"Ducking" TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)

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This paper is an evaluation of the decision in Novartis AG v. Union of India, where the Madras High Court decided on both, the constitutionality of s. 3(d) of the Indian Patents Act, 1970 and its compatibility with the TRIPS regime. The authors agree with the Court insofar as the court upheld the constitutionality of the section. They are, however, critical of the Court's decision to 'duck' out of deciding TRIPS compatibility on jurisdictional grounds. The authors disagree with the reasoning and contractual framework within which the Court found it had no jurisdiction, and posit that principles of constitutional law ought to have been used instead. It is argued that although the Madras High Court had the jurisdiction to adjudicate the present dispute, given the dualist approach of the Indian legal system in the enforcement of treaty obligations, it could not have in any event enforced TRIPS obligations.

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A separate paper focussing only on section 3(d) and the various crudities inherent in this section has been published in S.C.RIPT-ed. See S. Basheer and T.P.Reddy, "The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)" 5 S.C.RIPT-ed 2 (August 2008).

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I. Introduction

Glivec, a path-breaking anti-cancer drug by Novartis[1] propelled Indian patent law onto the world stage in an interesting theatre involving TRIPS and the yet unresolved issue of pharmaceutical patents and their impact on access to medicines.

In 2006, the Indian patent office rejected a patent application covering Glivec (or 'Gleevec' as it is known in the United States). The rejection stemmed, *inter alia*, from a unique section in the Indian patent regime (section 3(d)) that prohibits the patenting of new forms of existing pharmaceutical substances that do not demonstrate significantly enhanced "efficacy".[2]

Not only did Novartis appeal the patent office decision, but in a rather controversial move, it challenged the TRIPS[3] compatibility and constitutionality of section 3(d). The Madras High Court ruled that section 3(d) was constitutional.[4] It also held that it did not have jurisdiction to rule on the TRIPS issue. This paper will critically examine the constitutionality and TRIPS compatibility issues thrown up by section 3(d). It will argue that the court was right in defending the constitutionality of section 3(d). It will also go on to demonstrate that section 3(d) is compatible with TRIPS.

However, it will question the court's ducking of the TRIPS issue by claiming that it lacked jurisdiction on this count. In particular, it critiques the reasoning of the Court and argues that the Court ignored a number of sound Indian precedents in favour of outdated case law from abroad.

II. The Glivec Patent Saga

Like all drug sagas, the story of Glivec begins with two outstanding scientists, who rarely figure in the narratives that are doing the rounds today.

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1. Novartis AG v. Natco Pharma and Others, Indian Patent Office, Application No.1602/MAS/1998 (25 January 2005), available at http://lists.essential.org/ pipermail / ip-health/2006-March/009200.html.
2. Section 3(d), Patents Act, 1970.
3. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 (1994).
4. Novartis AG v. Union of India, (2007) 4 M.L.J. 1153 [Madras High Court].

In 1960, Peter C Nowell, then a junior faculty member at the University of Pennsylvania School of Medicine, together with a graduate student, David Hungerford, discovered a genetic mutation in patients with Chronic Myelogenous Leukemia (CML), a debilitating form of cancer. The discovery of this abnormality – designated the "Philadelphia chromosome" after the city in which it was discovered – broke fresh ground and spurred the search for a potential cure for CML.[5] In the 1990s, researchers closed in on a promising candidate, "Imatinib", a free base.[6] In 1993, Novartis filed a patent covering this free base and all pharmaceutically acceptable salts.[7]

Imatinib was then further researched upon and improved – first, by converting it to a particular salt form, namely "imatinib mesylate". From this salt, Novartis found that the most stable version was a particular polymorphic form, namely the beta crystalline form. Novartis then formulated the beta crystalline form of imatinib mesylate into a pharmaceutically useful drug, Glivec.[8]

The patent dispute that sets the tone for this paper centres around the beta crystalline form of imatinib mesylate referred to above. To date, 40 patents covering this polymorph have been granted to Novartis in various countries.[9] However, owing to the unavailability of drug patents in India until 1 January 2005, Novartis claimed this polymorph[10] in a "mailbox" application.[11]

