basso, *Preliminary Background Paper on Prior Consent for Pharmaceutical Products by ANVISA in Brazil*, Institute of International Trade Law and Development, 2005, http://www.wissensgesellschaft.org/themen/publicdomain/priorconsent.pdf, (accessed 28 January 2018).
[108] See K. Shadlen, 'The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil', *Politics & Society*, vol. 39, no. 2, 2011, p. 143.
[109] Article 6, Law No. 9782/99.

authority to participate in the patenting process. Without any precedent from any other part of the world, even the Brazilian lawmakers did not know if ANVISA should examine the patentability criteria or limit itself to examining the public health and safety dimensions of an invention or do both. Hence, Maristela Basso has opined that:

> The Brazilian law, due to its laconic wording, let room for unending discussions regarding the mechanism's range of application, its functioning, goals and legality…[110]

Notwithstanding this uncertainty, ANVISA started examining the patentability criteria of applications that were forwarded for its 'prior consent'. Maurice Cassier notes that ANVISA recruited sixteen professionals in 2001 who were chemists, biologists and pharmacists who had received IP training and began denying consent when it had determined on its own that a pharmaceutical invention had not met the patentability criteria.[111] This troubled the INPI as it only forwarded applications that it had determined to be patentable. It saw no reason why its findings should be doubted by any external authority. Thus, INPI perceived ANVISA's duplicative patentability assessment to be unlawful as it was acting *ultra vires* its institutional purpose of *sanitary surveillance*. Therefore, when ANVISA denied its consent on the basis of its own patentability assessment, the INPI that was ideally required to reject those applications, started to 'shelve' them without a rejection or approval. Nevertheless, ANVISA continued to examine patentability as it was of the opinion that it should protect public health *broadly* even by preventing the grant of unworthy pharmaceutical patents.

ANVISA's jurisdiction became a serious cause for concern to the pharmaceutical industry who publicized its objection through the Brazilian Intellectual Property Association (APBI) in September 2001. The APBI resolved that ANVISA's participation should be *limited* to scrutinizing public health concerns without examining the patentability criteria and that the failure to do so would violate the Brazilian Constitution and the TRIPS Agreement.[112] To aggravate matters further, ANVISA adopted a technical note to deny the grant of 'prior consent' for pharmaceutical inventions that concerned new therapeutic uses of known substances and new polymorphic forms of existing substances. It considered such patents to be harmful to public health, to Brazil's scientific and technological development and hinder access to related

[110] Basso, n. 107, p. 1.
[111] See M. Cassier, 'Pharmaceutical Patent Law In-the-Making: Opposition and Legal Action by States, Citizens, and Generics Laboratories in Brazil and India', in J. Gaudillière and V. Hess (eds.), *Ways of Regulating Drugs in the 19th and 20th Centuries*, Palgrave Macmillan, 2013, p. 287 at p. 291.
[112] See Resolution No. 16 of 2008, Brazilian Intellectual Property Association (APBI).

drugs.[113] This contradicted the INPI's policy to grant patents for such inventions that meet the usual patentability criteria set-out in Article 8 of the Brazilian IP Act. Kenneth Shadlen notes that this further agitated the pharmaceutical industry, as although it is considered to be the 'bastion' of innovation, it is heavily dependent on *incremental* innovation.[114]

The relationship between the ANVISA and INPI further deteriorated with ANVISA adopting an internal Resolution in 2008 known as *RDC No. 45/2008* that sought to legitimize its own mandate. It set-out ANVISA's internal 'work flow' and Article 4 explicitly provided that it would examine the patentability of applications that are forwarded to it by the INPI. With this official text clearly showing ANVISA's unwillingness to stop examining the patentability criteria, the number of applications being 'shelved' at the INPI gradually increased. This led to an administrative proceeding being initiated by the INPI at the Attorney General's Office. In its Opinion in 2009, the Attorney General's Office noted that ANVISA should scrutinize patent applications only in accordance with its *institutional* purpose of *sanitary and public health protection* and that it is *not* its responsibility to examine patent criteria.[115] As this was a blow to ANVISA's mandate, it filed a request of reconsideration, which resulted in a similar Opinion being made in 2010.[116]

These calls to ensure that ANVISA adhered to its 'institutional purpose' in the context of Article 229-C, however, were counter-productive as there was a problem in applying the 'institutional purpose' reasoning here. ANVISA's institutional role was to examine the sanitary requirements of products that are about to be placed on the market. In the case of medicine, these products often encompassed patented inventions. When these products are submitted to ANVISA, there is usually an array of evidence and data suggesting the safety and efficacy of the *product*. Conversely, a patent application *precedes* an actual pharmaceutical product. A patent application does not usually contain sufficient information to demonstrate the safety and efficacy of a future product that will encompass the invention. In the context of medicine, there would never be clinical trials at the time of applying for a patent. Eventually, requiring ANVISA to examine the health and safety of pharmaceutical patent applications resulted in many applications being denied consent as they did not contain sufficient evidence to demonstrate health and safety of any pharmaceutical product.[117]

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[113] See Basso, n. 105, p. 3; Kunisawa, n. 103, p. 304; ANVISA, *Technical Note, Clarifications Patent Applications for Pharmaceutical Products and Processes*, 2004.
[114] Shadlen, n. 108, p. 149.
[115] Opinion No. 210/PGF/AE/2009, Attorney General's Office.
[116] Opinion No. 33/PGF/EA/2010, Attorney General's Office.
[117] *Brazil's Patent Reform*, n. 94, p. 138.

With tensions mounting once again, an Inter-Ministerial Working Group was appointed by the Government in 2011 to find a lasting solution. It included the Ministry of Health, Ministry of Development, Industry and Foreign Trade, the ANVISA, Attorney General's Office and the INPI. This culminated in the *Inter-Ministerial Ordinance No. 1065 of 2012* and a Final Report. They resolved that the INPI would forward a patent application to ANVISA after a formal 'initial' patentability assessment and that INPI would conduct a full substantive assessment only after it receives 'prior consent' from ANVISA. They also agreed that ANVISA would examine a patent application only in light of 'public health'. These decisions were adopted by ANVISA by its *Resolution RDC 21/2013*. This Resolution amended the former *RDC 45/2008* and the new Article 4 explicitly stated that ANVISA shall scrutinize applications 'in the light of public health'. It also stated that a patent application would be considered to be *contrary* to public health where: (a) the pharmaceutical product or process *presents a health risk*,[118] or (b) the application concerns a product or process *that is of interest to an access to medicines policy or to a pharmaceutical care programme under the Public Healthcare System (SUS) and did not meet the patentability criteria*.[119] Article 4(3) stated that a pharmaceutical product or process would be of interest to drug policy or pharmaceutical services under the SUS either, when it falls within a list resulting from an Ordinance of the Ministry of Health relating to the products relevant for the SUS or, relates to a treatment listed in that Ordinance. Consequently, the *patentability criteria* could be examined by ANVISA only when the pharmaceutical product or process was of interest to the Public Healthcare System according to the Ordinances maintained by the Ministry of Health.

This was an important limitation on the power of ANVISA. Nevertheless, the Ordinances of the Ministry of Health referred to in *RDC 21/2013* listed a broad range of medications that fell within ANVISA's official power to examine patentability. As Mueller and Costa note, *Ordinance No. 1248/2010* of the Ministry of Health contained long lists of therapeutic categories including antiretroviral medication, medicines for neglected diseases and for several other diseases prevalent in Brazil.[120] Coupled with the fact that INPI was still bound by ANVISA's 'prior consent' relating to these medications, the reforms in 2013 did not change the mechanism as much as the pharmaceutical industry had originally desired. The Washington-based Pharmaceutical Research and Manufacturers of America (PhrMA) incessantly complained about Brazil's 'fourth criterion' when obtaining patents for pharmaceutical

[118] Article 4(1)(i), RDC 21/2013.
[119] Article 4(1)(ii), RDC 21/2013.
[120] L. Mueller and S. Costa, 'Should ANVISA Be Permitted to Reject Pharmaceutical Patent Applications in Brazil?', *Expert Opinion on Therapeutic Patents*, vol. 24, no. 1, 2014, p. 1 at p. 2.

inventions.[121] They submitted to the US Trade Representative in 2016 that Article 229-C of the Brazilian Act has been:

> …interpreted to inappropriately permit the health regulatory agency, the Brazilian National Health Surveillance Agency (ANVISA) to review all patent applications for pharmaceuticals products and/or processes, resulting in both: i) application of patentability requirements *contradictory* and/or *additive* to those established by Brazilian Patent Law and adopted by the Brazilian Patent Authority (INPI); and ii) *duplicative*, *prolonged patent review processes* that contribute to the already existing patent backlog that averages more than 10 years.[122]

This summed up the allegations that were being made by the pharmaceutical industry even against this streamlined mechanism of Article 229-C, which resulted in Brazil continuing to be on the 'priority watch list' of United States Trade Representative's annual Section 301 Reports. With the Brazilian pharmaceutical market being forecasted to value USD 19.2 billion by 2021,[123] reducing ANVISA's power in the patenting process was of utmost importance to the industry. This endeavor was complemented by numerous decisions of the Federal Courts of Brazil. When ANVISA prolonged their assessment or denied consent based on the patentability assessment, patent applicants resorted to filing action in the Federal District Courts to obtain writs of mandamus to expedite and/or overturn these decisions. Mueller and Costa note that of a near eighteen cases filed against ANVISA, a majority have been decided in favour of the patent applicants.[124] The reason for this was the Courts' disapproval of ANVISA duplicating and contradicting the patentability assessment conducted by the INPI. For example, in *Novartis AG v. ANVISA*, ANVISA had been delaying its 'prior consent' assessment and Novartis filed for a writ of mandamus against ANVISA, *inter alia*, praying for a preliminary injunction compelling ANVISA to grant prior approval within a prescribed time-frame.[125] The Court granted the preliminary injunction compelling ANVISA to complete its analysis within 15 days *and* held that ANVISA should *not* examine patentability requirements.[126]

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[121] Shadlen, n. 119, p. 146. Also see Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission 2016, p. 91, http://phrma-docs.phrma.org/sites/default/files/pdf/PhRMA_2016_Special_301_Submission.pdf, (accessed 27 January 2018).
[122] Ibid., Emphasis added.
[123] Brazil Pharmaceuticals & Healthcare Report - Q1 2017, *Business Monitor International*, London, 2017.
[124] Mueller and Costa, n. 120, p. 3.
[125] *Novartis AG v. ANVISA*, Docket No. 1009743-75.2016.4.01.3400 of 22nd Federal District Court.
[126] Also see *Genentech Inc. v. ANVISA*, Docket No. 1004397-46.2016.4.01.3400 of 5th Federal District Court.

With the Federal Courts' increasing intervention to limit its authority and mounting pressure from the developed countries, it became apparent that ANVISA could not continue its assessment of the patentability criteria even in respect of inventions that were of interest to Brazil's National Healthcare System. In a significant move aimed at solving this power struggle, the ANVISA and INPI signed *Inter-Agency Ordinance No. 1/2017* on April 2017. Article 5 of this Ordinance curtailed the *relevance* of ANVISA's patentability assessment of pharmaceutical inventions that are of interest to the Public Healthcare System to the level of 'technical opinions'. These technical opinions are to be considered only as *third-party* observations during INPI's substantive patentability assessments. Article 6 further provides that if INPI disagrees with ANVISA's technical opinion, it should identify technical grounds for such disagreement. Hence, INPI is entitled to state technical grounds and continue to grant a patent notwithstanding ANVISA's opinion that might suggest otherwise. This Ordinance was recognized by ANVISA by internal rule *RDC 168/2017* of August 2017, and it is apparent that it has severely curtailed ANVISA's power under the Article 229-C mechanism that was created to ensure the better scrutiny of pharmaceutical patent applications.

- *CONCLUSION*

There has not been any empirical data that has been published or examining the exercise of ANVISA's power under Article 229-C of the Brazilian IP Act, except for a qualitative analysis conducted by ANVISA itself in November 2009.[127] This Report stated that it had analyzed 1346 pharmaceutical patent applications between 2001 and October 2009, and that ANVISA had denied prior consent for 119 of those applications. 47.9% of those denials were due to the lack of novelty, whereas 22.7% were due to the lack of inventive step. Interestingly, none of the denials were due to public health/sanitary reasons. While these statistics show that ANVISA had applied more stringent patentability criteria, they do *not* show how Article 229-C operated under the work-flows implemented in 2013 and 2017. It will be recalled that ANVISA was only entitled to examine the patentability of applications that were of interest to the Public Healthcare System since 2013, and the legal effect even of those assessments was limited to mere 'technical opinions' in 2017. Hence, the practical impact that the 'prior consent' mechanism currently has on the patenting of pharmaceutical inventions cannot be derived from the 2009 data.

[127] See *Technical Opinion of ANVISA Concerning Bill No. 3.709/2008*, Intellectual Property Coordination, 25 November 2009.

While these developments have clearly reduced the power of ANVISA in the patent granting process, it must be noted that Article 229-C of the Brazilian IP Act has remained unchanged. It still merely states that the 'prior consent' of ANVISA is necessary for the grant of patents for pharmaceutical products and processes. While the scope and application of this mechanism has changed over time, there is still an explicit hurdle to obtain patents for pharmaceutical inventions. The next Chapter will examine whether Article 229-C triggers a violation of the non-discrimination obligation in TRIPS Article 27.1, and if so, whether the recent developments relating to its operation could weigh in favour or against Brazil in defending an inconsistency with this obligation.

C. THE AUSTRALIAN PATENT TERM EXTENSION SCHEME

- *AUSTRALIA'S HISTORY WITH PATENT TERM EXTENSIONS*

Patent term extensions have been a part of the Australian patent system for a long period of time. Such extensions were first provided by the *Patents Act of 1903(Cth)*. This Act set-out a scheme for the extension of the term of a patent that was available to patents in all fields of technology. The Act granted an original fourteen-year monopoly and Section 84(1) permitted the extension for a further term of seven years, and fourteen years in exceptional cases.[128] These durations were later modified by the *Patents Act of 1921(Cth)* that conferred a sixteen-year monopoly with extensions for a period of five years, and up to ten years in exceptional cases.[129] However, it was the Courts that had the power to grant extensions under these Acts, which made it significantly different to the current system in Australia. Patentees seeking extensions had to petition the Court at least six months before their patent lapsed,[130] and the Court could grant an extension if it was satisfied that the patentee had been 'inadequately remunerated by his patent'[131] that had to be determined by taking into account the following factors:

> … the nature and merits of the invention in relation to the public and to the profits made by the patentee as such and to all the circumstances of the case.[132]

[128] Patents Act 1903(Cth), Section 84(5).
[129] See Patents Act 1921(Cth), Sections 3(1) and 84(5).
[130] See Patents Act 1903(Cth), Section 84(1).
[131] See Patents Act 1903(Cth) Section 84(5).
[132] See Patents Act 1903(Cth), Section 84(4).

As Charles Lawson notes, the basis for extensions under those Acts was the concept of 'inadequate remuneration'.[133] This was a near identical basis adopted by the British Courts at that time to grant patent term extensions before their scheme was withdrawn by the *Patents Act 1977*.[134] Lawson states that the Australian Courts formulated a guiding principle in determining whether there had been such 'inadequate remuneration': it was the existence of a *disproportionate* difference between the benefit given to the public and the remuneration that the patentee had received.[135] However, this determination was always subject to public interest. This meant that the Courts often placed restrictions on the enforcement of those 'extended' patents against public uses and even specified price limits and licensing terms to ensure that the public was not unduly burdened by such extensions. After scrutinizing each of the non-exhaustive elements that the Courts were statutorily required to examine, Lawson notes that the Courts began to look at the quality of the inventiveness of the invention, its utility, the profit that was made by the patentee and any other circumstances that affected the patentee from obtaining the benefit that he deserved.[136]

The *Patents Act of 1921(Cth)* was replaced by the *Patents Act 1952(Cth)* that contained near identical provisions on term extensions for patents in all fields of technology.[137] As before, the Court had the power to grant extensions based on 'inadequate remuneration'. While there were some basic guidelines deducible from the case-law as to how this had to be assessed, a developing problem at that time was that the Court process to obtain an extension was time consuming, subjective and uncertain. This was aggravated by the fact that parties were entitled to oppose extensions, and this resulted in lengthy Court battles.[138] Another problem was that the concept of 'inadequate remuneration' was so broad that it even covered losses suffered during times of war. With the scope of the extension scheme being so ambiguous and time consuming, the Australian Government commissioned the first whole-scale review of the country's patent system in 1979 that was conducted by the Industrial Property Advisory Committee (IPAC).

The IPAC submitted its Final Report in August 1984.[139] It is evident from the Report that the pharmaceutical industry had called for the *increased* availability of extensions citing the

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[133] C. Lawson, 'How Are Pharmaceutical Patent Term Extensions Justified? Australia's Evolving Scheme', *Journal of Law and Medicine*, vol. 21, 2013, p. 379 at p. 380.
[134] J. Baxter, *World Patent Law and Practice Vol. 2*, Sweet & Maxwell, 2005, p. 6.
[135] Lawson, n. 133, p. 384, citing *Re Robinson's Patent* (1918) 2 CLR 116.
[136] Ibid.
[137] Patents Act 1952(Cth), Sections 90-96.
[138] Lawson, n. 133, p. 385.
[139] Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, AGPS, 29 August 1984, p. 36.

marketing delays they faced due to regulatory processes.[140] As the existing extension scheme was based on the concept of 'inadequate remuneration' that often involved lengthy and uncertain Court processes, the industry had wanted more certainty in this respect. To its surprise, the IPAC recommended that the extension scheme should be abandoned in *toto*.[141] Its reasoning was straightforward. There was simply no evidence to show that the extension scheme was operating beneficially, either to the patent system or to Australia as a whole. As term extensions are only granted at the end of a patent term, it noted that it is hardly conceivable that they could influence innovation-oriented investment decisions made at the very beginning of the innovation cycle *and* that it only increases social costs.[142] Refusing to accept the industry's call for extensions due to the delays it faced by the regulatory process, the IPAC noted that pharmaceuticals were *not* the only type of inventions that faced marketing delays in this manner. It further noted that there were other reasons beyond the control of the Government that caused delays in marketing a product.[143] Hence, it found that granting extensions purely on the basis of regulatory delays was simply illogical. The only logical option in the opinion of the IPAC was, therefore, to abandon the extension scheme completely.

IPAC's recommendation to remove the only scheme that even marginally seemed to compensate the pharmaceutical industry for its regulatory delays was disheartening to the industry to say the least. Therefore, subsequent to this Report, the pharmaceutical industry actively lobbied against the full implementation of its recommendations. The Australian Government deliberated on the IPAC report for nearly four years before taking any action. This was also the period during which the Government decided to adopt a programme known as the 'Pharmaceutical Industry Development Programme'.[144] Its aim was to encourage the growth of the pharmaceutical industry in Australia at a time when the Australian patent environment was considered to be 'hostile' to the international pharmaceutical industry.[145] Perhaps, the lengthy Court-based extension scheme was an example of the 'inadequate' protection of pharmaceutical investments. The Government feared that pharmaceutical corporations would move away from Australia and that this would hamper the country's economic progress. These fears were not wholly unfounded, as corporations like Eli Lilly, Ciba-Geigy and Upjohn ceased the local manufacture of their products and Roche even closed its research and development facilities in

[140] Ibid., p. 37.
[141] Ibid., p. 36.
[142] Ibid., p. 39.
[143] Ibid.
[144] See Industry Commission, *The Pharmaceutical Industry*, Report No. 51, Melbourne, 1996.
[145] Ibid., p. 95.