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5. G.A. Koretzky, *The Legacy of the Philadelphia Chromosome*, 117 J. CLINICAL INVESTIGATION 2030 (2007).
6. B. Vastag, *Leukemia Drug Heralds Molecularly Targeted Era*, 92(1) J. NAT'L CANCER INST. 6-8 (2000). See also *Gleevec: Highlighting the Power of Rational Drug Design*, 18(4) J. YOUNG INVESTIGATORS (2008).
7. U.S. Patent No. 5,521,184 (issued May 28, 1996).
8. Novartis AG v. Natco Pharma and Others, Indian Patent Office, Application No.1602/MAS/1998 (25 January 2005), *available at* http://lists.essential.org/pipermail /ip-health/2006-March/009200.html
9. *Novartis, Glivec Patent Case in India: FAQs, available at* http://www.novartis.com/downloads/about-novartis/india-glivec-patent-case-faq.pdf. However, in pleadings filed before the Madras High Court, Novartis claims that it filed patent applications covering the beta crystalline form in over 50 countries and that it had procured patents in 35 of them. *See* Novartis AG v. Union of India, Writ Petition No. 24759 of 2006, ¶ 9 (High Court of Judicature at Madras).
10. Application No.1602/MAS/98 (July 17, 1998).
11. Under Article 65 of TRIPS, India had 10 years from the date of coming into force of TRIPS to implement product patent protection in pharmaceuticals. However, in the interim, as per Article 70.9 of TRIPS, all applications claiming pharmaceutical inventions were to be accepted and put away in a mailbox, to be examined in 2005 – these applications are commonly referred to as 'mailbox applications.' Pursuant to a

Pursuant to the 2005 amendment to India's patent regime,[12] which introduced product patents for pharmaceuticals, the mailbox application by Novartis was opened and examined. The grant of a patent was opposed by several generic drug companies (and an NGO, the Cancer Patients Aid Association (CPAA)) on several grounds including:

i) lack of novelty/anticipation;

ii) lack of significantly enhanced "efficacy" under section 3(d);

iii) obviousness, and

iv) wrongful priority.

Agreeing with the above arguments, the Assistant Controller of Patents rejected the patent application.[13] Aggrieved by this rejection, Novartis AG, along with its Indian subsidiary, Novartis India, filed two writ petitions in the Madras High Court. These petitions not only sought a reversal of the Assistant Controller's order, but also a declaration that Section 3(d) was unconstitutional and in violation of India's obligations under TRIPS.[14]

WTO dispute filed by the United States against India for a failure to comply with this TRIPS provision, India amended her patent regime to provide for such a "mailbox" facility. *See* The Patents (Amendment) Act 1999 (Act 17 of 1999). This Act was given retrospective effect from 1 January 1995. *See* WTO Appellate Body, *India: Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997), *available at* http://docsonline.wto.org/imrd/directdoc.asp?D DFDocuments/t/WT/DS /50ABR.WPF. Novartis, Glivec Patent Case in India: FAQs, available at http://www.novartis.com/downloads/about-novartis/india-glivec-patent-case-faq.pdf. However, in pleadings filed before the Madras High Court, Novartis claims that it filed patent applications covering the beta crystalline form in over 50 countries and that it had procured patents in 35 of them. See Novartis AG v. Union of India, Writ Petition No. 24759 of 2006, ¶ 9 [Madras High Court].

12. The Patents (Amendment) Act, 2005 was published as law in the Gazette of India on April 5, 2005.

13. Novartis AG v. Natco Pharma and Others, Indian Patent Office, Application No.1602/MAS/1998 (25 January 2005), *available at* http://lists.essential.org/pipermail/ip-health/2006-March/009200.html. It bears noting that this case also involved significant issues pertaining to Exclusive Marketing Rights (EMRs). For an account of the EMR issues and the ensuing litigation on this count, *see* S. Basheer and T.P. Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 S.C.RIPT-ED 2 (2008).

14. Novartis AG v. Union of India, Writ Petition No. 24759 of 2006 (High Court of Judicature at Madras).

Pursuant to a government notification,[15] the High Court transferred the first petition to the Intellectual Property Appellate Board (IPAB), a specialist tribunal set up to deal with appeals from the various intellectual property offices across the country. As on the date of writing this paper, the matter was still pending before the IPAB.[16]

In order to contextualize the constitutional challenge to section 3(d), one needs to delve briefly into the merits of the patent dispute before the IPAB, i.e. whether Novartis' beta crystalline form is patentable or not under section 3(d).

III. Section 3(d): The Structure and Context

Section 3 is the key section on "patent eligibility" and lists out what are not "inventions" under the Indian Patents Act. Section 3(d) lists out one such non eligible patentable subject matter:

> 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 process results in a new product or employs at least one new reactant.
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> Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures

15. The notification under the Section 117G, Patents (Amendment) Act, provided that all pending appeals in the High Court shall be transferred to the newly constituted Appellate Board. *See* Notification by the Ministry of Commerce & Industry, No. 12/15/2006-IPR-III (Mar. 2, 2007) *available at* http://ipindia.nic.in/ipr/patent/gazetteofindia_apr2007.pdf.