Australia in the early 1980's.[146] With the Government policy adopted in 1987 to make Australia more attractive to the industry, it was almost clear that it was not going to ignore the industry's calls for a better formulated patent term extension scheme.

It was during such a state of affairs that the Government introduced the *Patents Amendment Act of 1989(Cth)* that amended the *Patents Act of 1952(Cth)*. In line with the IPAC's recommendations, it abolished the extension scheme that had applied to *all* patents, but simultaneously introduced a new and more stream-lined extension scheme that only applied to 'pharmaceutical substances for human use'. The Government stated that the objective of this new scheme was to:

> … recognize the time necessarily taken to obtain marketing approval for new pharmaceuticals, but the present uncertain and costly court actions are replaced with more straightforward administrative procedures.[147]

The administrative procedure introduced by the 1989 amendment shifted the power of granting extensions from the Court to the Patents Commissioner. The Commissioner was entitled to grant a one-off four-year extension for claims covering pharmaceutical substances. Patentees were required to make an application for such extensions no later than twenty-one months before their patents lapsed along with an 'extension eligibility certificate' from the health authority and indicating the specific claims that had to be extended.[148]

The 1989 amendments made it clear that the patent extension scheme was an added privilege that was only available to the pharmaceutical industry while all other inventions were only entitled to the standard term of sixteen years. While the regulatory delays coupled with the relatively greater innovation costs in this field were highlighted to be the reason for such a preferential treatment, the Government had not given any regard to the IPAC's observation that there were *other* fields of technology that faced similar obstacles. Be that as it may, this scheme made its way in identical form to the current *Patents Act 1990(Cth)*. However, with the culmination of TRIPS in 1994, the Australian legislature passed the *Patents (World Trade Organization Amendments) Act of 1994* to bring its patent law into conformity with TRIPS's minimum standards. One of the most significant changes brought about by the 1994 amendments was the expansion of the term of *all* patents from the then prevailing sixteen years

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[146] Ibid.
[147] See Ministry for Industry, Technology and Commerce, *Explanatory Memorandum for Patents Amendment Bill 1988*, para. 1, [hereinafter referred to as '1988 Explanatory Memorandum'].
[148] Patents Act 1952 (as amended in 1989), Section 90.

to the TRIPS mandated term of twenty years. With the term of all patents being enhanced in this manner, the Government thought that there was no immediate need to provide further term extensions for pharmaceuticals. Therefore, the 1994 amendments also *repealed* the extension scheme in *Patents Act 1990(Cth)* that had been applied to pharmaceutical patents since 1989.[149]

This was not the end of patent term extensions in Australia, as abiding by its policy to attract investments from foreign corporations and develop its economy, the Government once again expressed its commitment to ensure that pharmaceutical patents receive an *effective* patent life of fifteen years as pharmaceutical inventions still faced significant regulatory delays.[150] Hence, the Government initiated fresh consultations with interest groups to create a new scheme which resulted in the current scheme that now prevails in Australia.

- *THE CURRENT EXTENSIONS SCHEME OF 1998*

The Australian Government examined a number of proposals for a new extension scheme between 1994 and 1997. Unlike with previous schemes, however, it conducted detailed studies as to how the proposed schemes could affect Australia's healthcare system. It paid particular attention to the potential impact on the Pharmaceutical Benefits Scheme (PBS) that contained a list of drugs that were subsidized for the benefit of its citizens. It concluded its consultations in 1997 and passed the *Intellectual Property Laws Amendment Act of 1998* that introduced the current scheme into the *Patents Act of 1990(Cth)*. The objective of the new scheme is clear in the Explanatory Memorandum that accompanied the *Amendment Bill of 1997*:[151] It states in relevant part as follows:

> Extensions of up to five years on the standard 20 year term are available for pharmaceutical patents in the United States, the European Union and Japan in recognition of the *exceptionally long development time and regulatory requirements involved in developing and commercialising a new drug*. The aim is to provide an 'effective patent life', or period after marketing approval is obtained during which companies are earning a return on their investment, *more in line with that available to inventions in other fields of technology*.[152]

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[149] See D. Bucknell, *Australian Patent Law*, LexisNexis Butterworths, 2004, p. 102.
[150] See Commonwealth, House of Representatives, *Parliamentary Debates of 18 October 1994*, p. 2189 (Gordon Bilney, Minister for Development Cooperation and Pacific Island Affairs).
[151] See Ministry for Industry, Science and Tourism, *Explanatory Memorandum for Intellectual Property Laws Amendment Bill 1997*, [hereinafter referred to as '1997 Explanatory Memorandum'].
[152] Ibid., p. 3. Emphasis added.

The 'exceptionally long development time and regulatory requirements' faced by the pharmaceutical industry was perceived as preventing its innovators from benefiting from the patent system in a manner that was 'more in line' with inventions in other fields of technology. Therefore, the extension of their patent terms was meant to 'level' the playing field and ensure that sufficient incentives are maintained for the technological development in the field of pharmaceuticals. The Memorandum also proceeds to state that the effect of granting such term extensions would be Australia being more attractive to investments from international pharmaceutical corporations that would in turn develop its economy.[153] These constitute the objectives of the current scheme that is found in Sections 70 to 79 of the *Patents Act 1990(Cth)*.

❖ *The Basic Formula*

In terms of Section 70(2), a patent is eligible for extension if it discloses and claims a pharmaceutical substance *per se, or* discloses and claims a pharmaceutical substance that is *produced by means of recombinant DNA technology*. Section 70(3) provides that the goods containing or consisting of such a substance should be included in the *Australian Register of Therapeutic Goods* and that the difference between the date of the patent and first regulatory approval should be at least five years. In terms of Section 65, the 'date of the patent' is ordinarily the date on which the patent application is made. An applicant is required to make an application for extension to the Commissioner of Patents while the patent is in force, either within six months from the date the patent was granted or within six months of the product being included in the Australian Register of Therapeutic Goods, whichever is later.[154] Once the Commissioner is satisfied that the substantive requirements of Section 70 and the other procedural requirements have been met, the *whole* patent is eligible to be extended for a period that is equivalent to the period between the date of the patent and the date of first regulatory approval, reduced by five years.[155] Finally, Section 77(2) states that the term of an extension cannot exceed five years.

This constitutes the basic formula of the Australian extension scheme. By compensating patents that claim pharmaceutical substances in this manner, it seeks to provide a minimum effective patent life of fifteen years for such patents. There are certain specificities relating to this

[153] Ibid.
[154] Patents Act 1990(Cth), Section 71(2).
[155] Patents Act 1990(Cth), Section 77.

structure of the mechanism that relate to its scope of application and they are discussed in the following sub-sections.

- *The Significance of Claiming New and Inventive Pharmaceutical Substance*

Section 70(2) of the Act identifies the types of patents that are eligible for extensions in Australia:

> (a) one or more pharmaceutical substances *per se* must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification;
>
> (b) one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology, must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification.

In essence, it requires that a patent should *either* claim a *pharmaceutical substance per se* (Section 70(2)(a)) or a *pharmaceutical substance* that is produced *by means of recombinant DNA technology* (Section 70(2)(b)). Hence, claiming a 'pharmaceutical substance' is vital under both the sub-provisions of Section 70(2). A 'pharmaceutical substance' is defined in Schedule 1 of the Act as a substance that has a therapeutic application:

> "pharmaceutical substance" means a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves: (a) a chemical interaction, or physico-chemical interaction, *with a human physiological system*; or (b) action on an infectious agent, or on a toxin or other poison, *in a human body*; but does not include a substance that is solely for use in *in vitro* diagnosis or *in vitro* testing.[156]

Accordingly, it should be a substance that works *in* a human body or a human physiological system. In other words, the substance should be capable of being used in the treatment of humans.[157] Therefore, Andrew Christie, Saba Elkman and Melanie Howlett note that the type of substances that fall within the scope of Australia's patent term extensions scheme are more limited than those covered under concepts such as 'medicinal product' under the European

[156] Emphasis added.
[157] See Bucknell, n. 149, p. 104.

Union's scheme of Supplementary Protection Certificates.[158] The limited nature of this scheme is further confirmed by the definition given to 'therapeutic use'. Schedule 1 of the Act provides that:

> "therapeutic use " means use for the purpose of: (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury *in persons*; or (b) influencing, inhibiting or modifying a physiological process *in persons*; or (c) testing the susceptibility *of persons* to a disease or ailment.[159]

The significance of claiming a 'pharmaceutical substance' for a patent to be eligible for an extension under the current scheme can be traced to the legislative policy that underpins this scheme. The 1997 Explanatory Memorandum states in relevant part:

> The extension of term provisions will be available for patents that include claims to pharmaceutical substances per se (provided that the other criteria are met). *These claims to pharmaceutical substances per se would usually be restricted to new and inventive substances*. Patents that claim pharmaceutical substances *when produced by a particular process* (product by process claims) *will not be eligible unless that process involves the use of recombinant DNA technology*. Claims which limit the use of a known substance to a particular environment, for example claims to pharmaceutical substances when used in a new and inventive method of treatment, are not considered to be claims to pharmaceutical substances per se.[160]

It was the legislative policy that a patent must claim a 'new and inventive substance' in order to be eligible for an extension. Such claims are considered to be necessarily *different* to claims directed at processes or methods of use.[161] The Australian Courts have noted that this legislative policy must be borne in mind when determining a patent's eligibility for an extension. Interpreting the concept of 'pharmaceutical substance *per se*' in Section 70(2)(a) for the first time in *Boehringer Ingelheim International v. Commissioner of Patents*, Justice Heerey stated that:

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[158] See A. Christie, S. Elkman and M. Howlett, *Review of Pharmaceutical Patent Extension and Spring Boarding Provisions in Various Jurisdictions*, Commonwealth Department of Industry, Tourism and Resources, 2002, p. 26.
[159] Emphasis added.
[160] *1997 Explanatory Memorandum*, n. 151, p. 18.
[161] See Australian Patent Office, *Manual of Practice and Procedure*, available at http://manuals.ipaustralia.gov.au, Section 3.12.1.1.

> The 1990 Act in its present form manifests a policy which draws a distinction between, on the one hand, a pharmaceutical substance that is the subject of patent claim and, on the other hand, a pharmaceutical substance that forms part of a method or process claim. The specific *exception* to the latter (an exception which proves the rule) is the provision for recombinant DNA technology in s 70(2)(b).[162]

Heerey J indicated that the general legislative policy is to apply the extension scheme to 'pharmaceutical substances' that form the subject matter of a patent claim. Claims directed at processes or methods of use in which the pharmaceutical substance is *merely a part of* do *not* amount to claims directed at 'a pharmaceutical substance *per se' unless* the specific exception in Section 70(2)(b) is applicable. Further explaining the requirement of '*per se*' in Section 70(2)(a), the Courts have reiterated that it requires a pharmaceutical substance to have a significant degree of unity, the operation of which should be devoid of any extraneous factors. It was held in *The Children's Medical Center Corporation* that the term 'pharmaceutical substance *per se*' is intended to mean a pharmaceutical that is presented as a single entity, and therefore, claims to kit forms or separate dosage forms did not satisfy this.[163] Even the Australian Patent Office Manual states that the use of the words '*per se*' requires the claim to the pharmaceutical substance to be *unqualified* by process, temporal or environment components.[164]

As Heerey J indicated in *Boehringer*, Section 70(2)(b) is an *exception* to the general rule that there should be a claim to a 'pharmaceutical substance *per se*'. It is an exception to the general rule that there should be a claim directed at a 'new and inventive substance'. Hence, Section 70(2)(b) was regarded as permitting the extension of patents that claimed processes or products-by-processes provided there was a use of *DNA technology*. However, in *Commissioner of Patents v. AbbVie Biotechnology*,[165] the Federal Court of Australia reiterated the significance of the general legislative policy that there should be a 'new and inventive substance' in the interpretation and application of *both* the sub-provisions of Section 70(2).

This case concerned AbbVie's Swiss type claim relating to a pharmaceutical substance known as *adalimumab*. The claim was specifically for the use of adalimumab for the manufacture of a medicament using recombinant DNA technology for the treatment of ulcerative colitis.[166] The

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[162] [2000] FCA 1918. Emphasis added.
[163] [2011] APO 80.
[164] See Manual of Practice and Procedure, n. 161, Section 3.12.1.1.
[165] [2017] FCAFC 129.
[166] Ibid., para. 16.

Court noted that even though Section 70(2)(b) does not contain the terms 'pharmaceutical substance *per se*' and is an exception to the general rule that there should be a claim for a 'new and inventive' pharmaceutical substance, the exception only goes so far as allowing an extension when there is in fact a claim for a 'product' that is made by using recombinant DNA technology. In other words, even Section 70(2)(b) requires a claim to be directed to a product and it is not a licence to claim a process or use that cannot be regarded as a 'new and inventive substance'. Therefore, a Swiss type claim that was directed at the *manufacture* of a medicament did not satisfy this requirement in Section 70(2)(b) even though it used recombinant DNA technology. In the words of the Court:

> With specific reference to the present case, adalimumab is a pharmaceutical substance produced by a process that involves recombinant DNA technology. However, the claims in suit are not directed to adalimumab produced by recombinant DNA technology. They are directed to different subject matter. First, they are directed to a method or process in which adalimumab is used to produce a medicament. Secondly, they are directed to a medicament containing adalimumab that is to be used for specific therapeutic purposes, being those identified at [16] above. These claims do not meet the requirements of s 70(2)(b).[167]

Consequently, the legislative policy that patent term extensions should only be available to patents that claim 'new and inventive' pharmaceutical substances is fundamental feature of the current Australian scheme.

- *Limitations*

Another feature of the Australian scheme that deserves consideration relates to the scope of rights of a patentee during the *extended* term. A patentee has the exclusive right to 'exploit' the invention during the original twenty-year term of a patent.[168] Schedule 1 of the Act defines 'exploitation' broadly to include making, selling, hiring and the importation of an invention. Interestingly, there is no provision in the Australian Act that explains how the *scope of protection* must be determined. In a similar vein, the Act does not explicitly state the rights of a patentee during the extended period of a patent. This appears to be a rather odd omission as the scheme itself requires the presence of two specific types of 'claims' for a patent to be

[167] Ibid., para. 50.
[168] See Patents Act 1990(Cth), Section 13(1).

eligible for extension in the first place. The insistence of such prerequisites would not make any sense if all the other claims were similarly extended.

However, Section 78 specifies two limitations on the rights of a patentee during the 'extended' period. Firstly, a person who uses the types of substances mentioned in Section 70(2) for 'a purpose other than therapeutic use' does *not* infringe the patent.[169] Secondly, an extended patent is *not* infringed by someone who uses 'any form of the invention' other than the two types of substances referred to in Section 70(2). This is a rather complex way of setting out the rights of a patentee during the extended term, but it shows that the rights are limited to the *therapeutic uses* of the pharmaceutical substance that has been claimed in the patent. As the rights of a patentee are inseparable from the pharmaceutical substance and therapeutic uses of that substances, it shows the reason why Australian Courts insist on there being a 'new and inventive' pharmaceutical substance. Therefore, Charles Lawson accurately points out that although the patent is technically extended as a *whole* in Australia, the exclusive rights of a patentee are *limited* to the pharmaceutical and therapeutic uses of the pharmaceutical substance that has been claimed in the patent.[170] This is also reflected in the Patent Examiner's Manual which states as follows:

> Although the term of the patent *as a whole* is extended, exploitation of any form of the invention that is *not* a pharmaceutical substance and exploitation of pharmaceutical substances for *non-therapeutic uses* do not constitute infringement of the patent during the extended term.[171]

- *CALLS FOR REFORM*

The current scheme has been subjected to a number of reviews since its inception in 1998. They have recommended the reformation and even the total abandonment of the current scheme of extensions in the light of its alleged failure to meet the intended objectives of technological and economic development. The Government has signified its intention to maintain the current scheme without adopting any of these recommendations, but this section examines these reviews to get a sense of the criticisms that have been levelled against this scheme.

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[169] Patents Act 1990(Cth), Section 78(a).
[170] Lawson, n. 133, p. 383.
[171] Manual of Practice and Procedure, n. 161, on the 'Overview' of the Extension of Term of Standard Patents Relating to Pharmaceutical Substances at Section 3.12. Emphasis added.

It was highlighted that the Industrial Property Advisory Committee (IPAC) recommended the total abandonment of scheme in 1984 that applied to all patents under the then *Patents Act 1952(Cth)*. While the IPAC did not conduct a detailed analysis of the scheme's economic impact or its effect in attracting investments, it stated that the extension scheme only increased social costs, that there was no empirical evidence to suggest the contrary and that pharmaceuticals did not deserve special treatment for its regulatory delays as this issue was not unique to the pharmaceutical industry.[172] This recommendation was only partially implemented by the Government, as although it abolished the previous scheme, it simultaneously introduced a new one that applied only to pharmaceuticals in 1988. The IPAC Report is insightful as even though it was made in the context of a previous extension regime, the recent reviews of the current scheme express similar sentiments.

One of the first reviews of the current scheme was conducted by the Pharmaceutical Patents Review (PPR) that was initiated by the then Parliamentary Secretary for Innovation, Hon. Mark Dreyfus QC MP in October 2012. It was meant to examine whether the patent system ensured the timely access to affordable drugs, supported innovation and had provided employment to Australian citizens. An important part of its terms of reference was to evaluate the extension scheme that applied to pharmaceuticals. The PPR published its Final Report in May 2013 in which it made some interesting observations about the current system.[173] It noted that the *United States-Australia Free Trade Agreement* requires Australia to grant extensions for pharmaceutical patents beyond the TRIPS mandated twenty-year period.[174] However, it stated in no ambiguous terms that this scheme established in 1998 that gives preferential treatment to pharmaceuticals is inconsistent with the non-discrimination obligation in TRIPS Article 27.1. In its own words:

> Using the patent scheme to preferentially support one industry is inconsistent with the TRIPS rationale that patent schemes be technologically neutral.[175]

Notwithstanding such a bold statement, the PPR did not explain how or why the scheme is inconsistent with this TRIPS obligation. In fact, the quoted sentence is the only sentence in the whole Report that even mentioned the non-discrimination obligation in TRIPS. The PPR stated

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[172] Industrial Property Advisory Committee, n. 139, pp. 36-39.
[173] See T. Harris, D. Nicol and N. Gruen, *Pharmaceutical Patents Review Report*, Canberra, 2013, [hereinafter referred to as 'PPR Report'].
[174] Ibid., p. vi.; Article 17.9.8(b) of AUSFTA requires each country to 'make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent terms as a result of the marketing approval process… [related for drugs]'; Also see R. Chalmers, 'Evergreen or Deciduous? Australian Trends in Relation to "Evergreening" of Patents', *Melbourne University Law Review*, vol. 30, no. 2, 2006, p. 29.
[175] PPR Report, n. 173, p. vi.

that one of the vital objectives of the extensions scheme was to attract investments by the pharmaceutical industry but that it had manifestly failed in achieving this objective.[176] Scrutinizing investment data between 1991 and 2011, it noted that there had not been any notable increase in investments after the introduction of the current scheme.[177] It also noted that even with this scheme that had been in operation since 1998, R&D in Australia as at 2013 represented a mere 0.3% of global pharmaceutical R&D, while countries like US, Japan and UK represented 53%, 14% and 8% respectively.[178] It stated that this was not surprising as there were *other* factors that influenced investment decisions. It stated:

> We should not be surprised that the outcomes expected by Government have not materialised. Pharmaceutical companies endeavouring to maximize shareholder benefits could be expected to make decisions about where to locate pharmaceutical R&D on the basis of countries' relative costs (after taxes and subsidies) and skills, although other influences, such as the location of company headquarters also play an important role in those decisions.[179]

The colossal financial impact that the extension scheme was having on Australia's Pharmaceutical Benefits Scheme (PBS) was another serious concern to the PPR. The extension scheme increased the costs of the PBS as it took longer for generic versions to enter the state-subsidized list of drugs. The Explanatory Memorandum to the 1997 Bill estimated this cost to be approximately $6 million in 2001- 02, which was to peak to a maximum of around $160 million in 2005-06.[180] However, the PPR estimated that the cost for 2012-13 alone was a near $240 million.[181] As there was 'no evidence or convincing argument' to demonstrate that the scheme was contributing to the development of the Australian industry or to Australian R&D in a way that was commensurate with its 'very substantial costs', the PPR noted that the scheme needed reformation.[182]

The PPR suggested two alternative reforms: to reduce the maximum term for which a patent could be extended *or* to reduce the effective patent life of pharmaceutical patents. It estimated that the mere reduction of the maximum extension period from five to four years would save the Government $45 million per annum.[183] It also estimated that the mere reduction of the

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[176] Ibid., pp. 64-80.
[177] Ibid.
[178] Ibid.
[179] Ibid., p. 67.
[180] *1997 Explanatory Memorandum*, n. 151, p. 2.
[181] PPR Report, n. 173, p. viii.
[182] Ibid., p. 80.
[183] Ibid., p. 76.

effective life of a pharmaceutical patent from fifteen to fourteen years would save the government $46 million per annum.[184] The PPR highlighted that such amendments were necessary as the only provision that had exercised some form supervision over the extended patents had also become ineffective. This provision that the PPR referred to is Section 76A of the Patents Act that was also introduced by the 1997 Amendment Bill. By the time this Bill was introduced to the legislature, the Government had decided to invest $800 million to assist pharmaceutical R&D with the intention that the pharmaceutical firms would retain their operations in Australia. As a form of assurance that these objectives will be met by each extended patentee, the Senate introduced Section 76A to the Bill to make a patentee of an extended patent demonstrate how these objectives were being met.[185] This system, however, is only a notification system that requires a patentee to disclose details relating to, *inter alia*, the amount of Commonwealth funds used in the research and development of the drug that is the subject matter of the application during each financial year. While such notifications hardly showed how Australia benefited from each extended patent, the more practical issues related to the non-observance of this provision and the lack of access to this information by the public.[186] Consequent to the PPR Report, the Government gradually distanced itself from it by stating that it was commissioned by a previous Government and that the views and recommendations expressed in the Report did not reflect Government policy.[187]

The next and most recent call for amendment of the scheme came from the Australian Government's Productivity Commission in its Report titled 'Intellectual Property Arrangements' in September 2016.[188] The Commission did not only examine Australia's patent system, but examined Australia's intellectual property system as a whole to scrutinize its effect on investment, competition, trade, innovation and consumer welfare.[189] In this process, it dedicated an entire chapter to patents and pharmaceuticals. It noted that the pharmaceutical industry was a prominent user of the patent system because of the significant costs involved in the development of drugs.[190] According to a submission by *Medicines Australia* that represented the research-based medicines industry, the average cost to develop a drug was estimated to be

[184] Ibid., p. 78.
[185] See Lawson, n. 133, p. 395.
[186] PPR Report, n. 173, pp. 89-92.
[187] See *Government Statement on the Pharmaceutical Patent Review Final Report*, https://www.ipaustralia.gov.au/sites/g/files/net856/f/government_statement_on_the_pharmaceutical_patent_review_final_report.pdf, (accessed 28 January 2018).
[188] See Productivity Commission Inquiry Report, *Intellectual Property Arrangements*, Canberra, 2016, [hereinafter referred to as 'Productivity Commission'].
[189] Ibid., Terms of Reference, p. iv.
[190] Ibid., p. 290.

around US$2.6 billion.[191] The Commission also noted, however, that the vast majority of pharmaceutical patent applications filed in Australia were by foreign applicants. It found that between 2001 and 2014, only 4.3% of pharmaceutical patent applications were filed by Australian residents.[192] With these observations, the Commission stated that a patent system should not only provide incentives to develop new drugs, but that it should also ensure that these drugs are accessible and affordable.[193] Tracing the objectives of the current extensions scheme, the Commission noted that it is meant to compensate pharmaceutical innovators for the heavy burden of expenses and risks incurred by them due to the regulatory review process.[194] However, it saw four glaring problems with such a justification for the current scheme.

Firstly, it was *not* entirely clear that the standard patent term that had been increased from sixteen years to twenty years in 1994 was insufficient. Secondly, 'parity' was not a convincing rationale. It will be recalled that the Australian Government intended that system would give pharmaceuticals an 'effective patent life' that was equal to that enjoyed by inventions in other fields of technology.[195] This justification did not make much sense to the Commission for two reasons. Firstly, as the IPAC had noted in 1984, there were other industries that faced similar regulatory hurdles. Secondly, and more importantly, it ignored the reality of the significant returns that the pharmaceutical industry made in the market given that its product life-cycle was not as short as in other fields of technology which reduced the effective patent life of patents of those technologies.[196] Hence, the pharmaceutical sector could not really be equated with other fields of technology as it was in fact *benefiting more* from the patent system than any other field of technology.

The third problem with this compensatory justification was that there was no evidence to show that the scheme was attracting more investments from the industry.[197] This was similar to the opinion of the Pharmaceutical Patents Review (PPR) in 2013. Scrutinizing the information submitted to the Health Department by patentees in terms of Section 76A of the Patents Act, the Commission found that only 39% of the returns reported any R&D expenditure in Australia

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[191] Ibid., p. 288. Also see Medicines Australia, *Submission to the Productivity Commission's Draft Report on Intellectual Property (IP) Arrangements in Australia 2016*, June 2016, https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20160603-sub-submission-PC-IP-Draft-Report-June-2016-FINAL.pdf, (accessed 29 January 2018).
[192] Productivity Commission, n. 188, p. 290.
[193] Ibid., p. 292.
[194] Ibid., p. 293.
[195] See *1997 Explanatory Memorandum*, n. 151, p. 3.
[196] Productivity Commission, n. 188, pp. 294-295.
[197] Ibid., p. 295.

and that this has only been declining since 2011.[198] Simply put, the Commission could did not see any nexus between the extension scheme and pharmaceutical R&D in Australia.

The fourth and final problem was the enormous costs that had to be borne by the Pharmaceutical Benefits Scheme (PBS). The Commission estimated that the cost to the Australian Government was $260 million per annum.[199] This estimate was almost similar to the figure that the PPR had estimated in 2013. For these reasons the Commission concluded that:

> Overall, the Commission considers that the policy case for Extension of Terms was never made and that such provisions impose a net cost on the community.[200]

However, the Commission did *not* suggest the total abandonment of the scheme. It made two recommendations to reform the system. Its first recommendation was to amend the manner in which 'regulatory delay' is calculated. It stated that calculating the length of extension solely based on the period that that has elapsed between the date of the patent and the first regulatory approval did *not* necessarily signify any delay on the part of the regulatory body. Hence, it recommended that the clock to calculate the term of an extension should start running only after a lapse of 255 working days, which is the reasonable time frame that has been allocated for the *Therapeutic Goods Administration* by the Australian legislature.[201] It stated that most drugs obtain regulatory approval within 255 days and that such a period should not be considered to be 'unreasonable'. The Commission estimated that such a mechanism will save the Government $258 million per year.[202] The Commission also recommended that the availability of extensions be limited to Active Pharmaceutical Ingredients (APIs). While such was and still is the case in Singapore, it is based on the premise that it is the development of new APIs that is most expensive and time consuming. It stated that the original legislative intention was to limit the scheme to APIs although subsequent case law broadened the availability of the scheme to all types of pharmaceutical inventions.[203]

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[198] Ibid., p. 295.
[199] Ibid., p. 298.
[200] Ibid.
[201] Ibid., p. 306.
[202] Ibid.
[203] Ibid., p. 307. However, it is difficult to accept that the Australian legislature only intended that the scheme be applicable to APIs. As discussed above, it was meant to apply to 'new and inventive' pharmaceutical substances. In the absence of anything to the contrary that was intimated by the government at the time of the 1997 amendments, this cannot be understood as only referring to APIs.

The Government announced its response to the Commission's Report in August 2017.[204] With regard to its recommendations concerning patent term extension scheme, the Government indicated in no uncertain terms that it was not willing to alter the current system. It stated that:

> The Government notes this recommendation, however has no plans to proceed with this recommendation in the form proposed by the Productivity Commission. The Government will discuss ways to improve the patent term extension system with the sector.[205]

The response also continued to explain the significance of the patent system to the pharmaceutical industry. Highlighting that regulatory processes reduce the effective patent life of pharmaceutical patents, it stated that the failure to grant patent term extensions as done under the current mechanism would *erode* the incentives to introduce new pharmaceutical products to the Australian market.[206] It concluded by stating that any consideration of changes to the extensions regime must strike a balance 'between ensuring that new pharmaceutical products are developed and that they are safe and effective, but also ensuring that they are accessible and affordable'.[207] This was perhaps a subtle hint that the Commission's recommendations were not adequately 'balanced'.

It also deserves to be noted that during the time that lapsed between the Productivity Commission's Report and the Government's response, many submissions were made to the Australian Department of Industry, Innovation and Science. One such submission was by Medicines Australia.[208] A brief observation of this submission provides some vital context to understand the Government's response to the Report. Unsurprisingly, Medicines Australia submitted that patent extensions should not be limited to APIs as such a restriction would affect the incentive to engage in research of follow-on inventions relating to existing drugs. It stated that:

> Restricting patents to APIs limits the scope and incentive for pharmaceutical companies to invest, discover and develop new pharmaceutical substances. As

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[204] See Commonwealth of Australia, *Australian Government Response to the Productivity Commission Inquiry into Intellectual Property Arrangements*, August 2017, https://archive.industry.gov.au/innovation/Intellectual-Property/Documents/Government-Response-to-PC-Inquiry-into-IP.pdf, (accessed 28 January 2018).
[205] Ibid., p. 11.
[206] Ibid.
[207] Ibid., p. 12.
[208] See Medicines Australia, *Submission to the Department of Industry, Innovation and Science on the Productivity Commission's Final Report on Intellectual Property Arrangements in Australia*, February 2017, https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20170207-sub-Medicines-Australia-submission-on-PC-Inquiry-into-IP-Arrangements-Final-Report.pdf, (accessed 29 January 2018).

> an example, a number of combination products have been developed, which, although scientifically not creating a new API, had extensive inventiveness that led to improved patient health outcomes. Additionally, the invention of new pharmaceutical substances can allow different methods of administration that treat completely new indications.[209]

It also submitted that patent extensions should not be calculated with reference to regulatory delay that only exceeds 255 working days as this ignores the very rationale for patent term extensions by discounting the significant time and costs involved in conducting clinical trials mandated by the regulatory requirements.[210] These submissions that showed the industry's perspective of the Productivity Commission's recommendations appear to have influenced the Government's response in 2017 and to preserve the existing system of extensions.

- *CONCLUSION*

Patent term extension schemes are prevalent in the patent systems of several WTO Members. The examination of the Australian scheme demonstrates the broad objectives that such schemes aim to pursue by maintaining adequate incentives for the pharmaceutical industry. It is evident that the Australian scheme only applies to patents that claim a 'pharmaceutical substance', to the exclusion of all the other inventions that similarly face marketing delays due regulatory processes. Whether conferring a patent term that goes beyond the TRIPS mandated twenty-year term is subject to the rule against 'discrimination' in Article 27.1, and if so, the Australian scheme's potential consistency with this obligation will be addressed in the next Chapter.

[209] Ibid., p. 7.
[210] Ibid.

CHAPTER 6

THE CONSISTENCY ANALYSIS

This Chapter examines the potential consistency (or inconsistency) of the national measures that have been discussed in the previous Chapter of this thesis with the rule against the 'discrimination' of fields of technology in TRIPS Article 27.1. Its objective is *not* to make a case for or against the consistency of those measures, but more significantly for the purposes of this thesis, to understand how the elements of this obligation and the concept of 'justification' that have been revealed in this thesis would potentially apply in practice.

A. THE INDIAN REQUIREMENT OF ENHANCED EFFICACY

- *THE DISADVANTAGEOUS TREATMENT OF PHARMACEUTICALS*

It will be recalled that one of the rules of Section 3(d) of the Indian Patents Act (1970) requires an invention that is a *new form of a known substance* to demonstrate an enhancement of the known *efficacy* in order to be patentable. As in the previous Chapter, it should be noted that any reference to 'Section 3(d)' here onwards is a reference to this particular rule of Section 3(d). Its legislative history demonstrates that it was meant to apply to chemical based pharmaceutical substances *and* agricultural chemicals with a view to prevent the problem of 'ever-greening'. However, the Supreme of Court noted in *Novartis v. Union of India* that almost 80% of the legislative debates relating to Section 3(d) concerned medicines and drugs, whereas only 20% related to agro-chemicals.[1] This signified the obvious concerns that the Indian legislature specifically had in relation to the practice of ever-greening in the field of *pharmaceuticals* in the light of its potential detrimental impact on public health. The High Court of Madras also noted in the same *Novartis* dispute that these concerns relating to pharmaceuticals were confirmed by the fact that the *Explanation* accompanying Section 3(d) *only* refers to the field of pharmacology.[2] Consequently, although Section 3(d) is meant to apply to pharmaceuticals and agro-chemicals, the text and legislative intentions indicate that preventing ever-greening of pharmaceutical patents was clearly the *core* objective of this provision.

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[1] *Novartis AG v. Union of India and Others,* 6 SCC 1 (2013), para. 97, [hereinafter referred to as 'Novartis v. UOI (SC)'].

[2] *Novartis AG v. Union of India and Others*, High Court of Judicature of Madras, 2007 (4) MLJ 1153 (W.P. No. 24759 and 24760 of 2006), para. 12, [hereinafter referred to as 'Novartis v. UOI (HC)].

To establish an inconsistency with the non-discrimination obligation in TRIPS Article 27.1, a complainant bears the initial burden of establishing a *prima facie* case that a field of technology is being subjected to disadvantageous/preferential treatment. While this could be both *de jure* and *de facto*, a presumption to that effect is raised in the case of a *de jure* allegation when a respondent's measure *explicitly* imposes *additional criteria* or *restrictions* that affect the availability and enjoyment of the patent rights of a field of technology. As the text and history of Section 3(d) distinctly demonstrates that it is meant to apply to new forms of known substances in the field of pharmaceuticals and imposes an additional requirement of demonstrating 'enhanced efficacy', it is submitted that this explicitly affects the availability of patent rights for pharmaceutical inventions. Therefore, its disadvantageous effect on pharmaceuticals would be presumed in this context.

This presumption is augmented by the manner in which the Indian judiciary has interpreted the elements of Section 3(d). The narrow interpretation of 'efficacy' as *therapeutic* efficacy in the context of pharmaceutical inventions and largely disregarding any enhancements of other properties relating to a pharmaceutical substance only confirms its disadvantageous impact on the patentability of those inventions. These interpretations of the elements in Section 3(d) that have now been incorporated into the Patent Office Manuals have been the reason for pharmaceutical research-intensive members to have expressed their disapproval of Section 3(d). For example, in its Special 301 Report of 2017, the United States Trade Representative (USTR) noted that the US pharmaceutical industry continues to face challenges due to Section 3(d) and has continued to keep India on its 'priority watch' list.[3] This is because the Pharmaceutical Research and Manufacturers of America (PhRMA) that represents the research based pharmaceutical industry in US have continuously referred to Section 3(d) as an 'impermissible hurdle to patentability' in their Special 301 Submissions to USTR.[4] In a similar vein, a report published by the European Commission highlights the restrictive patentability criteria for pharmaceuticals and chemicals in India which is a clear reference to Section 3(d). It similarly places India on a so-called Second Tier priority list.[5]

[3] Office of the United States Trade Representative (USTR), *2017 Special 301 Report*, p. 42.
[4] See Pharmaceutical Research and Manufacturers of America (PhRMA), *Special 301 Submission 2017*, p. 51 and *Special 301 Submission 2018*, pp. 84-5.
[5] See European Commission, *Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries*, February 2018, p. 13.

When a WTO Member takes a bold move to impose additional criteria for the patentability of inventions in a given field of technology in this manner, the interpretation of the non-discrimination obligation suggests that it should have had good reasons to do so. With a presumption being made that Section 3(d) is disadvantageous to pharmaceuticals, the burden shifts to the respondent to demonstrate *either* that its measure does *not* disadvantage pharmaceuticals and is of 'mere' differential treatment *or* that such treatment could be *justified*. It is submitted that it is unlikely that India would succeed in the first of these counter-arguments for the following reason. As highlighted in Chapter 4, the concept of 'mere' differential treatment broadens when such treatment is accorded in the context of the patentability criteria of novelty, inventive step and industrial application. It was argued that this is a consequence of the autonomy that that TRIPS has preserved on the part of the membership to interpret and apply those criteria. On the other hand, the concept of 'mere' differentiation narrows when the differential treatment is caused by measures extraneous to the patentability criteria because such treatment goes beyond the autonomy preserved in the interpretation and application of those criteria.

While there was a period when there was some ambiguity in the Indian jurisprudence as to whether Section 3(d) was a patent eligibility or patentability standard, these doubts were cleared by the High Court of Delhi which held that it is a patent *eligibility* standard.[6] In other words, it is meant to regulate patentable subject matter, which is an assessment that is conducted before the patentability criteria come into operation. The consequence of this is that India cannot claim that it falls within its autonomy that relates to the patentability criteria, which effectively makes it difficult for it to rebut the presumption that Section 3(d) is disadvantageous. While Section 3(d)'s limitation of patentable *subject matter* may render India to be in potential violation of the first sentence of TRIPS Article 27.1 which specifies that '*patents shall be available* to *any inventions* in *all fields of technology'*, this issue will not be examined here.

- *ANALYSIS OF A JUSTIFICATION*

  - ❖ *A Legitimate Policy Objective- Public Health*

The previous Chapter discussed India's dramatic transformation of its patent laws relating to pharmaceutical inventions since it gained independence up until it implemented the TRIPS

[6] See *F. Hoffmann La Roche Ltd. & Anr. v. Cipla Ltd* 2016 (65) PTC 1 (Del).

standards in 2005. Its vast population, low-hygiene standards, low levels of income and thriving generic drug industry made its lawmakers wary of granting product patent protection for pharmaceuticals. Section 3(d) was introduced to alleviate the concerns that product patents in the field of pharmaceuticals would lead to 'ever-greening' that would in turn affect its public health. Although the concept of 'ever-greening' was not strictly defined at that time, and is, perhaps, beyond any precise definition even today, the Indian legislators considered it to be a type of patent abuse that resulted in the grant of a series of patents by making minor additions or alterations to existing drugs. By requiring the 'enhancement' of the known efficacy before granting such patents, the Government reiterated that only deserving inventions would be given any patent monopoly, thereby reducing the likelihood of such patent abuse.