16. *See* http://www.ipab.tn.nic.in/ for more details on the IPAB. The IPAB is currently embroiled in a controversy around the appointment of one of its members, Mr. Chandrasekharan, who was the Controller of Patents when the patent office rejected Novartis' application. When Novartis objected to the appointment of Mr. Chandrasekharan on the grounds of bias, the IPAB decided to hear the matter without Mr. Chandrasekharan i.e. without a technical expert. The High Court confirmed the IPAB Decision to hear the appeal without a patent expert. However, Natco Pharma, one of the parties opposing Novartis in this case, objected to this ruling by the High Court. Section 84(2) of the Trade Marks Act, 1999 states that every IPAB Bench sitting in a patent matter must consist of at least one technical member i.e. a patent expert. *See* C.H. Unnikrishnan, *Natco to challenge HC Ruling on Glivec Patent Case*, Mint (Nov. 18, 2007) *available at* http://www.livemint.com/2007/11/18180746/Natco-to-challenge-HC-ruling-o.html.

> 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.**

In essence, section 3(d) aims to prevent a phenomenon commonly referred to as "ever-greening"[17] by providing that only those pharmaceutical derivatives that demonstrate significantly enhanced efficacy are patentable.[18]

According to a report of the US National Institute of Healthcare and Medicines (NIHCM):[19]

> Drug manufacturers patent a wide range of inventions connected with incremental modifications of their products, including minor features such as inert ingredients and the form, colour and scoring of tablets.

The underlying assumption behind section 3(d) is that derivatives, such as salt forms, polymorphs, isomers etc. that are structurally similar to known pharmaceutical substances are likely to be functionally equivalent as well, and if this is not the case and the new form of an existing substance works better than the old form, it is up to the patent applicant to demonstrate this and justify the claim to a patent.

To this extent, section 3(d) draws a distinction between "ever-greening" and incremental innovation.[20] By making derivatives with enhanced efficacy patentable, section 3(d) encourages the sequential development of existing products or technologies to help bring in improved products that address unmet public health needs.

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17. Under one definition, "ever-greening" occurs when a manufacturer "stockpiles" patent protection by obtaining separate 20-year patents on multiple attributes to a single product. *See* Press Release, *Patentee Attorneys Challenge Assertions re FTA Patent Practices* (Aug. 4, 2004) *available at* http://www.ipta.com.au/forms&notices/FTA_Release.doc.

18. During the Parliamentary debates, Sri Kamal Nath, Minister of Commerce and Industry, in response to concerns by other Parliamentarians over "me too" drugs and the likely impact on prices, stressed that Section 3(d) was introduced to prevent "ever-greening." Suresh Kurup, a Parliamentarian, specifically cited the ongoing case of Glivec to demonstrate the ill effects of ever-greening. *See* LOK SABHA DEBATES (Mar. 22, 2005) (statement of Suresh Kurup) *available at* http://164.100.24.230/Webdata/datalshom001/dailydeb/22032005.htm.

19. *Changing Patterns of Pharmaceutical Innovation*, NAT'L INST. HEALTH CARE MGMT. (2002) *available at* http://www.nihcm.org/~nihcmor/pdf/innovations.pdf.

20. Classifying all "incremental innovations" as tantamount to "ever-greening" is misguided. *See* S. BASHEER, LIMITING THE SCOPE OF PHARMACEUTICAL PATENTS AND MICRO-ORGANISMS: A TRIPS COMPATIBILITY REVIEW (Intellectual Property Institute 2005).

In order to determine whether the Novartis invention is more efficacious than an earlier known form or a mere "ever-greened" variety, let us examine what the invention entails. Broadly speaking, it involves a transition from the discovery of a free base in the laboratory to the useful drug, Glivec. The various steps in this transition can be encapsulated as under:

i) Synthesizing imatinib as its free base, a compound that was patented in the US, EU and several other countries.[21] However, this could not be patented in India, owing to the fact that in 1993, India did not provide product patents for pharmaceutical substances.

ii) Converting the free base to a particular salt form, imatinib mesylate, by adding methanesulfonic acid.

iii) Crystallising the imatinib mesylate to obtain the beta crystalline form, which is allegedly the most stable polymorphic form of the salt. A patent application was filed for this and it is this application that is the subject matter of dispute.[22]

iv) Formulating the beta crystalline form of imatinib mesylate into a pharmaceutically useful drug, Glivec.

Novartis claims that the active ingredient in Glivec (beta crystalline form of imatinib mesylate) is more effective than the imatinib free base, since it displays better bio-availability properties, i.e. it is absorbed more easily into the blood.[23] To this effect,

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21. 184 Patent, *supra* note 7. *See also* corresponding European Patent No. 0564409.

22. Novartis AG v. Natco Pharma and Others, Indian Patent Office, Application No.1602/MAS/1998 (25 January 2005), *available at* http://lists.essential.org/pipermail/ip-health/2006-March/009200.html. Novartis also filed a patent application covering the alpha crystalline form of imatinib mesylate, which is currently being opposed by Okasa, an Indian pharmaceutical company. However, Novartis claims that that the Beta form *"stores better, is less hygroscopic, is easier to process and guarantees a constant quality of the final drug product."* *See* Novartis AG v. Union of India, Writ Petition No. 24759 of 2006 at ¶ 4. Interestingly, CIPLA claims that it owns a process patent covering the alpha crystalline form and that it has been selling a drug containing this particular form. *See* C.H. Unnikrishnan, *Novartis Faces Fresh Patent Fight in India*, MINT (Jan. 1, 2008) *available at* http://www.livemint.com/2008/01 /10000215/Novartis-faces-fresh-patent-fi.html.

23. In its writ petition filed before the Madras High Court, Novartis claimed that, *"the Beta Crystalline form of Imatinib Mesylate also results in a higher bio-availability over the 1993 compound and, hence, differs significantly in properties with regard to efficacy."* Novartis AG v. Union of India, Writ Petition No. 24759 of 2006. *See also* G. Kamath, *Interview with Paul Herrling, Head of Corporate Research, Novartis AG*, BUS. WORLD (Feb. 19, 2007) *available at* http://www.businessworldindia.com /feb1907/indepth04.asp.

it submitted evidence before the Assistant Controller demonstrating an increase in bio-availability of upto 30%. However, the Assistant Controller held that this was not sufficient to constitute "increased efficacy":[24]

> As per the affidavit, the technical expert has conducted studies to compare the relative bio-availability of the free base with that of beta crystalline form of imatinib mesylate and has said that the difference in bioavailability is only 30% and also the difference in bioavailability may be due to the difference in their solubility in water. The present patent specification does not bring out any improvement in the efficacy of the beta crystal form over the known substances, rather it states the base can be used equally in the treatment of diseases or in the preparation of pharmacological agents wherever the beta crystal is used. Even the affidavit submitted on behalf of the Applicant does not prove any significant enhancement of known efficacy.

As can be seen from the above, the decision of the patent office is not very illuminating and the patent controller did not give any detailed reasons as to why he thought the beta crystalline form lacked enhanced efficacy.

It is hoped that a final resolution of this dispute at the IPAB will provide guidance in this regard.

IV. Section 3(d) and TRIPS Compatibility

As mentioned in the introduction, Novartis challenged both the TRIPS compatibility and constitutionality of section 3(d). It bears mention that the TRIPS challenge was couched in constitutional law terms i.e. that the Constitution of India mandated the honouring of international treaty commitments. However, for analytical purposes, we treat them separately (under different headings) in this paper.

The Madras High Court avoided making a determination on the TRIPS issue by holding that it did not have jurisdiction in this regard. It noted that the proper forum to bring this before would be the Dispute Settlement Body (DSB), a body under the WTO (World Trade Organisation) Agreement.[25]

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24. *Novartis AG*, No.1602/MAS/1998.

25. *Novartis AG*, No.1602/MAS/1998, at ¶ 8. It is interesting to note that the Swiss government indicated that it was not willing to take up cudgels on behalf of Novartis. *Swiss Govt. not to take Novartis case to the WTO*, Bus. Standard (Aug. 8, 2007) *available at* http://www.businessstandard.com/common/storypage_c.php?leftnm=10&autono=2 93771.

Interestingly, it used a "contractual" approach to justify its lack of jurisdiction i.e. it held that an international treaty such as TRIPS amounted to a contract between nations. Therefore, it was to be interpreted in accordance with normal contractual principles. The court held as below:

> When such participating nations, having regard to the terms of the agreement and the complex problems that may arise out of the agreement between nation to nation, decide that every participating nation shall have a Common Dispute Settlement Mechanism, we see no reason at all as to why we must disregard it. ....International Agreement possesses the basic nature of an ordinary contract and when courts respect the choice of jurisdiction fixed under such ordinary contract, we see no compelling reasons to deviate from such judicial approach when we consider the choice of forum arrived at in International Treaties.[26]

We argue that the Madras High Court was wrong in relying on an overly simplistic contractual framework to assess whether or not a domestic court could enforce an international treaty. Rather, it ought to have assessed this issue from the vantage point of constitutional law. Supreme Court precedents suggest that keeping in line with a dualist tradition, the Indian Constitution precludes the applicability of the "direct effect" theory of international treaties in India.