In establishing a 'justification' in the context TRIPS Article 27.1, the first hurdle that India should surmount is demonstrating that Section 3(d) pursues a legitimate policy objective. It was noted that TRIPS Article 8.1 is instructive for this purpose and that members have a significant level of discretion to pursue a wide spectrum of policy objectives provided *they* perceive such policies to be of vital importance to their socio-economic and technological development. As the WTO Panel noted in *Australia- Plain Packaging*, the protection of public health is 'unquestionably' such a legitimate policy as Article 8.1 explicitly refers to the protection of public health and nutrition.[7] Moreover, WTO jurisprudence also demonstrates that a WTO Member has the right to determine the desired *level* of protection of the policy that it seeks to pursue.

Given Section 3(d)'s objective to prevent 'ever-greening' and to keep medicines affordable to its citizens, India would most certainly claim that its measure seeks to protect public health. Its objective of protecting public health was aptly explained by the Indian Supreme Court in the *Novartis* case in the following manner:

> To anyone going through the debate on the Bill, Parliament would appear *keenly alive to national interests, human- rights considerations and the role of India as the producer and supplier of drugs to different parts of the world where impoverished humanity is critically in need of those drugs at cheap and affordable prices*. Cutting across party lines, member after member from the Opposition benches highlighted the *grave risk in creating private monopolies*

[7] Panel Report, *Australia- Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/R, WT/DS441/R, WT/DS456/R and WT/DS467/R, para. 7.2406.

> *in an area like pharmaceuticals, the abuses to which product patents in pharmaceutical products were vulnerable, and the ploys used by big companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high.*[8]

Similarly, in a statement that was subsequently endorsed by the Supreme Court, the High Court of Madras identified the legislative policy of Section 3(d) in its judgment in the *Novartis* dispute in the following manner:

> …the object which the Amending Act wanted to achieve namely, to prevent ever-greening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.[9]

To this end, the Supreme Court noted that Section 3(d) sets up a 'second tier' of qualifying standards for chemical substances/pharmaceutical products and thereby:

> …leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.[10]

The significance that must be given to the protection of public health in the context of the patent system in India is highlighted by another provision of the Patents Act that concerns compulsory licences. This provision, namely Section 83, lays down the general principles that the Controller of Patents should have regard to when determining the grant of compulsory licenses *for the non-working* of patented inventions. It states in relevant part as follows:

> (d) that patents granted *do not impede protection of public health and nutrition* and should act as instrument to *promote public interest specially in sectors of vital importance for socio- economic and technological development of India*;
>
> (e) that patents granted *do not in any way prohibit Central Government in taking measures to protect public health.*[11]

While these sub-provisions of Section 83 in particular have great textual similarities to the Objectives (Article 7) and Principles (Article 8.1) of the TRIPS Agreement, the precise

[8] *Novartis v. UOI (SC)*, n. 1, para. 79. Emphasis added.
[9] *Novartis v. UOI (HC)*, n. 2, para. 19.
[10] *Novartis v. UOI (SC)*, n. 1, para. 103.
[11] Emphasis added.

objective of mentioning them so late in the Indian Patent Act still remain ambiguous. While they appear to be ideally relevant only to the Controller in determining an application for a compulsory licence, Section 83(d) suggests that patents *already granted* are presumed to *not* impede the protection of public health and nutrition. If such is the case, it must also follow that there should be some assessment of a patent's potential impact on public health at the time the patentability of an invention is examined. However, the assessment of an invention's impact on public health is not mentioned in any of the provisions dealing with patentability. While an invention's impact on public health in determining its patentability is not strictly relevant, or largely vague at best, it was puzzling to find that the Supreme Court quoted Section 83's general principles in its judgment in *Novartis*.[12] The Court did not mention why it did this given that the case was totally unrelated to compulsory licences, other than merely stating that 'it might not be out of place to take note of Section 83' when explaining the development of India's patent system.[13]

Consequently, although it is still premature to state that the Section 83 considerations relating to the protection of public health and nutrition constitute *general principles* of the Indian patent system, it is at least apparent that public health is given some prominence under the Indian Act. While the precise contours of this prominence are yet to be fully understood, it suffices to note for the current purposes that Section 83 enhances India's stance in demonstrating the heightened significance of public health in the context of its patent laws and that Section 3(d) is one of its manifestations.

- *Necessity*

The test of 'necessity' borrowed from its textual reference in TRIPS Article 8.1 is meant to scrutinize the 'necessity' of the national measure to pursue the policy objective. It was argued in Chapter 4 that 'necessity' in the context of TRIPS Article 8.1, and therefore in the context of a 'justification' in Article 27.1, should entail a more flexible analysis than under the General Exceptions of GATT/GATS. As TRIPS concerns intellectual property laws that are not directly related to public health and other societal interests that must be balanced as per Objectives (Article 7) of the Agreement, 'necessity' in this context is meant to examine a measure's capability to contribute towards a stated policy objective within the jurisdiction of a given WTO Member. This must be determined by weighing and balancing a number of factors that include

[12] See *Novartis v. OUI (SC)*, n. 1, para. 73.
[13] Ibid.

the importance of the public interest, the level of contribution of a measure and the availability of alternatives.

WTO jurisprudence demonstrates that the more important the public policy is, the more likely that a measure would be considered 'necessary'.[14] While the protection of public health has always been considered to be the most important public policy in the context of the covered agreements of the WTO that concern goods and services, this was specifically acknowledged in the context of TRIPS in *Australia- Plain Packaging* where the Panel noted that the preservation of human life and health is 'both vital and important in the highest degree'.[15] This is buttressed by the fact that the protection of public health and nutrition is explicitly mentioned in TRIPS Article 8.1 which indicates that it should be one of the more significant policies objectives that could be pursued in the context of a justification in TRIPS Article 27.1.

The second factor relates to Section 3(d)'s level of contribution towards the protection of public health. In the context TRIPS Article 27.1, this involves an examination of the design, structure and application of a measure in order to determine if it has *contributed* or, more importantly, is *capable* of contributing towards the public policy objective. Hence, India should be able to demonstrate Section 3(d)'s ability to contribute towards the protection of public health.

In a report that criticized the impact that Section 3(d) *would* have on incremental pharmaceutical innovation, the US-INIDA Business Council stated that, contrary to its legislative intentions, Section 3(d) would harm public health by inhibiting the development of better versions of existing drugs that would suit the local conditions of the country.[16] However, India's counter-argument is that Section 3(d) was never meant to prevent the patenting of incremental pharmaceutical inventions.[17] It only serves to ensure that *genuine* incremental developments are granted patent monopolies. As the Supreme Court stated in *Novartis,* Section 3(d) serves to check if an incremental invention is *true and genuine*.[18] The manner in which the Indian courts and Patent Offices have interpreted the elements of Section 3(d) demonstrate the

[14] See Appellate Body Report, *Korea- Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, para. 164; Appellate Body Report, *European Communities- Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/AB/R, para. 172.
[15] Panel Report, *Australia- Plain Packaging*, n. 7, para. 7.2587.
[16] See US-India Business Council, *The Value of Incremental Pharmaceutical Innovation: Benefits For Indian Patients and Indian Business*, 2009.
[17] See T. James, *Patent Protection and Innovation: Section 3(d) of the Patents Act and Indian Pharmaceutical Industry*, Department of Industrial Policy and Performance, 2009.
[18] See *Novartis v. UOI (SC)*, n. 1, para. 103.

circumstances in which such incremental pharmaceutical inventions are to be considered *true and genuine*.

A new form of a known substance should enhance the *therapeutic effectiveness* of the known substance. A patentee must demonstrate this with comparative data comparing the invention and the *closest* form of the known substance.[19] Improvements relating to other properties of a pharmaceutical substance would not *necessarily* be sufficient to enhance the therapeutic effectiveness of a substance.[20] These strict checks serve to ensure that patents are not granted for pharmaceutical inventions that entail minor modifications of already known substances, as it would otherwise hinder generic competition. The previous Chapter discussed a number of cases in which patents have been denied due to the lack of such enhancements. While *Novartis* is one such fine example, it also demonstrates how Section 3(d) contributes towards the protection of public health. As the Supreme Court noted in its judgment, the monthly treatment of Novartis's Glivec was a near Rs. 120,000, whereas the generic version only cost around Rs. 8,000.[21] Thus, the denial of a patent for Glivec significantly enhanced access to the anti-cancer drug by thousands of patients. Since then, the Courts and Patent Offices in India have struck off several applications on this basis, resulting in the same outcome of more competition and affordable prices. It is submitted that in the context of patent law, this is perhaps one of the finest examples of a measure that is *capable* of contributing towards the protection of public health. The prevention of patents for incremental pharmaceutical inventions that do not enhance the therapeutic effectiveness of known drugs effectively render the known drug and its advanced versions to be accessible by the public without any monopolistic pricing. There is a significant level of evidence to show that this has been the outcome in cases where Section 3(d) has been applied and this would suffice to demonstrate its contribution and the capability of contribution towards the protection of public health.

The final factor in this 'necessity' analysis concerns the availability of alternatives. As the Appellate Body has highlighted in the context of GATT Article XX, a respondent does *not* have the burden of showing that it did *not* have any other alternatives. It is the complainant who bears the initial burden of showing the availability of a less 'discriminatory' alternative which the respondent could negate by demonstrating that it was not so.[22] Hence, India does not have

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[19] See *In the Matter of Patent Application* No. 293/MUMNP/2008; *In the Matter of Patent Application* No. 2076/DEL/1997.

[20] *Novartis v. UOI (SC)*, n. 1, para. 187. Also see *In the Matter of Patent Application* No. 2485/DEL/1998

[21] *Novartis v. UOI (SC)*, n. 1, para. 82.

[22] See Appellate Body Report, *China- Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*, WT/DS363/AB/R, para. 319.

the initial burden of showing that it did not have any alternatives unless a complainant identifies a less inconsistent alternative. One of the chief criticisms that has been levelled against Section 3(d) is that the concept of *inventive step* or non-obviousness is sufficiently capable of dealing with the problems of ever-greening. For example, the United States uses the *lead compound theory* in which structural similarities between a known compound and an invention raises a presumption of obviousness, *unless* the invention contains unexpected or surprising results. This presumption is made, however, only when there is some motivation that would have led a person of ordinary skill in the art to select and modify the known compound (i.e. a lead compound) in a particular way to achieve the claimed invention.[23] As none of the other WTO Members, now to exclusion of Philippines, have adopted special rules like India to address ever-greening concerns in the field of pharmaceuticals, the inventive step requirement is most likely to be suggested as the alternative in this context.

In addressing such alternatives, it is important to bear in mind as the Appellate Body reiterated in *EC-Asbestos*, that the suggested alternative should meet the same desired level of protection of the policy in issue.[24] This was reiterated in the context of TRIPS by the WTO Panel in *Australia – Plain Packaging*. In determining if Australia had other alternatives to its Tobacco Plain Packaging (TPP) measures, the Panel noted that any suggested alternative should protect public health to the same extent that Australia had sought to achieve by its TPP measures.[25] This is a consequential effect of the fact that determining the desired level of protection falls within the exclusive ambit of a Member's autonomy. Moreover, any suggested alternative should not be merely theoretical in the light the development standards of the respondent Member.

Accordingly, India would need to demonstrate that the inventive step requirement would not protect public health by preventing ever-greening to the same extent as Section 3(d) or that it is only a theoretical possibility in the light of its standard of development. It is submitted that India is likely to succeed in both these counter-arguments. As mentioned above, while countries like US tend to prevent ever-greening through certain presumptions in the analysis of an invention's inventive step, such rules are not as clear and specific as Section 3(d). For example, the presumption based on the lead compound theory is only made in specific circumstances that

[23] See J. Lief and P. Schuyler, 'Pharmaceutical Patents after KSR: What Is Not Obvious?', *Journal of Commercial Biotechnology*, vol. 15, no. 1, 2009, p. 44; A. Trask, '"Obvious to Try": A Proper Patentability Standard in the Pharmaceutical Arts?', *Fordham Law Review*, vol. 76, no. 5, 2008, p. 2625; G. Liang, 'The Validity Challenge to Compound Claims and the Unpredictability of Chemical Arts', *Wake Forest J. Bus. & Intell. Prop. L.*, vol. 13, 2012, p. 38.
[24] See Appellate Body Report, *EC- Asbestos*, n. 14, para. 168.
[25] Panel Report, *Australia- Plain Packaging*, n. 7, para. 7.2600.

relate to the teachings in the prior art. Further, rebutting such a presumption is not too burdensome as, for example, even advancements that increase the bioavailability of a drug are considered to be sufficient. This is *not* necessarily the case under Section 3(d). It makes a *presumption* that certain derivatives mentioned in its Explanation are the *same* as the known substance, *irrespective* of the teachings in the prior art. This could be rebutted *only* by evidence relating to 'therapeutic efficacy'. As already observed, this stringent examination discounts the enhancement of any other properties in a pharmaceutical substance including bioavailability, unless there is evidence to show that an increase in bioavailability also enhances the therapeutic effect of the drug.

These factors demonstrate the high level of protection of public health that India seeks to achieve by Section 3(d), which is greater and distinct to the objectives that could be met by concepts such as non-obviousness. As the Supreme Court has noted, Section 3(d) is evidently an *extra* hurdle for certain types of pharmaceutical inventions and is purely aimed at protecting public health. This is buttressed by the fact that India barely has over ten years of experience in granting pharmaceutical product patents. In the light of its poverty and vast population, the harm that would have been caused to its public health would have been substantial if it had to wait until its Courts and Patent Offices acquainted themselves of how to apply the patentability criteria to complex fields of technology. Hence, the reliance on the inventive step requirement to address ever-greening concerns might have been limited to a mere theoretical possibility in India.

Consequently, in the light of the vital policy of protecting public health, its capability to do so and the unavailability of alternatives, it submitted that India would be in a good position to establish the 'necessity' of Section 3(d) for the protection of public health within its jurisdiction.

- *Even-handedness*

The final requirement that India would need to establish is the requirement of even-handedness. It was highlighted in Chapter 4 that such a requirement finds its genesis in the chapeau conditions of the General Exceptions in GATT/GATS and similar justificatory concepts in the substantive non-discrimination obligations under the other covered agreements. It serves to examine whether a WTO Member genuinely pursues its stated public policy objective by scrutinizing whether the Member has addressed similar concerns in other fields of technology without limiting itself to one field of technology. Hence, in the context of Section 3(d), the

enquiry is whether there were other fields of technology with similar concerns relating to ever-greening, and if so, whether India applied similar rules to those fields of technology.

As highlighted above, Section 3(d) is also meant to apply to agro-chemicals. However, its application to agro-chemicals has not attracted as much attention as it has done in the context of pharmaceuticals. While this is perhaps because the rule tends to have a greater impact on pharmaceuticals than on agro-chemicals, it is submitted that India could prove the even-handedness of Section 3(d) even if it did not extend it to the latter. This is because the ever-greening concerns are most dramatic in the field of pharmaceuticals than in any other field of technology. The public health concerns that it triggers are so unique that it makes the problem of ever-greening in this field nearly incomparable to similar concerns in *any* other field of technology. India tackling ever-greening concerns in the light of public health will also be justifiable in the light of the *WTO Ministerial Declaration on TRIPS and Public Health* that specifically highlighted that TRIPS 'does not and should not prevent members from taking measures to protect public health'.[26] Consequently, India would be able to demonstrate that no other field of technology has necessitated such regulation than in the field of pharmaceuticals, thereby satisfying the final requirement of 'even-handedness' in its potentially successful demonstration of a 'justification' within the non-discrimination obligation in TRIPS Article 27.1.

B. THE BRAZILIAN 'PRIOR CONSENT' REQUIREMENT

- *THE DISADVANTAGEOUS TREATMENT OF PHARMACEUTICALS*

Article 229-C of the Brazilian *Industrial Property Law No. 9.729/1996* explicitly requires 'prior consent' to be obtained from Brazil's health and sanitary agency (ANVISA) before granting patents for pharmaceutical products or processes. Therefore, as highlighted in the previous Chapter, in a complicated yet observable fashion, the grant of pharmaceutical patents does *not* fall within the exclusive competence of the Brazilian Patents and Trademarks Office (INPI). Although the precise competence of the ANVISA in this patent granting process has been unpredictable for a number of years, it appears to have been limited by a relatively recent Inter-

[26] World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, WT/MIN(01)/DEC/2, Doha, 2001, para. 4.

Agency Ordinance[27] and Administrative Rule.[28] According to these developments, ANVISA is entitled to verify the object of a patent application *in the light of public health*.[29] ANVISA is entitled to with-hold consent only when a patent application discloses a product or process that presents a *health risk*.[30] Such a health risk is deemed to be present, for example, when the pharmaceutical product or process results in a substance that is banned in Brazil.[31] ANVISA's Administrative Rule further states that it could issue *technical opinions* regarding the *patentability* of pharmaceutical products or processes that are of interest to Brazil's Public Healthcare System (*Sistema Único de Saúde*).[32] The Inter-Agency Ordinance notes that when the Patent Office disagrees with ANVISA's technical opinion, the Patent Office should state the *technical grounds* for such disagreement.[33]

Notwithstanding this apparent curtailment of ANVISA's power relating to its ability to examine the patentability criteria of pharmaceutical inventions, it has not completely alleviated the concerns of its critics. In its Special 301 Submission to the United States Trade Representative (USTR) in 2018, PhRMA stated that:

> This "dual examination" is incompatible with Brazil's obligations under the "anti- discrimination" provisions of Article 27.1 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[34]

Recognizing that the recent developments have sought to reduce ANVISA's technical opinions to non-binding opinions, PhRMA notes that there is still much ambiguity as to what constitutes 'health risks' which is still a basis on which ANVISA is entitled to withhold its 'prior consent'.[35] Hence, PhRMA has argued that Brazil's dual examination system must be removed completely. Even the USTR in its Special 301 Report of 2017 noted that this 'duplicative review' process 'lacks transparency, exacerbates delays and prevents patents being examined by the Patent Office'.[36] Noting that there have been developments in 2017, the report further states that US will review these developments and closely monitor the impact of ANVISA's new role.[37]

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[27] Inter-Agency Ordinance No. 1/2017 of 12 April 2017.
[28] RDC 168/2017 of August 2017.
[29] Ibid., Article 2; Inter-Agency Ordinance, n. 27, Article 4.
[30] Ibid., Article 4(1); Inter-Agency Ordinance, n. 27, Article 4(1).
[31] Ibid., Article 4(2).
[32] Ibid., Article 7.
[33] Inter-Agency Ordinance, n. 27, Article 6.
[34] *Special 301 Submission 2018,* n. 4, p. 137.
[35] Ibid.
[36] *2017 Special 301 Report*, n. 3, p. 66.
[37] Ibid.