A. Does TRIPS exclude the jurisdiction of the Indian Judiciary?

As per jurisdictional terms agreed to by member states in the Dispute Settlement Understanding (DSU),[27] the dispute settlement board (DSB) could resolve any disputes between member states regarding any of the WTO Agreements including TRIPS. However, it is important to note a critical distinction between a jurisdictional clause that forces member states to subject themselves to the jurisdiction of the WTO and one that clearly excludes any other forum from having jurisdiction. Whilst the DSU supports the former, it does not endorse the latter, as explained below.

The WTO provides some level of automacity by ensuring that once a member state complains of a WTO violation to the DSB, the defendant member

26. Novartis AG v. Union of India, (2007) 4 M.L.J. 1153, at ¶ 8 [Madras High Court].

27. Dispute settlement mechanism of the WTO is governed by the DSU. *See* Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2, Marrakesh Agreement Establishing the World Trade Organization, *available at* http://www.wto.org/english/tratop_e/ dispu_e/dsu_e.htm.

state has to subject itself to the jurisdiction of the WTO.[28] This is made clear by Article 23.1 of the DSU which gives member states the right to have recourse to the WTO dispute settlement mechanism, when faced with an allegedly WTO-inconsistent measure adopted by another member state.[29]

However, Article 23.2 qualifies Article 23.1 by stating:

> ..in such cases, members shall not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding...

As can be seen from the above, Article 23 prevents a complaining member state from unilaterally determining that there has been a WTO violation. In other words, the Swiss government (home government of Novartis) cannot unilaterally determine that section 3(d) violates TRIPS. However, nothing in Article 23 of the DSU or any of the WTO agreements prevents an Indian court from making such a determination.

In other words, India or any other defendant member state is free to give what is commonly termed as a "direct effect" to its international obligations and provide complaining member states or their nationals the option of raising WTO issues before its domestic courts. Nothing in the WTO Agreement prevents this.

The Madras High Court was therefore wrong in holding that it lacked jurisdiction to entertain the TRIPS challenge by Novartis, since the WTO/TRIPs agreement provided for an exclusive dispute settlement mechanism. Rather, it ought to have held that its inability to strike down section 3(d) as contravening TRIPS stemmed from the fact that Indian law did not permit the direct enforcement of international treaties. We discuss this in detail below.

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28. *Understanding the WTO: Settling Disputes, A Unique Contribution, available at* http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm.

29. *"When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding." National and Regional Law*, 1 J. INT'L ECON. L. 83-122 (1998).

A. Does the TRIPS agreement have a "direct effect" in India?

A scholarly paper defines the doctrine of "direct effect" to mean:

> a private person in a state (or union) may base a claim in, and be granted relief from, the domestic courts of that state against another private person or the state on the basis of the state's obligations under an international treaty. Such claims can be made without a transformation of the obligation by national or regional rule makers. They may equally be made against implementing legislation on the grounds that such legislation is not compatible with international law.[30]

The concept of direct effects is normally applicable in countries with a monist tradition, as opposed to a dualist tradition.[31] The Indian Constitution, and, in particular, Articles 51(c) and 253 desist from stipulating that a treaty is to have "direct effect" in India. Article 51(c) directs the State to observe principles of international law. However, since this Article is only a Directive Principle of State Policy, it is non-justiciable.[32] Similarly, Article 253 merely confers on Parliament the power to make any law for the whole or any part of the territory of India for implementing any treaty, agreement or convention with any other country. It does not place treaties on par with domestic law. Therefore, the Indian Constitution does not require that treaties be given "direct effect" and be enforced domestically. In other words, absent an express mandate in the Indian Constitution, one cannot invalidate a statutory provision such as section 3(d) as being in contravention of an international treaty.[33]

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30. T. Cottier and K.N. Schefer, *The Relationship between World Trade Organization Law, National and Regional Law*, 1 J. INT'L ECON. L. 83-122 (1998).

31. Through several judgments, the ECJ has confirmed the non-applicability of the doctrine of direct effect in the EC. Illustratively, *see* Cases C-93/02 and C-94/02, Biret International SA & Etablissements Biret et Cie. SA v. Council of the European Union, [2003] ECR I-10497. Although international agreements sometimes have direct effect in the US, a statute (URAA) expressly provides that there is no such "direct effect" in the context of the WTO. Section 102 (a) of the URRA (Uruguay Round Agreements Act) states that no provision of the WTO agreements will have effect within the United States if it is *"inconsistent with any law of the United States"*.