Similarly, the European Commission in its report on intellectual property protection in non-EU countries has stated that:

> Another continued grave concern for EU stakeholders is the scrutiny of ANVISA in pharmaceutical patent applications before they have been examined by INPI, although *steps have been taken to supposedly realign the procedures with international standards*.[38]

Therefore, many concerns still linger regarding Brazil's 'prior consent' mechanism. The palpable reason for these concerns to have lasted beyond the 2017 developments is that Article 229-C of the *Industrial Property Law* itself has remained unchanged. The text still states that the patentability of pharmaceutical products and processes *depends on the prior consent of ANVISA*. None of the apparent curtailments of its competence are reflected in the Industrial Property Law. Whatever the mandate of ANVISA might be in this process, it is still a rule that applies only to pharmaceutical inventions and imposes an additional hurdle to obtain patent protection for those inventions. Therefore, this *de jure* rule would generate a presumption that it is disadvantageous to pharmaceuticals.

Brazil may attempt to rebut this presumption by demonstrating that the 2017 developments have limited ANVISA's influence under this mechanism, and is therefore, not disadvantageous to pharmaceuticals. As these developments only took place in 2017, it is clearly too soon to evaluate how the new rules have impacted or would impact the functioning of ANVISA. While this will be clearer in time to come, it is submitted that the new rules are facially still too ambiguous to give Brazil any real possibility to rebut such a presumption if a TRIPS violation complaint is brought against it in the near future. As PhRMA has noted in its submissions to the USTR, the concept of 'health risk' has barely been defined under the new rules. There is nothing to prevent ANVISA from interpreting the concept of 'health risk' more broadly to include types of pharmaceutical substances other than those prohibited in Brazil, and thereby withhold its consent for a wide-array of pharmaceutical inventions. This concern is not wholly speculative, as ANVISA has had a history of denying consent for certain types of incremental pharmaceutical inventions alleging that patents for such inventions are detrimental to public health.[39] This is aggravated by the fact that both, the Inter-Agency Ordinance and ANVISA's

[38] *Report on the Protection and Enforcement of Intellectual Property*, n. 5, p. 25. Emphasis added.
[39] See ANVISA, *Technical Note, Clarifications Patent Applications for Pharmaceutical Products and Processes*, 2004, in which ANVISA stated that it would deny 'prior consent' for pharmaceutical inventions that concern new therapeutic uses and new forms of known substances on the basis that they were harmful to public health.

Rule, still expressly state that ANVISA is entitled to analyze patent applications 'in the light of public health'.

It will also be recalled that ANVISA is entitled to provide *technical opinions* regarding the patentability of pharmaceutical inventions that are of interest to Brazil's Public Healthcare System (SUS). A pharmaceutical product or process is considered to be *of interest* to SUS when it relates to a product that has been listed by the Ministry of Health as being relevant for SUS or relates to the treatment of a disease has been similarly listed by the Ministry. As the rules currently stand, the Patent Office could hold differently only by showing technical grounds for its own opinion. There is still much ambiguity as to what technical grounds may serve justify the Patent Office from having its own conflicting opinion relating to the patentability of such a pharmaceutical invention.

Even if the above arguments are potentially too premature, there is another more pressing reason why Brazil is unlikely to rebut the presumption that Article 229-C is disadvantageous to pharmaceuticals. Whatever the impact of ANVISA's patentability assessment might be in the future, there is still a *duplication* of the patentability assessment of pharmaceutical inventions that are of interest to Brazil's Public Healthcare System. As ANVISA's examination is not limited by any time-frames, Article 229-C would necessarily add delays to the patent granting process for those pharmaceutical inventions as they do *not* fall within the exclusive competence of the INPI. This could potentially affect a wide array of pharmaceutical inventions as Brazil may decide on its own as to which pharmaceuticals are vital to its SUS. This duplication of the patentability assessment would also prevent Brazil from claiming that it is 'mere' differential treatment as the entire replication of the patentability assessment *cannot* be regarded as an interpretation or application of the patentability criteria set-out in TRIPS Article 27.1. On the contrary, such a duplication results in a replication of the interpretation and application all the patentability criteria that would lead to policy inconsistencies between the ANVISA and the INPI. Thus, it is submitted that Brazil is unlikely to be able to rebut the presumption that Article 229-C is disadvantageous and would need to be able to demonstrate a 'justification' to defend an inconsistency.

- *ANALYSIS OF A JUSTIFICATION*

❖ *A Legitimate Policy Objective- Public Health*

The rising costs of drugs that followed the introduction of the new Brazilian patent regime was the principal reason for the creation of Article 229-C. It was created to ensure 'better technical standards' in the patentability assessment of pharmaceutical inventions and reduce the impact that pharmaceutical patents were having on its Public Healthcare System by preventing the grant of unworthy pharmaceutical patents.[40] The rationale was that by denying unworthy patents in this fields, the prices of drugs will be reduced through generic competition, which would also reduce the financial impact that patents were having on the Healthcare System. Therefore, Brazil would claim that Article 229-C seeks public health protection by reducing the cost of pubic health, which is one of the most vital policy objectives that could be pursued by a WTO Member in this context.

❖ *Necessity*

As noted in the previous Part of this Chapter, the 'necessity' of a measure must be examined in the light of the importance of the policy objective, the level of contribution of the measure and the availability of other alternatives. It was noted that that these factors should be weighed and balanced in order to determine if a measure is *capable* of contributing towards a stated policy objective within the jurisdiction of a given Member as the public interests mentioned in TRIPS's Objectives and Principles are by themselves progressive long-term objectives that could barely be achieved within a short period of time.

Although the policy objective that Article 229-C pursues is vital to the highest degree, it is submitted that Brazil is to face a number of set-backs in demonstrating the other elements of 'necessity' in this context. The duplicative patentability assessment and non-binding nature of the current scheme is such that the design, structure and operation of Article 229-C makes it incapable of making any contribution towards the protection of public health. Although ANVISA is entitled to provide *technical opinions* relating to the patentability of pharmaceutical inventions that are of interest to its SUS, there is nothing that currently identifies any specific public health concern that ANVISA should examine in relation to such inventions. It is merely

[40] See Inter-Ministerial Explanatory Statement No. 92/99 for Provisional Act No. 2006/99.

meant to duplicate the entire patentability assessment in the hope that it would be more stringent than that of the INPI. It is also unlikely that ANVISA would be able to develop its own more restrictive patentability standards to address any public health concerns as the history of the power struggle between the ANVISA and the INPI shows that this was precisely what the *Inter-Agency Ordinance* in 2017 sought to prevent.

Even if ANVISA adopts restrictive patentability standards and gives a technical opinion as to why a pharmaceutical invention that is of interest to SUS should not be patented, the INPI is now entitled to proceed to grant such a patent by indicating technical grounds for the difference in opinion. The INPI may demonstrate that the policy adopted by ANVISA does not correspond to the patent policy of the INPI. Consequently, the duplicative patentability assessment that results from Article 229-C is such that it only adds delay to the process without any commensurable benefit to public health. It is submitted that this shows the lack of any *genuine* relationship between Article 229-C and the protection of public health. Moreover, the lack of any commensurable benefit to public health and the delays caused by this mechanism to the patenting process renders Article 229-C to be potentially counter-productive in the protection of public health. As such delays would necessarily impede the effective patent life of these pharmaceutical inventions that are of interest to Brazil's SUS, it would deteriorate the incentives to develop the very pharmaceuticals that are vital to its Public Healthcare System.

As to the alternatives that Brazil could have utilized to protect public health by ensuring better technical standards in the granting of pharmaceutical patents, a complainant is likely to suggest that the proper application of the usual patentability criteria would have been a better alternative. This is particularly so as ANVISA is not entitled to scrutinize any particular public health concern relating to pharmaceutical inventions that are of interest to its SUS in a manner that contradicts the patent policy of the INPI. Hence, INPI is already in a position to perform the same task as ANVISA. Two Government bodies performing the same task is problematic particularly in this context, as the history of the power struggle between ANVISA and INPI show that there could be fundamental differences with regard to the policies that they are likely to adopt. In the light of the fact that Article 229-C is incapable of making any contribution towards the protection of public health in Brazil, it appears that providing better teeth to the Patent Office through better technical expertise, training and infrastructure would have been a better alternative that was available to Brazil.

Consequently, while much depends on how the 2017 developments relating to ANVISA's mandate would actually function in practice and how the INPI would perceive ANVISA's technical opinions, the current state of the scheme shows that these issues are potentially fatal to showing a genuine relationship between Article 229-C and the protection of public health. For these reasons Brazil is unlikely to be able to demonstrate its 'necessity', and therefore, a legitimate 'justification' for the disadvantageous treatment that it accords to pharmaceuticals.

❖ *Even-handedness*

If the operation of the new work-flow introduced in 2017 *subsequently* recognizes more competence on the part of ANVISA to scrutinize the patentability of pharmaceutical inventions that are of interest to its SUS by adding certain particular public health dimensions to the patent examination so as to satisfy the notion of 'necessity' that the concept of 'justification' in Article 27.1 demands and ANVISA's opinions are recognized by the INPI, it is submitted that Brazil would *not* have an issue in satisfying the condition of even-handedness. This is because Article 229-C would then ensure better technical standards and prevent unworthy pharmaceutical patents by examining particular public health dimensions of such inventions. Given the detrimental impact that the non-observance of technical standards in the field of pharmaceuticals could have on a WTO Member's public health, it is submitted that Brazil's pre-occupation with pharmaceuticals in this respect would be considered to be 'even-handed'.

C. AUSTRALIAN PATENT TERM EXTENSION SCHEME

- *TRIPS 'PLUS' MEASURES AND THE RULE AGAINST 'DISCRIMINATION'*

The Australian Patent Term Extension scheme provides for the extension of the term of patents that claim 'pharmaceutical substances' for a maximum added period of five years. Prior to examining whether such a scheme is consistent with the non-discrimination obligation in TRIPS Article 27.1, an issue that requires preliminary examination is whether measures that confer rights that go beyond TRIPS's minimum standards *should* abide by the non-discrimination obligation. TRIPS Article 33 requires WTO Members to grant a minimum of a twenty-year term of patent protection that is calculated as from the date of filing of a patent application. The Agreement does not specify any obligation to compensate patentees for the reduction of the effective patent life caused by regulatory processes. Hence, patent term

extension schemes *potentially* extend the term of a patent beyond the minimum term required by TRIPS Article 33 making them TRIPS 'Plus' measures. Whether such measures that go beyond TRIPS's own minimum standards should comply with the non-discrimination obligation in Article 27.1 is informed by TRIPS Article 1.1 that sets-out out the *nature and scope* of TRIPS obligations. It states in relevant part:

> Members may, but shall not be obliged to, implement in their law *more extensive protection* than is required by this Agreement, *provided that such protection does not contravene the provisions of this Agreement*.[41]

Carvalho identifies that the only condition for TRIPS Plus measures is that of *non-contravention* specified in TRIPS Article 1.1.[42] The precise test of non-contravention has not been clearly specified in the Agreement, except for the fact that it should be assessed in the light of the 'provisions of the Agreement'. Speaking in the context of bilateral TRIPS Plus FTA obligations that inhibit TRIPS flexibilities, Henning Grosse Ruse-Khan argues that the condition of non-contravention is not violated when they merely contravene a flexibility that a WTO Member *may* have exercised under the Agreement.[43] To support his argument, he makes a distinction between mandatory and optional TRIPS flexibilities, only the contravention of the former that attracts the non-contravention rule in TRIPS Article 1.1. It is similarly submitted that the non-contravention rule comes into operation when a TRIPS Plus measure contravenes a *mandatory* minimum standard that imposes an obligation on a WTO Member. This includes the non-discrimination obligation in TRIPS Article 27.1 as WTO Members are bound to ensure that their patent rules do not discriminate, *inter alia*, between fields of technology with regard to the availability and enjoyment of patent rights. This reasoning is supported by Carlos Correa who states that the non-discrimination obligation in Article 27.1 is an example of a minimum standard that is potentially contravened by a Member who grants more extensive protection to one field of technology. In his words:

> A more extensive patent protection that discriminates according to the field of technology, the place of invention or whether the infringing products are

[41] Emphasis added.
[42] N. de Carvalho, *The TRIPS Regime of Patents and Test Data*, Fourth edition, Kluwer Law International, 2014, p. 13.
[43] H. Ruse-Khan, *The Protection of Intellectual Property in International Law*, Oxford University Press, 2016, p. 117.

> locally produced or imported may also be deemed a violation of Article 27.1 and, hence, of Article 1.1.[44]

As Correa rightly points out, when a TRIPS Plus measure is inconsistent with non-discrimination obligation in Article 27.1, this necessarily violates the non-contravention obligation in Article 1.1. Thus, TRIPS Plus measures that extend the term of patents beyond the mandated twenty-year term *should* comply with the non-discrimination obligation in Article 27.1.

However, a more difficult issue that particularly relates to measures that extend the term of patents is whether they actually amount to TRIPS Plus measures in the above-mentioned manner. This is because there are instances when it is unclear as to what such measures actually extend. Such measures will not fall within the ambit of TRIPS if such extensions cannot be regarded as conferring a *patent term* that goes beyond TRIPS Article 33. If it does not fall within the ambit of TRIPS in this manner, it would also not constitute '*more extensive protection than required by this Agreement*'. Therefore, such a measure need not satisfy the condition of non-contravention in TRIPS Article 1.1. This in turn depends on whether what is actually extended is the entire patent or whether it is something more specific and narrower than the whole patent. How problematic this determination could be can be observed in the context of Supplementary Protection Certificates (SPC) in the European Union.[45] SPCs grant a maximum of an added five-year period of protection only in respect of the *therapeutic indication* for which the pharmaceutical product has received regulatory approval.[46] Therefore, although Article 5 of the Regulation states that the certificate 'shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations', there is clearly an ambiguity as to whether the SPC mechanism provides a sort of extension that goes beyond TRIPS Article 33.[47]

It is submitted that the Australian scheme does not run into such difficulty. As discussed in the previous Chapter, the Australian scheme extends the *whole* patent provided that it claims a pharmaceutical substance. Although Section 78 of the Act limits the rights of a patentee during this extended period with reference to the pharmaceutical substance and the therapeutic uses of

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[44] C. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, 2007, p. 26.
[45] Regulation (EC) No. 469/2009.
[46] Ibid. Article 2 and Article 4.
[47] See F. Porcuna, 'The Extension of the Exclusive Right to Pharmaceuticals under the European Law: The Supplementary Protection Certificate', *Pharmaceuticals, Policy and Law*, vol. 13, 2011, p. 61.

that substance, it is a fact that the entire patent is extended. Therefore, there is a greater case for the Australian scheme to be considered as a TRIPS Plus measure that falls within the ambit of TRIPS Article 1.1 and requires compliance with the non-discrimination obligation in Article 27.1.

- *THE PREFERENTIAL TREATMENT OF PHARMACEUTICAL PATENTS*

The first step for a complainant is to demonstrate a *prima facie* case of preferential treatment of pharmaceuticals. This would be the case if the complainant could show that an added privilege has been conferred upon the field of pharmaceuticals that relates to the availability or enjoyment of patent rights. Reversing the circumstances in which the disadvantageous treatment of a field of technology could be presumed, preferential treatment could be presumed when a national measure explicitly confers an advantage affecting the availability or enjoyment patent rights that goes beyond the minimum standards mandated by TRIPS. As highlighted in the previous Chapter, the Australian patent term extension scheme is only available to patents that claim 'pharmaceutical substances'[48]. By conferring a maximum five-year extension of the entire patent, it goes beyond TRIPS Article 33 that only requires the patent term to be no less than twenty years as from the date of filing of the patent application. This treatment relates to the *enjoyment* of patent rights as it extends the term of such patents, which would have otherwise lapsed in Australia after twenty years that is calculated from the date of filing of the application.[49] Therefore, the fact that no similar advantage is conferred upon any other field of technology raises a presumption that pharmaceutical patents are accorded preferential treatment and a *prima facie* case of inconsistency with Article 27.1.

The burden then shifts to Australia to either demonstrate that its measure does not actually confer any *preferential* treatment or that such treatment could be 'justified'. Given that its extension scheme constitutes a TRIPS Plus privilege that confers rights that go beyond TRIPS's minimum standards, it is unlikely that Australia could rebut the presumption of preferential treatment. Therefore, Australia would need to establish a 'justification' to defend a finding of inconsistency.

[48] See Patents Act 1990(Cth), Section 72.
[49] See Patents Act 1990(Cth), Section 67.

- *ANALYSIS OF A JUSTIFICATION*

❖ *Legitimate Policy Objectives- Technological and Economic Development*

The first limb that Australia would need to establish is that its scheme pursues a legitimate policy objective. It will be recalled that the objective of the Australian scheme is to provide an 'effective patent life' to pharmaceutical inventions by compensating them for the market delays they face due to the regulatory approval process. As the Explanatory Memorandum to the 1997 Amendment Bill that introduced the current extension scheme states:

> Extensions of up to five years on the standard 20 year term are available for pharmaceutical patents … in recognition of the *exceptionally long development time and regulatory requirements involved in developing and commercialising a new drug*. The aim is to provide an '*effective patent life*', or period after marketing approval is obtained during which companies are earning a return on their investment, more in line with that available to inventions in other fields of technology.[50]

The Australian legislators also intended that such extensions would create an environment that is more attractive to foreign direct investments by pharmaceutical corporations that would in turn benefit its economy.[51] Therefore, there are two distinct but related objectives of the extension scheme. The first is to ensure an effective patent life for pharmaceutical patents and to provide incentives that are 'more in line' with other fields of technology. Secondly, to attract investments and develop Australia's economy. These two objectives could be respectively identified as *technological* and *economic* development. Given the significant level of discretion on the part of the WTO Members to determine which policy objectives that they may legitimately pursue in terms of Article 8.1, it is submitted that both these objectives are legitimate in the context of a 'justification' in TRIPS Article 27.1.

[50] See Ministry for Industry, Science and Tourism, *Explanatory Memorandum for Intellectual Property Laws Amendment Bill 1997*, p. 3, [hereinafter referred to as '1997 Explanatory Memorandum']. Emphasis added.
[51] Ibid.

❖ *Necessity*

The next limb that Australia would need to establish is that its extension scheme is 'necessary' to meet either or both its policy objectives of technological and economic development. The importance of the policy objective, the measure's level of contribution and the availability of alternatives form part of this analysis to determine if the national measure in issue is capable of contributing towards the stated policy objective within the jurisdiction of that Member.

A few points deserve to be mentioned with regard to the importance of the objectives that are pursued by the Australian extension scheme. The promotion of technological development is one of the most vital objectives in the context of TRIPS. While this may not be as intense as the protection of public health in the context of the WTO as a whole, it necessarily fits within the top hierarchy of the policies in the context of the TRIPS Agreement as TRIPS identifies technological development as one of the basic objectives of intellectual property protection. This is evident in its Objectives (Article 7) which provides that the protection of intellectual property rights must promote, transfer and disseminate technology. As technological development is the objective of its own minimum standards, it is difficult to think of any other covered agreement of the WTO in which technological development must be considered to be as vital as under the TRIPS Agreement.

The objective of economic development is identified as an important policy objective to a certain degree in TRIPS Article 8.1 which explicitly provides that WTO Members may adopt measures to promote '*socio-economic* and technological development'. The importance of economic development should be understood in the context of the WTO system and its broader objectives that have been identified in the first Recital of the Preamble to the *Agreement Establishing the Word Trade Organization* (WTO Agreement). It provides as follows:

> Recognizing that their relations in the field of trade and economic endeavour should be conducted *with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand*, and *expanding the production of and trade in goods and services*, while allowing for the *optimal use of the world's resources in accordance with the objective of sustainable development*, seeking both to *protect and preserve the environment* and to enhance the means for doing so

> in a manner *consistent with their respective needs and concerns at different levels of economic development*,[52]

Accordingly, economic development is fundamental to meet the WTO's objectives of raising the standards of living, ensuring full employment, maintaining a steady growth of real income and expanding the production and trade of goods and services. As TRIPS is one of the covered agreements within the WTO's multilateral system, the pursuance of such economic development even in the context of intellectual property protection must be regarded as an important policy objective.

The level of contribution that the Australian measure makes towards each of these objectives deserves some detailed discussion. One of its objectives is to provide and maintain adequate incentives to the pharmaceutical industry in order to promote technological development of this field. Nevertheless, one of the reasons that influenced the Industrial Property Advisory Committee (IPAC) to recommend the total abandonment of the extension scheme in 1984 was its reasoning that the grant of such extensions in the latter part of a patent term is too remote to influence R&D investment decisions made in the early stages of the innovation process.[53] In other words, the IPAC did not find it logical that something bestowed at the end of a patent term could enhance the incentives to engage in R&D and contribute to technological development in this field. The Productivity Commission made similar observations in its Report in 2016, although it did *not* go to the extent of stating that the scheme is *incapable* of it. The Commission found, however, that the scheme had not made any substantial contribution to the technological development of Australia's pharmaceutical industry to the extent that was actually *desired* at the time of its creation.[54] This was because it had found that only 4.3% of the total pharmaceutical patent applications made between 2001-2014 were actually made by Australians. The vast majority of the applications were still being made by foreigners.[55] Hence, its pragmatic observation was that although the scheme is capable of contributing towards greater technological development, there is still a lack of evidence to demonstrate that it has already made any substantial contribution.

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[52] Emphasis added.
[53] See Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, AGPS, 1984, p. 39.
[54] Productivity Commission Inquiry Report, *Intellectual Property Arrangements*, Canberra, 2016, p. 295- 296, [hereinafter referred to as 'Productivity Commission']
[55] Ibid., p. 290.

It was also noted that the scheme seeks to promote economic development by attracting foreign investments. The Pharmaceutical Patents Review Report (PPR) made some interesting observations in this respect. It examined investment data between 1991- 2011 and found that there had not been any noticeable increase in investments by pharmaceutical corporations after the current extension scheme was introduced in 1998.[56] It noted that as at 2011, R&D in Australia only represented a mere 0.3% of the global pharmaceutical R&D, whereas countries like US, Japan and UK represented 53%, 14% and 8% respectively.[57] It pointed out that the reason for this is that the patent term extension scheme is by *itself insufficient* to attract investments. There are several other factors such as R&D costs involved in a particular jurisdiction, the skills available and the location of the headquarters of the parent corporation that play a prominent role in this process.[58] The Productivity Commission Report (2016) also made similar observations after examining the returns submitted by patentees in terms of Section 76A of the Patents Act. It will be recalled that the notification system in this section is the only form of supervision to determine whether the extension scheme was contributing to R&D in Australia, and therefore, the development of its economy. While the Commission found that only a handful of patentees actually submitted R&D information under this provision, only 39% (36 of 92 returns) reported any R&D expenditure in Australia. It also found that of those who chose to invest in Australia, their actual expenditure was very low averaging to a mere $3.9 million a year.[59] The Commission also interestingly noted that the scheme is in fact more likely to influence foreign corporations in planning the launch of a product in a given market rather than at the stage of R&D, again showing that it is rather difficult by itself to attract foreign investments.[60]

What transpires, therefore, is that there is clearly a lack of evidence to show that the Australian scheme has made any significant contribution towards any of its objectives. The current literature and data show that the scheme's actual contribution is anything but astounding. However, it is incorrect to conclude that the absence of such evidence necessarily renders the patent term extension scheme to be incapable of contributing towards technological and economic development. It is submitted that the more reasonable observation that could be made in the light of these statistics is that the measure has not yet met the desired levels of contribution that had been originally intended. The level of contribution is just one of the factors in this

[56] T. Harris, D. Nicol and N. Gruen, *Pharmaceutical Patents Review Report*, Canberra, 2013, pp. 64-80.
[57] Ibid.
[58] Ibid., p. 67.
[59] Productivity Commission, n. 54, p. 295.
[60] Ibid.

holistic analysis as to whether a measure is capable of contributing towards a stated policy objective within the jurisdiction of a given WTO Member. It just might be that notwithstanding these low levels of contribution, the patent term extension scheme is the only realistic option available to Australia to pursue these objectives in this context.

The final factor in this 'necessity' analysis is whether Australia could be considered to have had any other alternative to pursue its objectives. It will be recalled that the Productivity Commission proposed two recommendations to amend the current scheme in 2016. The objective of those recommendations was to reduce the impact that the scheme had on the Australian Pharmaceutical Benefits Scheme (PBS).[61] The first of these recommendations was that the clock to calculate the extended term should begin to run only upon the lapse of 255 working days after making the application for regulatory approval.[62] Secondly, it recommended that the scheme should be limited to patents that claim Active Pharmaceutical Ingredients (APIs).[63]

Although these recommendations were influenced by patent term extension schemes in other jurisdictions, most notably Singapore, the Australian Government did not adopt them because they had a fundamental problem: they did not meet the *desired level* of technological and economic development that Australia had sought to achieve. This is notwithstanding the fact that there was hardly any evidence to show that the current scheme had made any significant contribution in these respects. This is evident in the Government's response to the Productivity Commission Report which reiterated that regulatory processes reduce the effective patent life of all pharmaceutical patents and that the failure to grant extensions in the current manner would erode the incentives to introduce new pharmaceutical products to the Australian market.[64] The reasons why these recommendations fell below the desired level of technological and economic development can be deduced from the submission made by Medicines Australia to the Department of Industry Innovation and Science consequent to the Productivity Commission Report. It highlighted that restricting term extensions only to patents that claim APIs would affect the incentives to engage in R&D relating to follow-on inventions of existing drugs.[65] It

[61] Ibid., p. 298.
[62] Ibid., p. 306.
[63] Ibid.
[64] See Commonwealth of Australia, *Australian Government Response to the Productivity Commission Inquiry into Intellectual Property Arrangements*, August 2017, https://archive.industry.gov.au/innovation/Intellectual-Property/Documents/Government-Response-to-PC-Inquiry-into-IP.pdf, (accessed 28 January 2018), p. 11.
[65] See Medicines Australia, *Submission to the Department of Industry, Innovation and Science on the Productivity Commission's Final Report on Intellectual Property Arrangements in Australia*, February 2017,

also stated that only taking into account a delay that exceeds 255 working days would not reflect the costs and time spent in conducting the clinical trials mandated by the regulatory requirements.[66] Hence, the Commission's recommendations were inconsistent with the very rationale that underpinned the current system.

The desired level of protection of the policy objectives that is sought by the Australian scheme makes it difficult to identify an alternative in this context. Although similar extension schemes are found in the patent systems of many Members of the WTO, they are far from being uniform. They differ significantly with regard to their scope and duration because of the different levels of protection of similar objectives that they seek to achieve.[67] Thus, it would be difficult for a complainant to successfully identify a reasonable alternative in this context.

It is in the light of these factors that the 'necessity' of Australia's scheme must be holistically determined. Although there is currently a lack of evidence to demonstrate that the extension scheme has made any significant contribution towards technological or economic development in Australia, its ability to satisfy the 'necessity' threshold in this context should not be ruled out. This determination should acknowledge the fact that demonstrating how the extension of a patent term contributes or could contribute to technological and economic advancement is not a straightforward task. This is because R&D and investment decisions are commonly influenced by a myriad of factors in any given jurisdiction. In fact, there is barely any evidence to even show that the twenty-year term that is mandated by TRIPS contributes to greater technological and economic development than the shorter terms that existed before the TRIPS Agreement. For example, Grootendorst and Matteo who examine the effect of TRIPS's twenty-year term on pharmaceutical R&D expenditure in Canada argue that although the duration of a patent *may* positively influence R&D decisions in favour of a particular jurisdiction, this is often *set-off* by external factors such price controls that affect the pharmaceutical patent or product.[68] Hence, the lack of evidence to show that the Australian patent term extension scheme has actually contributed towards these policies must considered pragmatically.

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https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20170207-sub-Medicines-Australia-submission-on-PC-Inquiry-into-IP-Arrangements-Final-Report.pdf, (accessed 29 January 2018), p. 7.

[66] Ibid.

[67] For a comparative analysis of the current schemes see Law Library of Congress, *Patent Term Extensions and Adjustments*, Global Research Center, 2016, http://www.loc.gov/law/help/patent-terms/index.php, (accessed 16 January 2018).

[68] P. Grootendorst and L. Matteo, 'The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada', *Healthcare Policy*, vol. 2, no. 3, 2007, p. 63.

Many WTO Members including EU, France, Germany, Israel and Japan have enacted similar schemes that grant patent term extensions for pharmaceutical patents. While they differ with regard to their specificities, there is barely any concrete evidence in any of those jurisdictions to show that such schemes have *by themselves* made significant contributions towards technological or economic development that are usually the objectives of such schemes. The current data in Australia show that pharmaceutical R&D and foreign investments have increased during the past few years, but they do not show that this is purely attributable to its patent term extension scheme. Nonetheless, as Grootenhorst and Matteo have noted, the term of a patent is one of the factors that influence R&D decisions particularly in the field of pharmaceuticals, although this is often set-off by other factors. Thus, it is submitted that even if the contribution that the Australian scheme is capable of making towards technological and economic development has been set off by other factors, its ability to constitute one of the influencing factors to the pharmaceutical industry in making its investment decisions suffices to demonstrate its *capability* to contribute towards these objectives and satisfy the test of 'necessity' in this context.

- *Even-handedness*

The principal concern that the Australian patent term extension scheme seeks to address is the diminution of the effective term of pharmaceutical patents caused by the regulatory approval process. However, pharmaceuticals are not the only products that face marketing delays due to such regulatory processes. As the Industrial Property Advisory Committee (IPAC) noted in 1984, inventions relating to automotive emissions, building and sanitary systems, telecommunications and even agrochemicals similarly face significant regulatory delays in marketing their products.[69] Hence, the majority of the IPAC was of the opinion that it was illogical to single out the detriment caused to pharmaceuticals and grant extensions solely on that basis.

It was noted, however, that this majority opinion was *not* followed by the then Government, nor by any subsequent Government to date. The reason for this can be deduced from the Explanatory Memorandums that introduced the extension schemes in 1989 and 1998. In the former, the Government noted that the scheme is meant to acknowledge the time necessarily taken to obtain marketing approval for pharmaceutical products.[70] In the light of the IPAC's

[69] Industrial Property Advisory Committee, n. 53, p. 39.
[70] See *1997 Explanatory Memorandum*, n. 50, p. 2.

observation that the detriment suffered by pharmaceuticals could not be singled-out, this statement in the memorandum was a clear indication that the Government perceived the detriment caused to pharmaceuticals to be greater than that caused to any other product category. The same reasoning can be found in the Explanatory Memorandum to the 1998 Bill that introduced the current scheme. It stated that the scheme is meant to recognize the '*exceptionally* long development time and regulatory requirements' involved with a new drug.[71]

The fact that pharmaceuticals are so singled-out by many WTO Members who currently grant similar patent term extensions suggests that there is some justifiable reason for this. It is submitted that the reason can be traced to the time and costs associated with innovation in the field of pharmaceuticals. In its report in 2016, the Productivity Commission noted that development costs are 'significant' in the pharmaceutical industry.[72] Referring to the previous Pharmaceutical Patents Review Report (2013), the Commission stated that:

> The data and clinical trials that inform approval processes can be costly. The PPR noted that nearly half — $700 million of the estimated $1.5 billion — of R&D costs are spent on clinical trials. Regulatory approval costs are increasing due to the growing size (number of patients) and complexity of clinical trials (increasing the cost per patient).[73]

It further stated:

> The multi-stage development and regulatory approval process also impacts on the time it takes to get pharmaceutical products to market. Medicines Australia submitted that the time to market is 'between 10 and 15 years'.[74]

Medicines Australia had further submitted to the Commission that the average cost to develop a single drug was a near US$2.6 billion. Although the Commission noted that there was some doubt regarding the accuracy of these figures given the confidential nature of the data used in this determination, a factor that evidently increased costs were the substantial risks *inherent* in the field of drug development. It noted that many drugs fail during the stage of clinical trials and never make it to the market. Medicines Australia had stated that almost 93% of potential therapeutic molecules never make it beyond the clinical stage.[75] Consequently, unlike the IPAC,

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[71] Ibid, p. 3.
[72] Productivity Commission, n. 54, p. 287.
[73] Ibid.
[74] Ibid.
[75] Ibid., p. 289.

the Commission did not doubt that these factors rendered pharmaceuticals to require some form of special treatment.

Therefore, although there are other fields of technology that face regulatory delays, the times, costs and risks involved in the innovation of pharmaceuticals show that regulatory delay affects the pharmaceutical industry more severely. This is reinforced by the fact that, to the knowledge of the author, none of the WTO Members currently grant such extension schemes to any other field of technology. Thus, until other fields of technology could demonstrate that the regulatory process affects them in an equal manner, it is submitted that Australia's preoccupation with the field of pharmaceuticals would be considered to be even-handed.

CHAPTER 7

CONCLUSION

This final Chapter discusses a range of important implications that potentially flow from the more developed interpretation of the rule against the 'discrimination' of *fields of technology* that has been revealed in this thesis and highlights some important developments in relation to the TRIPS Agreement that serve to buttress the argumentation in this work. Accordingly, it consists of four Parts. Part A scrutinizes the practical implications relating to the circumstances in which a complainant may demonstrate a *prima facie* case of inconsistency with the rule against the 'discrimination' of fields of technology *and* the implications on a respondent who may seek to rely on the autonomy that this thesis has argued to have been preserved within the concept of 'justification'. Part B discusses the theoretical implications that this interpretation of the rule relating to 'fields of technology' could have on the interpretation and application of the concept of 'discrimination' with regard to the *other* grounds in Article 27.1 *and* the National Treatment and Most-Favoured Nation Treatment obligations of the TRIPS Agreement. Part C discusses how the only TRIPS amendment to date and the WTO Panel Report in *Australia-Plain Packaging* lends support to the main reasoning in this thesis as to how the concept of 'justification' ought to operate in the context of the non-discrimination obligation relating to fields of technology. Finally, Part D entails an overall conclusion and explains how this 'unravelling' of the non-discrimination obligation highlights the balance that is mandated between WTO obligations and the autonomy of the WTO Member States to pursue important national interests.

A. PRACTICAL IMPLICATIONS ON THE RULE CONCERNING FIELDS OF TECHNOLOGY

- *TRIGGERING A CLAIM*

The rule against the 'discrimination' of fields of technology constitutes a general prohibition of 'discrimination' of a field of technology that affects the availability and enjoyment of patent rights. There are no standards of comparison between the fields of technology, nor any *de minimis* level of disadvantageous/preferential treatment that a complainant needs to demonstrate. What is required of a complainant is the demonstration of the

disadvantageous/preferential treatment of a field of technology that affects the *availability* or *enjoyment* of its patent rights. Demonstrating a *prima facie* case would be straightforward where a national measure explicitly imposes *additional* criteria for the patentability of inventions *or* imposes explicit *limitations* or *advantages* on the scope of patent rights of inventions that belong to a field of technology. A respondent may rebut such a presumption by showing the legitimate exercise of its autonomy under Article 27.1, Article 30 or Article 31. The examination in the previous Chapters of three national measures that explicitly confer such treatment on pharmaceutical inventions demonstrates that members are likely to impose such explicit conditions/limitations on patent rights when the concerns relating to a group of inventions are so significant that they warrant the enactment of legislative provisions that are specifically directed towards such inventions.

Where, on the other hand, the disadvantageous/preferential treatment is not so explicit and is allegedly caused by a national measure that is not explicitly linked to a particular group of inventions, this assessment demands a deeper analysis. Such is the realm of *de facto* 'discrimination' of TRIPS Article 27.1. In this context, it specifically refers to two types of national measures: (a) those that facially only appear to confer *differential treatment* on certain types of inventions but serve in practice to subject them to disadvantageous/preferential treatment, and (b) those that appear to confer disadvantageous/preferential treatment on all inventions but serve in practice to affect only a certain group of inventions. It must be noted, however, that although WTO Members may choose to subject certain fields of technology to *de facto* disadvantageous/preferential treatment in order to pursue vital policy interests, this might not be common in the context of patent law as WTO Members are more inclined to address vital concerns in a given field of technology by explicitly imposing additional hurdles for their patentability or by explicitly imposing restrictions/advantages that affect their patent rights.

In order to establish a *prima facie* case of inconsistency in such *de facto* circumstances, a complainant would need to adduce satisfactory evidence to support its claim that a measure that is *not* explicitly disadvantageous/preferential to a particular field of technology, *in fact* accords disadvantageous/preferential treatment to that field of technology. While the type of evidence to demonstrate this should necessarily relate to the *application* of a given measure, the level of proof required would depend on the particular facts of the case. As Chapter 4 of this thesis

highlighted, the WTO Panel Report in *Canada- Pharmaceuticals*[1] and the final arbitral award in *Eli Lilly v. Canada*[2] show that a complainant has a higher evidentiary burden when establishing a *prima facie* case in such a context. This higher evidentiary burden that the tribunals have seemed to require reflect a constant problem that WTO tribunals have had to deal with relating to the *de facto* application of the substantive non-discrimination obligations (National Treatment and Most-Favoured Nation Treatment) under the covered agreements: to ensure that these obligations are not thwarted while simultaneously ensuring that they are not interpreted too broadly so as to inhibit the autonomy of the Members that has been preserved under the covered agreements. In a similar vein, these tribunals seemed to have acknowledged that the *de facto* application of the rule against 'discrimination' of fields of technology should *not* inhibit two important forms of autonomy that Members have under the TRIPS Agreement, and that this must be reflected in the level of proof necessary to demonstrate a *prima facie* case in such a context. Accordingly, where a *de facto* an allegation concerns *availability* of patent rights, the level of proof required should recognize the autonomy of the Members to interpret and apply the usual patentability criteria that have been set-out in TRIPS Article 27. Similarly, the level of proof required when such an allegation relates to the *enjoyment* of patent rights should acknowledge the autonomy of the Members to make limited exceptions and grant compulsory licences that have been preserved in TRIPS Article 30 and Article 31.