32. INDIAN CONSTITUTION, art. 37.

33. It is clear from the Constitutional framework that a statute can be challenged on two grounds and two grounds only i.e. that the statute violates the fundamental rights or some other provision under the constitution or that the Parliament lacks legislative competence to enact. *See* State of Andhra Pradesh v. McDowell & Co., A.I.R. 1996 S.C. 1627 [Supreme Court].

It bears noting though that even in cases where internationally binding treaty norms were not legislated upon, the Supreme Court has applied such norms, when such application did not conflict with existing domestic law. To some extent, this is reflective of the doctrine of consistent interpretation—a doctrine carved out of cases such as *Charming Betsy*.[34] However, Indian Supreme Court cases go beyond the Betsy doctrine, in that they not only interpret domestic law consistently with international norms, but also go to the extent of importing those norms, when there is a gap in domestic law. We discuss some of these cases below.

In the case of Gramophone Co. v. Birendra Pandey,[35] some pirated cassettes on their way to Nepal were seized by the Indian customs. International conventions – notably the 1965 Convention on Transit Trade of Land-Locked States – provided for the right of innocent passage in order to facilitate Nepal's international trade. Since these appeared to be pirated cassettes which could never be imported into India under the Copyright Act, the court was faced with the question: Does the right conferred by international conventions permit the transit of goods which may not otherwise be imported into India? To answer this, the court had to answer two sub-questions:

1. What does the term import mean?[36]
2. Whether international conventions formed part of domestic law?

The Court resolved all issues in favour of the copyright owner i.e. that the term import in India's copyright regime included goods that were in transit through India and that the applicable international conventions and bilateral treaties between India and Nepal made specific exceptions to block transit, if the goods violated intellectual property of some kind.

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34. According to this doctrine, where a national rule allows for different interpretations, national or regional law has to be construed in accordance with international obligations. The doctrine of consistent interpretation was introduced early in the history of the United States with the Charming Betsy case (2 Cranch 64 (1804)), where Chief Justice Marshall held that *"an act of congress ought never be construed to violate the law of nations, if any other construction is possible"*. The ECJ used a similar reasoning in Warner (Case C-70/94 Fritz Werner Industrie-Ausrüstungen GmbH v. Germany, judgment of 17 October 1995, [1995] ECR I-3189) and Leifer (Case C-83/94 Criminal proceedings against Peter Leifer and Others, judgment of 17 October, [1995] ECR I-3231). *See* Cottier, *supra* note 30, at 88.
35. Gramophone Co. v. Birendra Pandey, A.I.R. 1984 S.C. 667 [Supreme Court].
36. If it was an import, then it ought to have been confiscated by the copyright authority and handed over to the copyright owner.

However, the ultimate conclusions of this case are not as important to us, as the court's findings on international treaties and their applicability within India. The Court deployed the doctrine of incorporation,[37] as applied by English courts, which suggests that *"rules of international law are incorporated into national law and considered to be part of the national law unless they are in conflict with an Act of Parliament"*. In other words, whenever the rules of international law changed, they would result in a change of the law of the land along with them, *"without the aid of an Act of Parliament"*. The only exception to this rule was when the said international norm conflicted with domestic law. The Court cited with approval a renowned authority on international law, Professor Lauterpacht who opined:[38]

> While it is clear that international law may and does act directly within the State, it is equally clear that as a rule, direct operation of international law is within the State subject to the overriding authority of municipal law. Courts must apply statutes even if they conflict with international law. The supremacy of international law lasts, *pro foro interno*, only so long as the State does not expressly and unequivocally derogate from it. When it thus prescribes a departure from international law, conventional or customary, judges are confronted with a conflict of international law and municipal law and, being organs appointed by the State, they are compelled to apply the latter.

Based on this, the court held that, *"....municipal law must prevail in case of conflict. National Courts cannot say yes, if Parliament has said no to a principle of international law."*[39]

The Court contrasted the doctrine of incorporation with the doctrine of transformation, an earlier doctrine applied by English courts,[40] which stipulated that *"rules of International law are not part of the law of the land, unless already so by an Act of Parliament, judicial decision or long established custom"*, whether or not they conflicted with domestic law. Although the Court did not expressly refer to an

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37. *Gramophone Co.*, A.I.R. 1984 S.C. 667, at ¶¶ 3-4.

38. INTERNATIONAL LAW BEING THE COLLECTED PAPERS OF HERSCH LAUTERPACHT (E. Lauterpacht ed., Cambridge University Press 1970); *Gramophone Co.*, A.I.R. 1984 S.C. 667, at ¶ 4.

39. *Gramophone Co.*, A.I.R. 1984 S.C. 667, at ¶ 5.