The need to preserve such autonomy particularly in the context of the *de facto* application of the rule against the 'discrimination' of fields of technology in TRIPS Article 27.1 is supported by the *WTO Ministerial Declaration on TRIPS and Public Health*. It will be recalled that it was declared that TRIPS is not meant to prevent Members from taking measures to protect public health.[3] Although this Declaration was made in the context of compulsory licences and public health, it is submitted that it highlights the significance all the other policy spaces that have been preserved in the TRIPS Agreement that permit the Members to pursue vital public policies *such as* public health and that this should *not* be inhibited even by the *de facto* application of the non-discrimination obligation in TRIPS Article 27.1. Therefore, while the standard of review to demonstrate a *prima facie* case of 'discrimination' of a field of technology is the same whether the allegation is *de jure* or *de facto*, a complainant will bear a greater and more

[1] See Panel Report, *Canada- Patent Protection of Pharmaceutical Products*, WT/DS114/R, para. 7.105, where the Panel states that it has not been proved that the 'adverse effects' of the regulatory review exception was limited to the pharmaceutical industry.
[2] *Eli Lilly & Co. v. Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Final Award, 16 March 2017, para. 439.
[3] World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, WT/MIN(01)/DEC/2, Doha, 2001, para. 4.

significant *initial* evidentiary burden in the case of the latter before any burden shifts to the respondent.

- *AUTONOMY WITHIN THE CONCEPT OF 'JUSTIFICATION'*

A respondent who may wish to rely on the concept of 'justification' that has been comprehensively examined in the previous Chapters of this work should be able to demonstrate that its measure is 'necessary' to pursue a legitimate policy objective and that such treatment is applied in an even-handed manner within its jurisdiction. The following sub-sections examine the practical implications that the scrutiny of each of these elements in the context of this obligation potentially have on a respondent who may seek to rely on this concept.

❖ *Legitimate Objectives*

The legitimacy of the purported exercise of the autonomy that is acknowledged by the concept of 'justification' fundamentally rests on whether the respondent could demonstrate that it pursues a policy objective that could be traced to TRIPS Article 8.1. The protection of public health and nutrition are explicitly mentioned in Article 8.1 and necessarily constitute legitimate objectives in this context. The significance of protecting public health is further buttressed by the *WTO Ministerial Declaration on the TRIPS Agreement and Public Health*. Article 8.1 also preserves a significant level of discretion on the part of a member to legitimately pursue a wide array of other policy objectives provided *it* is of the opinion that it is of vital importance to its 'socio-economic and technological development'. Therefore, it was observed in the context of the Australian patent term extension scheme that even the pursuance of technological and economic development by addressing industry concerns over marketing delays caused by regulatory processes constitute legitimate policy objectives within the concept of 'justification' in this context.

This discretion on the part of a Member to determine which policies it may legitimately pursue in terms of Article 8.1 was acknowledged by the WTO Panel in *Australia- Plain Packaging* where it noted that:

> … Article 8.1 express the intention of drafters of the TRIPS Agreement to preserve the ability for WTO Members to pursue certain legitimate societal interests…[4]

While the Panel noted that the protection of public health is evidently one such societal interest, it stated that the societal interests that a Member may legitimately pursue have *not* been exhaustively set-out in Article 8.1.[5] Consequently, one of the most fundamental implications of the concept of 'justification' within the non-discrimination obligation is the apparent breadth of the policy objectives that a respondent may legitimately pursue to 'justify' the disadvantageous/preferential treatment that it accords to a field of technology.

❖ *The Test of Necessity*

The test of 'necessity' in the context of a 'justification' in Article 27.1 is borrowed from Article 8.1. It was noted that a concept of 'justification' that is created in the context of the non-discrimination obligation in Article 27.1 to acknowledge the autonomy preserved in Article 8.1 cannot disregard the textual reference to such a concept in Article 8.1. This involves the 'weighing and balancing' of several factors including the importance of the policy, the measure's level of contribution and even the availability of alternatives if any have been suggested by a complainant. However, it was argued that the threshold of 'necessity' in this context is rather unique because of the nature of intellectual property law rules and the nature of the policies that fall within the ambit of Article 8.1. The TRIPS Agreement acknowledges that the balance that Article 8.1 is meant to achieve between intellectual property protection and other societal interests as highlighted in TRIPS Article 7 (Objectives) is progressive and cannot be achieved in the short term. Therefore, it was argued that 'necessity' in this context would be satisfied if a respondent could demonstrate the capability on the part of a measure to contribute towards the stated policy objective within its own jurisdiction. Consequently, the *lack* of proof that a national measure has already contributed towards the policy objective would not be fatal in this context.

The examination of the potential consistency of certain national measures in the previous Chapter also demonstrated that the scrutiny of such *capability* should appreciate the fact that a

[4] Panel Report, *Australia- Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/R, WT/DS441/R, WT/DS456/R and WT/DS467/R, para. 7.2404.
[5] Ibid., para. 7.2406.

measure could have such capability only by forming part of a host of other national measures that pursue similar objectives in a given jurisdiction. This is because intellectual property law measures are unlikely to have a direct impact on the policies traceable to Article 8.1. Hence, the lack of evidence to demonstrate any direct nexus between the national measure and its impact on the stated policy should not be fatal to this analysis. Hence, it was argued that the Australian patent term extension scheme would potentially satisfy this test of 'necessity'. Although there is a lack of evidence to show that the current scheme has already contributed to any technological or economic development in Australia, such extensions are recognized to be one of the many factors that influence R&D in the pharmaceutical sector that demonstrate the capability of the scheme to contribute to technological and economic development.

However, it was also noted that in order to benefit from these flexibilities inherent in this 'necessity' assessment, a respondent needs to be able to demonstrate that the design, structure, and application of its measure is such it has the *ability* to make some contribution towards the policy objective. Therefore, however important a measure's objective may be, such an inability on the part of a measure would prevent the flexible analysis of 'necessity' from coming into operation. Hence, in the context of the Brazilian measure that requires 'prior consent' from the sanitary agency (ANVISA) when patenting pharmaceutical inventions, it was argued that the duplicative patent assessment carried out by ANVISA without any binding effect of its findings, coupled with its inability to add any public health dimension to the patentability assessment potentially renders the mechanism to be incapable of ensuring a more stringent patentability assessment of pharmaceutical inventions in order to protect public health. Consequently, a vital implication of this is that WTO Members should be cautious in structuring their technology specific patent law measures as they should be able to demonstrate such structural ability of their measures if they intend to benefit from the unique 'necessity' threshold within the concept of 'justification' in the non-discrimination obligation.

Another layer is added to this 'necessity' analysis if a complainant is able to identify an alternative that is available to the respondent that it could have utilized to pursue its policy objective. A valid alternative in this context is one that does not accord *any* disadvantageous/preferential treatment to the field of technology *or* accords such treatment to a *lesser* degree and yet meet the respondent's *desired level of protection*. It was noted that such alternatives should *not* be merely theoretical to a respondent in the light of its standard of development. Hence, one of the basic implications, which is also prevalent in other areas of

WTO law, is that the less developed a respondent is, the more likely that it would be able to demonstrate that an alternative is not reasonably 'available'.

Moreover, it was noted that a respondent is entitled to demonstrate that an alternative does *not* meet the desired *level of protection* that it has sought to achieve by its own measure. It was apparent in the previous Chapter that examined the potential consistency of the Indian Section 3(d) requirement and Brazilian 'prior consent' mechanism that a complainant is likely to suggest that a national measure is essentially *superfluous* where it confers *disadvantageous treatment* upon a field of technology in the context of the *availability* of patent rights in order to pursue a policy objective. This is because a complainant is likely to point out to a minimum patent law standard of the TRIPS Agreement as an 'available alternative' that already addresses the public policy concern that the respondent has sought to address. For example, in the case of India's Section 3(d) requirement, it was noted that the alternative likely to be suggested is the 'inventive step' requirement that is used in other jurisdictions to address the problem of ever-greening in the field of pharmaceuticals. Similarly, in the case of the Brazilian 'prior consent' requirement, it is likely to be the correct application of the patentability criteria that is meant to ensure that only deserving inventions are granted patents in any field of technology.

However, the examination of whether a respondent's measure is in fact superfluous in the light of a suggested TRIPS minimum standard must give sufficient regard to the *level of protection* of the policy objective that the respondent seeks to achieve. It was noted that this level of protection sought by a respondent would be greater than a TRIPS alternative if the measure addresses a *specific* concern in a *specific* field of technology in a more concrete fashion than the TRIPS alternative would generally be capable of. In other words, the reasons for the pre-occupation with one field of technology must be evident in the design and structure of the national measure that shows that it addresses a specific concern in that field of technology. This does not mean that a respondent must show that its measure is necessarily better at achieving the policy objective, but that it is *capable* of doing something that cannot ordinarily be done by a TRIPS suggested alternative.

Hence, it was argued that India would potentially be in a better position to demonstrate that the 'inventive step' requirement is *not* an adequate alternative to Section 3(d) as the latter seeks to protect public health by addressing ever-greening concerns in three *distinctive* ways that demonstrate the heighted level of public health protection that India seeks to achieve. Firstly, as the Indian Courts have held, Section 3(d) is a patent eligibility standard rather than a

patentability standard. Therefore, the *modus* that India uses to address 'ever-greening' is very different to the way in which the 'inventive step' requirement could do it. Secondly, it specifies what renders a new form of a known substance to become patentable: it is the enhancement of the known efficacy of that substance. 'Efficacy' has been interpreted to mean 'therapeutic efficacy' in the case of pharmaceuticals. Consequently, a new form of a known pharmaceutical substance should be better at curing diseases compared to its previous known form. Thirdly, it sets out a presumption that new forms of known chemical substances shall be regarded to be the same as the known substances unless there is a significant difference in relation to their efficacy. These features show that Section 3(d) addresses ever-greening concerns more distinctly compared to the 'inventive step' requirement that generally requires an inventive advancement compared to the prior art.

It was argued that such a distinctiveness is not present in the case of the Brazilian 'prior consent' mechanism. As highlighted in the previous Chapter, the current mechanism relating to Article 229-C of the Brazilian *Industrial Property Law* does not permit its health authority (ANVISA) to add any public health dimension to the patentability assessment of pharmaceutical inventions even when they are of interest to its Healthcare System. Further, the recent 2017 developments in Brazil demonstrate that ANVISA is not entitled to adopt any policy that would be inconsistent with that of the Patent Office (INPI). This would potentially prevent Brazil from demonstrating that Article 229-C pursues any heightened level of public health protection than that which could ordinarily be achieved by applying the usual patentability criteria that are meant to examined by the Patent Office. These factors should necessarily be acknowledged by any member who intends to utilize its autonomy within the concept of 'justification'.

- *The Assessment of Even-Handedness*

Even-handedness is the final requirement that a respondent should demonstrate to establish a legitimate 'justification'. As highlighted in the previous Chapters, it serves to ensure that a respondent has exercised its right to 'justify' the disadvantageous/preferential treatment of a field of technology in *good faith*. It does this by acknowledging that a respondent Member is entitled to address public interest and industry-oriented concerns in a given field of technology, *but* that it should have addressed similar concerns in other fields of technology. It was argued that traceable to the need to acknowledge the economic and developmental disparities among the WTO Members, particularly in the context of patent law, is the need to recognize that the same public interest concern in a given field of technology could have a variable impact among

the WTO Members when left unregulated. These repercussions to a given WTO Member might be so severe that such a concern in a given field of technology might be *incomparable* to any similar concerns in other fields of technology. The public interest concerns surrounding the field of pharmaceuticals are fitting examples. The poorer and less developed a Member is, the slightest imbalance between patent rights and public interests in favour of the former could have a disastrous impact on the public health of its citizens. Such were India's concerns relating to ever-greening when it was introducing legislation to recognize product patents for pharmaceutical inventions. It foresaw that ever-greening would have a substantial impact on its public health by increasing the prices of drugs and putting them beyond the reach of a majority of its citizens without any corresponding therapeutic benefit to the public. These concerns were such that, except for some limited discussion relating to similar practices in the field of agro-chemicals, the Indian legislature did not think that it was comparable to the problem of ever-greening in any other field of technology. Thus, a WTO tribunal is entitled to examine if a member's pre-occupation with one field of technology is genuine under this notion of 'even-handedness'. However, one of the most pragmatic implications of the *WTO Ministerial Declaration on the TRIPS Agreement and Public Health* that highlighted the significance of the protection public health is that it is foreseeable that public interest concerns in the field of pharmaceuticals would almost always render them incomparable to similar concerns in other fields of technology.

Therefore, what fundamentally transpires from this discussion of the implications is that although a complainant could demonstrate a *prima facie* inconsistency with this obligation where a national measure *explicitly* imposes a restriction or privilege that relates to the availability or enjoyment of patent rights of a field of technology, this is equalized by the concept of 'justification' that acknowledges a significant degree of autonomy on the part of the Members to justify such treatment.

B. THE THEORETICAL IMPLICATIONS

- *THE OTHER GROUNDS OF DISCRIMINATION IN ARTICLE 27.1*

It will be recalled that TRIPS Article 27.1 prohibits 'discrimination' with regard to the availability and enjoyment of patents rights on *three* grounds: the place of invention, the field of technology and whether products are imported or locally produced. This thesis scrutinized the rule against the 'discrimination' of *fields of technology*. It examined the concept of

'discrimination' and the concept of 'justification' that the Panel recognized in *Canada-Pharmaceuticals* from the perspective of *fields of technology*. Consequently, it did not address what constitutes 'discrimination' as to the 'place of invention' or of 'products whether imported or locally produced'. Nonetheless, given the manner in which TRIPS's unique tripartite non-discrimination norm has been phrased in Article 27.1, the most palpable theoretical implication that deserves discussion relates to what extent the interpretation of the rule against the 'discrimination' of fields of technology *could* inform the interpretation of the obligation in relation to the other grounds in Article 27.1. This is particularly important in the light of the fact that the Panel in *Canada-Pharmaceuticals* formulated the concept 'discrimination' in Article 27.1 as the 'unjustified imposition of differentially disadvantageous treatment',[6] thereby highlighting that this formulation is applicable to *all* the grounds in Article 27.1 and *not* only to fields of technology. Hence, although this thesis built on this formulation from the perspective of fields of technology, the interpretation of the rule relating to fields of technology must be capable of providing some useful insights as to how the non-discrimination obligation must be understood in the context of the other grounds in Article 27.1.

The telling commonality between the three grounds of discrimination is that they all apply in the context of the *availability* and *enjoyment* of patent rights and are not directly concerned with the right-holders themselves. However, an observable distinction between 'fields of technology' and the other two grounds is that the latter effectively serve to protect *foreigners* from being discriminated. As highlighted in Chapter 2, one of the most pressing concerns that has been caused by the ambiguity relating to the concept 'discrimination' with regard to 'products based on their place of production' is whether it prohibits local working requirements of patented inventions. A strict interpretation of 'discrimination' in such a context would potentially mean that all local working requirements that provide for the grant of compulsory licences due to the lack of or insufficient working of patented inventions would be *inconsistent* with this obligation. Nonetheless, it will be recalled that the non-discrimination obligation in its final form was introduced as a 'compromise solution' when the negotiators could neither agree on the permissibility of local working requirements under the TRIPS Agreement, nor on the adoption of a more streamlined Paris Convention's Stockholm style compulsory licensing mechanism that permitted compulsory licenses for non-working only upon the lapse of four years from the date of the patent and subject to the ability of a patentee to justify its inaction by

[6] Panel Report, *Canada- Pharmaceuticals*, n. 1, para. 7.94.

legitimate reasons.[7] Such a compromise would be reflected only if this facet of the non-discrimination norm is also capable of acknowledging the legality of some form of local working requirements, at least according to the conditions set out in the Paris Convention.

Thus, the Panel in *Canada- Pharmaceuticals* rightly indicated that the concept of 'justification' is even applicable in these circumstances. The rationale is similar to that identified in this thesis in relation to 'fields of technology'. Just as much as the Objectives and Principles in TRIPS, together with the context relating to WTO's substantive non-discrimination norms, highlight the need for a concept of 'justification' within the rule relating to fields of technology to preserve the autonomy of the Members recognized in TRIPS, there is a similar need under the other grounds of discrimination in Article 27.1. Thus, as the Panel appears to have suggested in *Canada- Pharmaceuticals*, the interpretation of 'discrimination' based on the other grounds in Article 27.1 should recognize the ability on the part of a respondent to 'justify' the disadvantageous/preferential treatment in those contexts.

The substantive content of a concept of 'justification' and how it ought to operate within the grounds of 'place of invention' and 'place of production' would necessarily require further scrutiny in interpreting those obligations. However, it is foreseeable that the type of measures that a respondent may seek to 'justify' in the context of 'place of invention' and 'place of production' would often relate to *technology transfer*, the scrutiny of which would largely depend on *economic* factors. While the nature of those economic factors and how they ought to be scrutinized would inform the concept of 'justification' in those contexts, the most fundamental theoretical implication that flows from the analysis of the concept of 'justification' within the rule relating to fields of technology is that any such determination must acknowledge the varying economic, developmental and technological standards among the WTO Members.

This has been acknowledged to an extent by Thomas Cottier, Shaheeza Lalani and Michelangelo Temmerman in their examination of the TRIPS compatibility of local working requirements.[8] They state that national rules that explicitly *exclude importation* as a means of satisfying local working requirements for *all* patented inventions constitute 'discrimination' based on *place of production* under TRIPS Article 27.1.[9] They argue that this is because there

[7] See Paris Convention for the Protection of Industrial Property (as amended on September 28, 1979), Article 5A(4).
[8] T. Cottier, S. Lalani and M. Temmerman, 'Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements', *Journal of International Economic Law*, vol. 17, no. 2, 2014, p. 437.
[9] Ibid., p. 452.

may be instances when importation would suffice to meet the TRIPS objectives of *technology transfer*.[10] They also state:

> … there is no discrimination where the wording of a legislated local working requirement captures only *a particular patentee's abusive 'failure to work' the patented invention*.[11]

Consequently, they argue that whether importation is sufficient to meet TRIPS's objectives of technology transfer and whether the failure to work a patent is 'abusive' are dependent on a range of economic factors that should be determined in the light of the 'heterogeneity in capacity' across the Members of the WTO.[12] While this is indicative of what may constitute a 'justification' in the context of the ground of 'place of production', as they have noted, the economic factors should be examined in the light of the developmental and economic capabilities of that Member.

Hence, certain features of the concept of 'justification' that this thesis has highlighted in relation to the ground of 'fields of technology' are already observable in the academic literature that deal with the other grounds of discrimination in Article 27.1. However, more detailed studies are required to identify the specific economic factors and how they must be examined in the light of the state of development of a given Member to acknowledge their divergences in the process of permitting them to 'justify' the disadvantageous/preferential treatment within the grounds of 'place of invention' and 'place of production'.

- *THE NATIONAL TREATMENT AND MOST-FAVOURED NATION TREATMENT OBLIGATIONS IN TRIPS*

Chapter 4 of this thesis argued that the National Treatment (NT) and Most-Favoured Nation (MFN) Treatment obligations in TRIPS potentially have a broader scope of application than the NT/MFN obligations under the other covered agreements for the following reasons. Firstly, they apply to 'nationals' in relation to an extensive concept referred to as the 'protection of intellectual property rights'. The latter has been defined very broadly in TRIPS Article 1(2) and Footnote 3 to TRIPS Articles 3 and 4 as *including* matters affecting the availability, acquisition, scope, maintenance, enforcement and use of intellectual property rights addressed in the

[10] Ibid., p. 453.
[11] Ibid. Emphasis added.
[12] Ibid., p. 460.

Agreement. Secondly, they require the treatment accorded to such national to be 'no less favourable'. This has been interpreted broadly by the WTO Panel in *EC- Geographical Indications* to mean that there would be less favourable treatment if 'extra hurdles' are imposed on nationals of another WTO Member to exercise their intellectual property rights.[13] Thirdly, there are no exceptions that are applicable to these obligations.

However, it was also argued that unlike the NT/MFN obligations under the other covered agreements, the absence of any mechanism to balance TRIPS's NT/MFN obligations with the autonomy of the WTO Members to pursue vital public policies has not yet highlighted the need to recognize any justificatory concept in this context. This is probably because TRIPS by itself recognizes certain exclusions and limitations that permit a Member to pursue public policy objectives to some limited extent in relation to each form of intellectual property right that has been addressed therein.[14] Further, the WTO Panel on *EC- Geographical Indications* attempted to justify its opinion as to why TRIPS's NT obligation should *not* be subject to public policy exceptions by stating that intellectual property rights are *negative* rights. Thus, it explained that Members are inherently entitled to pursue legitimate public policy objectives as such measures mainly lie *outside* the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.[15]

It is submitted that this reasoning is not sufficient to completely rule out the need for a justificatory concept within TRIPS's NT/MFN obligations. To begin with, it is incorrect to state that public policy measures mainly lie outside the scope of intellectual property rights. For example, the *WTO Ministerial Declaration on TRIPS and Public Health* and TRIPS Article 31*bis* clearly acknowledge that intellectual property rights have a great impact on the protection of public health. More importantly, in the light of the autonomy on the part of the Members that this thesis has shown to have been preserved in TRIPS's Objectives and Principles, the need for a justificatory concept will become apparent when a Member seeks to address a concern outside its own jurisdiction by curtailing or conditioning the availability or enjoyment of intellectual property rights of nationals of another Member. While none of the Panel or Appellate Body Reports to date dealing with these obligations have highlighted the need for such a concept, it is uncertain as to how long more the WTO tribunals could ignore such a need

[13] See Panel Report, *European Communities- Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs (US)*- WT/DS174/R, para. 7.137.
[14] For e.g TRIPS Article 13 (Exceptions to Copyright), Article 17 (Exceptions to Trademarks), Article 20 (Encumbrances of Trademark Use), Article 30 (Exceptions to Patent Rights), Article 31(Compulsory Licensing of Patented Inventions).
[15] Panel Report, *European Communities- Geographical Indications*, n. 13, para. 7.210.

given that the conflict between TRIPS's NT/MFN obligations and the autonomy of the WTO Members to pursue important national interests has come to the spotlight in two recent disputes.

In *UAE- Goods/Services/TRIPS*, Qatar made a request to establish a Panel to consider certain measures adopted by the United Arab Emirates (UAE) alleging that the latter had adopted a host of measures that individually and collectively affected trade in goods, services and intellectual property rights of its nationals in violation of GATT, GATS and TRIPS.[16] In relation to TRIPS Articles 3 (NT) and 4 (MFN), Qatar alleged that these measures made it impossible for Qatari nationals to enforce and use their intellectual property rights in the UAE.[17] UAE objected to the establishment of a Panel contending that it was forced to take such measures in response to Qatar's funding of terrorist organizations and that GATT Article XXI, GATS Article XIVbis and TRIPS Article 73 entitled Members to take action in the interest of *national security*. Subsequently, the Dispute Settlement Body deferred the establishment of the Panel.[18] Although UAE relied on the security exceptions in TRIPS, this dispute demonstrates the mounting conflict between the NT/MFN obligations and Member autonomy.

A similar instance where this conflict has become apparent is in *China- Transfer of Technology*.[19] The European Union requested consultations with China alleging that the latter's imposition of mandatory contract terms concerning the importation of technology into China amounted to a violation of TRIPS's NT (Article 3) obligation. These consultations are still ongoing and if China's measures are found to fall within the ambit of Article 3, it is foreseeable that China would seek to justify them on the basis that they aim to ensure technology transfer, an objective that is so vital in the context of the TRIPS Agreement. With this tug of war between TRIPS's NT/MFN obligations on the one hand, and the autonomy of the WTO Members that has been preserved in its Objectives and Principles on the other, that is likely to manifest more clearly in future disputes concerning these obligations, it is foreseeable that the recognition of some concept that recognizes the autonomy of the Members in the context of these obligations is imminent.

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[16] See Request for Establishing of a Panel by Qatar, *United Arab Emirates- Measures Relating to Trade in Goods and Services and Trade-Related Aspects of Intellectual Property Rights*, WT/DS526/2.
[17] Ibid., para. 17.
[18] WTO Secretariat, *Qatar seeks WTO Panel review of UAE measures on goods, services and IP rights*, 2017, https://www.wto.org/english/news_e/news17_e/dsb_23oct17_e.htm, (accessed 13 August 2018).
[19] See Request for Consultations by the European Union, *China- Certain Measures on the Transfer of Technology*, WT/DS549/1.

C. TRIPS ARTICLE 31*BIS* AND PANEL REPORT IN AUSTRALIA-PLAIN PACKAGING

This part discusses two important developments in relation to the TRIPS Agreement that support the nature of the concept of 'justification' that this thesis has propounded in relation to the rule against the 'discrimination' of fields of technology.

- *ARTICLE 31BIS: THE SIGNIFICANCE OF PUBLIC HEALTH*

It has been argued that the concept of 'justification' in the context of the non-discrimination obligation serves to acknowledge the autonomy of the Members that has been preserved in the Objectives and Principles of the TRIPS Agreement. Thus, in the context of the ground of 'fields of technology', it was submitted that a Member is entitled to 'justify' the disadvantageous/preferential treatment of a field of technology by demonstrating that it is necessary to pursue a legitimate policy objective and that such treatment is applied even-handedly. The examination of whether measures such as the Indian Section 3(d) requirement and the Brazilian requirement of 'prior consent' would potentially satisfy the elements of this concept of 'justification' vitally demonstrated that the nature of the autonomy that the concept recognizes is most substantial in the context of public health and pharmaceuticals. It was argued that this is because its constitutive elements must be examined more flexibly to recognize the significance of public health and the varying economic, technological and developmental capabilities among the Members to address concerns relating to pharmaceutical inventions. The need for such a flexible analysis of the concept of 'justification' when a measure seeks to protect public health is reinforced by TRIPS Article 31*bis*.

Article 31*bis* is currently the only amendment to the Agreement since its inception in 1994. It permits a WTO Member to grant export oriented compulsory licences in respect of *pharmaceutical products* to enable the *exportation* those products to Members with *insufficient or no pharmaceutical manufacturing capacity*.[20] This was significant, at least in principle, as TRIPS Article 31(f) originally required products manufactured under compulsory licences to be *predominantly* for the supply of the *domestic* market. By permitting the exportation of pharmaceutical products manufactured under its mechanism, it removed certain safeguards in relation compulsory licences that other fields of technology still continue to enjoy under TRIPS

[20] See Annex to the Protocol Amending the TRIPS Agreement, Article 31*bis*, para. 1.

Article 31. Although Article 31*bis* authorizes WTO Members to *de jure* disadvantage pharmaceutical inventions in this manner, nothing has been mentioned as to how it could be reconciled with the non-discrimination obligation in TRIPS Article 27.1.

The Protocol to the amendment merely states that Members *shall* not challenge any measures taken in conformity with Article 31*bis*.[21] It is not clear as to whether this is because it constitutes an explicit *exception* to Article 27.1 *or* because the conformity with its conditions renders such measures to be *consistent* with the non-discrimination obligation. The first of these possibilities is unlikely given that the 'subject to' clause in Article 27.1 that explicitly recognizes certain exceptions to the non-discrimination obligation has remained unchanged. The stronger argument is that Article 31*bis* is consistent with the non-discrimination obligation. The manner in which it could be so can now be understood in the light of the previous Chapters of this thesis that have provided a more detailed understanding of the rule against the 'discrimination' of fields of technology and its concept of 'justification': Article 31*bis* constitutes an *explicit* 'justification' in the context of the non-discrimination obligation that recognizes the autonomy of the Members to protect public health. The reason for public health to be so singled out by Article 31*bis* is clear from the history relating to the amendment.

At the Fourth Ministerial Conference in Doha, the Ministers noted that WTO Members with 'insufficient or no manufacturing capacities in the pharmaceutical sector' face difficulties in making effective use of the compulsory licences under the TRIPS Agreement.[22] This was caused by the combined effect of TRIPS Article 31(f) and (h) which required any such authorization to be 'predominantly for the supply of the domestic market of the Member authorizing such use' and to be subject to the payment of 'adequate remuneration'. Thus, the Ministers instructed the TRIPS Council to find an expeditious solution to this problem. On the recommendation of the TRIPS Council, the General Council adopted a decision in August 2013 to temporarily waive TRIPS obligations in Article 31(f) and (h) with respect to *pharmaceutical products*.[23] Evidently, the General Council was not merely concerned as to how a WTO Member may protect its own public health. More importantly, it was concerned as to how a WTO Member could protect public health in the territory of another WTO Member. Subsequently, it adopted a decision to amend TRIPS and thereby make these waivers permanent, which came into force in January 2017 upon being accepted by two-thirds of the WTO Members.

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[21] Ibid., para. 4.
[22] See Ministerial Declaration, n. 3, para. 6.
[23] This waiver Decision was adopted by the General Council in the light of a statement read out by the Chairman as reflected in paragraphs 29-31 of the minutes of the General Council meeting, WT/GC/M/82.

It is apparent that Article 31*bis* was meant to address the inability of certain lesser developed country Members to make effective use of the compulsory licence mechanism in the context of pharmaceuticals as some of them did not have any pharmaceutical manufacturing infrastructure. Therefore, the principal rationale for Article 31*bis* was the recognition that pharmaceutical manufacturing capacity varied among the WTO Members. In terms of scope, this concern was addressed broadly. For example, 'pharmaceutical manufacturing capacity' is determined in relation to the specific *product* in question.[24] In other words, it is the insufficiency or lack of manufacturing capacity to produce a specific pharmaceutical product, rather than the general pharmaceutical manufacturing capability, that entitles a Member to benefit from this mechanism. In the light of such differences in capability among the Members of the WTO, Article 31*bis* recognized the necessity of WTO Members to issue export oriented compulsory licences in order to protect public health of lesser developed country Members. In this process, it acknowledged that the inability to use compulsory licences *in the context of pharmaceuticals* was a deeper concern than in any other field of technology in the light of its impact on public health. Consequently, Article 31*bis* is a manifestation of the flexible analysis that the concept of 'justification' is supposed to entail in the context of public health and pharmaceuticals. Not only does it highlight the legitimacy of pursuing public health, but it also supports the argument in this thesis that the analysis of the requirement of 'necessity' and 'even-handedness' should acknowledge the diverging economic, developmental and technological circumstances pertaining to the WTO Members, which has explicitly been done by Article 31*bis*.

- *AUSTRALIA- PLAIN PACKAGING: THE NEXUS BETWEEN INTELLECTUAL PROPERTY LAW MEASURES AND PUBLIC POLICY OBJECTIVES*

This thesis argued that the determination of whether a measure that subjects a field of technology to disadvantageous/preferential treatment is 'necessary' to pursue a legitimate policy objective must be examined *flexibly*. It was highlighted that this is because of the intrinsic nature of intellectual property law measures. Their impact on public policy objectives such as public health, technological development is not direct and is dependent on a number of other factors pertaining to a given WTO Member. Thus, it was further argued that the level of contribution required under the concept of 'necessity' in this context should be satisfied when

[24] See Article 31*bis* para. 2(a)(iii). Also see M. Abbas and S. Riaz, 'WTO "Paragraph 6" System for Affordable Access to Medicines: Relief or Regulatory Ritualism?', *The Journal of World Intellectual Property*, vol. 21, no. 1-2, 2018, p. 32.

the measure is shown to have the capability to contribute towards the policy even in combination with a host of other national measures.

This flexible determination of the nexus between intellectual property law measures and public policy objectives was acknowledged by the WTO Panel in *Australia- Plain Packaging*. This is one of the first disputes where a WTO tribunal had to address the conflict between TRIPS obligations and the protection of public health. In this dispute, several complainants alleged that Australia's Tobacco Plain Packaging (TPP) measures that imposed certain restriction on the use of trade marks on tobacco products were incompatible with, *inter alia*, the TRIPS Agreement. It was specifically alleged that the TPP measures imposed restrictions on the use of trade marks on tobacco products that constituted 'unjustified encumbrances' to trade mark use in violation of TRIPS Article 20.

The Panel found that the TPP measures constituted 'special requirements' that 'encumbered' the use of trade marks,[25] and therefore, the compatibility of the TPP measures was dependent on whether they were '(un)justified'. To identify what is 'unjustified' in this context, the Panel turned to the Objectives and Principles of the Agreement, which was the first ever instance that a WTO tribunal substantively dealt with these provisions. The Panel noted that each provision of the Agreement had to be interpreted in the light of the Objectives and Principles,[26] reiterating the sentiments expressed by the *WTO Ministerial Declaration on TRIPS and Public Health*.[27] The Panel even boldly declared, although subject to an appeal on this very point,[28] that Paragraph 5 of the *Declaration* constitutes a 'subsequent agreement' in terms of the Article 31(3)(a) of the Vienna Convention.[29] It noted that Article 8.1 specifically constitutes useful context in interpreting the concept of 'unjustified' in Article 20 as it preserves the ability on the part of a Member to address legitimate societal interests,[30] and that public health is evidently one such interest.[31]

The Panel further noted that whether an encumbrance is 'unjustified' depends on the following:

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[25] Panel Report, *Australia- Plain Packaging*, n. 4, para. 7.2173-7.2292.
[26] Ibid., para. 7.2398-7.2403.
[27] Ministerial Declaration, n. 3, para. 5.
[28] See Australia- Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, *Notification of an Appeal by Honduras under Article 16.4 and Article 17 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), and under Rule 20(1) of the Working Procedures foe Appellate Review*, WT/DS/435/23, p. 2.
[29] Panel Report, *Australia- Plain Packaging*, n. 4, para. 7.2409.
[30] Ibid., para. 7.2404.
[31] Ibid., para. 7.2406.

(a) The nature and extent of the encumbrance (bearing in mind the legitimate interests of a trademark owner),
(b) The reasons for the special requirements, and
(c) Whether the reasons provide sufficient support for the resulting encumbrance.[32]

After identifying the nature and extent of the encumbrances that the Australian TPP measures had caused to the use of trade marks on tobacco products, the Panel identified that the *reason* for the TPP measures (its objective) was to 'improve public health by reducing the use of, and exposure to, tobacco products'.[33] The most impactful analysis relates to how the Panel examined if those public health concerns 'sufficiently supported' the encumbrances on use of the trade marks. In the light of the risk that tobacco had caused to public health, notwithstanding submissions from several parties that the TPP measures would not be effective in reducing the use of tobacco products, the Panel found that the *capability* on the part of the TPP measures to improve public health even in combination with other tobacco-control measures sufficed to satisfy this requirement. In the words of the Panel:

> … TPP measures are applied address an exceptionally g*rave domestic and global health problem involving a high level of preventable morbidity and mortality*. The fact that these special requirements, as part of the overall TPP measures and *in combination with other tobacco-control measures maintained by Australia, are capable of contributing, and do in fact contribute*, to Australia's objective of improving public health by reducing the use of, and exposure to, tobacco products, suggests that the reasons for which these special requirements are applied provide sufficient support for the application of the resulting encumbrances on the use of trademarks.[34]

The Panel also stated that the removal of design features on retail packaging of tobacco products was 'apt' to reduce the appeal of tobacco products and protect public health.[35] As the burden was on the complainants to demonstrate that the encumbrance was 'unjustified' under Article 20, the Panel found that they had failed to do so because there was sufficient evidence to demonstrate that the TPP measures were *capable* of promoting public health.

[32] Ibid., para. 7.2529.
[33] Ibid., para. 7.2586.
[34] Ibid., para. 7.2592.
[35] Ibid., para. 7.2593.

This analysis by the Panel demonstrates a fundamental acknowledgement on the part of a WTO tribunal that the right of a Member to adopt the type of measures that fall within the scope of TRIPS Article 8.1 should be recognized broadly, and that this must be reflected in the assessment of the nexus between intellectual property law related measures and the important policy objectives that such measures seek to pursue. It acknowledged that the public health concerns relating to tobacco were such that the restrictions imposed in the context of trademark law that had *some capability* to mitigate those concerns had to be consistent with the TRIPS Agreement if the balance between intellectual property rights and other vital interests specified in TRIPS Article 7 is to be achieved. It is this broader analysis that thesis argued to form part of the 'necessity' assessment under the concept of 'justification' in the rule against the 'discrimination' of fields of technology. Hence, *Australia- Plain Packaging* is clear indication that WTO tribunals are willing to scrutinize the consistency of intellectual property law measures that pursue vital public policy objectives in a more flexible manner as argued in this thesis, acknowledging the difficulties in demonstrating a clear nexus between such measures and the objectives being pursued.

D. OVERALL CONCLUSION AND THE BROADER IMPLICATIONS

The developed interpretation of the rule against the discrimination of fields of technology in this thesis highlights the type of autonomy that the Panel in *Canada- Pharmaceuticals* sought to recognize in its formulation of this obligation. By identifying the substantive content of the concept of justification in this obligation, this work intended to provide the WTO Members with the necessary impetus to utilize this autonomy and subject fields of technology to disadvantageous or preferential treatment to pursue important national policy objectives and meet the requisite balance with intellectual property protection that is mandated by TRIPS Article 7. The examination of the potential consistency of certain national measures currently found among the WTO Members that explicitly subject pharmaceutical inventions to differential treatment highlighted certain important aspects relating to the concept of 'justification' that a Member should have regard to when structuring its technology specific patent rules in a manner that is compatible with Article 27.1. That said, it deserves to be highlighted that this autonomy must be exercised with a significant level of responsibility. Members should acknowledge that the political, economic, social and cultural circumstances immensely vary among the WTO Members, and therefore, the manner in which their patent systems could affect those circumstances within their jurisdictions vary even more. In effect, technology specific patent rules of one Member could hardly be transplanted into another

Member in *toto*. Thus, the adoption of any technology specific patent rule must be preceded by a comprehensive examination relating to the measure's capability to contribute towards the intended policy objective within the Member's jurisdiction.

The 'unravelling' of the non-discrimination obligation relating to fields of technology highlights a bigger picture relating to WTO obligations. It highlights the balance that must be struck between WTO obligations and the autonomy of the Members to pursue important national interests. This is traceable to the Preamble to the *WTO Agreement* (Marrakesh Agreement) that signifies the importance of 'sustainable' development which lingers throughout the WTO's multilateral system.[36] The interpretation of the non-discrimination obligation in TRIPS Article 27.1 highlighted the importance of the concept of justification to achieve this balance. This is evident even in the jurisprudence relating to the *Technical Barriers to Trade Agreement* (TBT), where WTO tribunals have sought to achieve such a balance by creating concepts in the interpretation of its obligations. Therefore, the broader implication of this thesis relates to the significance of this balance for the proper functioning of the WTO system.

[36] See the First Sentence of the Preamble to The WTO Agreement which provides 'Recognizing that their relations in the fields of trade… in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so *in a manner consistent with their respective needs and concerns at different levels of economic development*'.

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