40. The court noted that English courts and in particular, Lord Denning, in Trendtext Trading Corpn. v. Central Bank, 1977(I) All B.R. 881 had moved away from the doctrine of transformation and had adopted the doctrine of incorporation.

earlier Indian Supreme Court judgment which relied on the doctrine of transformation, its finding appears to overrule it.[41]

In *Vishaka*,[42] the court was requested through a public interest petition to implement obligations under an international convention, namely the Convention on the Elimination of All Forms of Discrimination against Women. Though India was one of the signatories to this convention, the obligations under this convention were not yet translated into domestic law. The court opined:

> The international conventions and norms are to be read into them in the absence of enacted domestic law occupying the field when there is no inconsistency between them. It is now an accepted rule of judicial construction that regard must be had to international conventions and norms for construing domestic law when there is no inconsistency between them and there is a void in the domestic law.[43]

From the above discussion,[44] it is clear that the Indian legal system is of a dualist nature and that the doctrine of 'direct effects' is not recognised. A treaty provision that is not yet enacted into domestic law is enforceable only to the extent that it does not conflict with domestic law. However, if it conflicts, then domestic law would clearly prevail. Therefore, even assuming that section 3(d) of the Patents Act, 2005 violates TRIPS, the courts cannot strike down this provision.

The lack of a "direct effect" doctrine is key to understanding why domestic courts cannot directly enforce international obligations, when such obligations conflict with existing domestic norms.[45] In fairness, the Madras High Court does

41. Jolly Varghese v. Bank of Cochin, A.I.R. 1980 S.C. 470 [Supreme Court]. The court also suggested that an earlier Supreme Court ruling (Tractoroexport, Moscow v. Tarapore & Co. MANU/SC/0003/1969 [Supreme Court]) appears to have endorsed the doctrine of incorporation, in spirit. *Trendtext Trading Corpn.*, 1977(I) All B.R. 881, at 6-8.

42. Vishaka v. State of Rajasthan, A.I.R. 1997 S.C. 3011. [Supreme Court]

43. *Vishaka*, A.I.R. 1997 S.C. 3011, at ¶ 14.

44. *See also* Nilabati Behera v. State of Orissa, MANU/SC/0307/1993 [Supreme Court], where a provision in the ICCPR was referred to support the view taken that "an enforceable right to compensation is not alien to the concept of enforcement of a guaranteed right", as a public law remedy under Article 32, distinct from the private law remedy in torts. *See also* Azadi Bachao Andolan v. Union of India, (2004) 10 S.C.C 1. [Supreme Court]

45. Section 3(d) reveals a clear legislative intent to prevent a phenomenon popularly referred to as "ever-greening". If this is what the legislature intended, then it has to be upheld, even if it is found that it contravenes TRIPS.

allude to such a doctrine by relying on Salomon v. Commissioner of Customs,[46] where Lord Diplock had held that:

> If the terms of the legislation are clear and unambiguous, they must be given effect to whether or not they carry our Her Majesty's treaty obligations, for the sovereign power of the Queen in Parliament extends to breaking treaties and any remedy for such a breach of an international obligation lies in a forum other than Her Majesty's own courts.[47]

Although the court was correct in relying upon Salomon, it did not follow through on its analysis. Nor did it bother to acknowledge the existence of several Indian precedents confirming the lack of a "direct effects" doctrine in India.[48] Rather it shifted its framework of analysis to one of contract law, as mentioned earlier. And to buttress its contractual framework of assessment, it relied on an antiquated 1884 American case.[49]

B. Could the Madras High Court have issued a Declaration?

Novartis argued that even if the Court could not invalidate a domestic law (section 3(d)) as being non-compliant with an international obligation (TRIPS), it could still issue a declaration to this effect. The Court however disagreed, stating

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46. Salomon v. Commissioner of Customs, [1966] 3 All E.R. 871.

47. The court also considered a House of Lords Decision in Equal Opportunities Commission and Anr. v. Secretary of State for Employment, [1994] 1 All E.R. 910, where the Lords held that a UK statute was in violation of an E.U. Directive on the same issue. The Court however very rightly distinguished this case form the current litigation by pointing out that the U.K. had enacted a legislation which gave E.U. Directives the force of domestic law.

48. By drawing its conclusions solely on the basis of American and English decisions the Madras High Court seems to have overlooked the principle of *stare decisis* or binding precedent, which operates in relation to Indian Supreme Court decisions and not in respect to House of Lords decisions or American Supreme Court decisions. This common law principle has been codified to some extent in Article 141 of the Constitution of India in that it declares all law laid down by the Supreme Court of India as the law of the land.

49. Edye v. Robertson, 112 U.S. 580 (1884) at 588, 599 [United States Supreme Court], which held in pertinent part that: *"A treaty is primarily a compact between independent nations, and depends for the enforcement of its provisions on the honour and the interest of the governments which are parties to it."*

    The court however overlooked the latter portion of the very same paragraph which held that a treaty may also partake the character of municipal law. In such a case, the provisions of the treaty are enforceable by private citizens in a national court.

that it would do so, only if such declaration served a "useful purpose".[50] In the case at hand, the Court could not have invalidated section 3(d) as contravening TRIPS. Therefore the Court held that even if it declared section 3(d) to be violative of TRIPS, such declaration could never help Novartis, as the law would have continued to remain in the statute book. In other words, Novartis would not be able to claim any further relief using such declaration.

This analysis is faulty. Novartis could argue that such a declaration might help induce the Swiss government to take up cudgels on behalf of Novartis and approach the Dispute Settlement Body (DSB) of the WTO.[51] It is also possible that a ruling by an Indian court might be somewhat influential with a panel, though not binding. Or better still, Novartis could use the Indian court ruling to negotiate with the Indian government to elicit TRIPS compliance.

Could the Court have simply disposed of the above argument by Novartis on the ground that it lacked jurisdiction to entertain the matter? We answer in the negative, as explained below.

C. Could the High Court have disposed of the Declaratory Petition on the ground that it lacked jurisdiction?

Firstly, it is important to appreciate the distinction between the court's inability to strike down a domestic legislation as violating international treaty norms and its lack of jurisdiction to make a declaration in the matter. One does not automatically follow from the other. In other words, the lack of a "direct effect" doctrine in India does not automatically mean that Indian courts do not have jurisdiction to make a declaration. Rather, courts have inherent jurisdiction to look into the matter.

The High Courts in India derive their jurisdictional power from Articles 225 and 226 of the Constitution of India and are considered to be courts of inherent jurisdiction i.e. they may hear any matter, unless specifically barred by statute or common law principles. The Supreme Court of India, in a landmark case pertaining to jurisdiction of High Courts, held:

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50. The Court relied on an unreported Supreme Court judgment, Katakis v. Union of India, (Writ Petition No. 54/68 of 1968) for this purpose.

51. Interestingly, counsel for the respondents had warned the court about this possibility: *"..addressing Novartis' request for a declaration that section 3(d) was incompatible with TRIPS, Lakshmikumaran asserted that if the Court did make such a declaration, without granting any further relief, Novartis would use it as ammunition to convince Switzerland to take India to the WTO Dispute Panel." See Novartis Update: 15th Feb 2007 - 16th Feb 2007, available at* http://www.lawyerscollective.org/content/novartis-update-%3A-15th-feb-2007-16th-feb-2007.

> The High Courts in India are superior courts of record. They have original and appellate jurisdiction. They have inherent and plenary powers. Unless expressly or impliedly barred, and subject to the appellate or discretionary jurisdiction of this Court, the High Courts have unlimited jurisdiction, including the jurisdiction to determine their own powers.[52]

In India, the only statute implementing India's TRIPS obligations is the Patent (Amendment) Act, 2005. Neither this Act nor any other statute expressly or impliedly bars the High Court from hearing a TRIPS challenge. Therefore, while the Court could not have struck down section 3(d) as being violative of TRIPS, it possessed inherent jurisdiction to entertain the matter. The court was therefore wrong in holding that it had *"no **jurisdiction** to decide the validity of the amended section, being in violation of Article 27 of TRIPS"*.[53] (emphasis by authors).

D. TRIPS Compatibility

As one can appreciate, the Madras High Court ruling does not settle the TRIPS issue but only shifts the jurisdictional venue. Assuming the matter was to come before the WTO, it is very unlikely that a panel will rule against India.

Article 27 of TRIPS stipulates that 'patents shall be available for any inventions ... provided that they are *new, involve an inventive step and are capable of industrial application*'. However, none of the terms used in this Article have been defined. This leaves some flexibility in the hands of member states to define patentability criteria in a manner that suits their specific national interests.[54]

Historically, member states have refined patentability criteria in the context of specific fields of technology, taking into account the unique concerns posed by such technologies. Illustratively, in 2001, the United States Patent and Trademark Office (USPTO) revised its utility guidelines to cater specifically to biotechnology inventions.[55] It is also pertinent to note a German provision brought in to ensure

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52. Elizabeth M. V. v. Harwan Investment & Trading Pvt. Ltd., MANU/SC/0685/1993, at ¶ 67. [Supreme Court]
53. Novartis AG v. Union of India, (2007) 4 M.L.J. 1153, at ¶ 28. [Madras High Court].
54. *Integrating Intellectual Property Rights and Development Policy*, 114 COMMISSION INTELL. PROP. RTS. (2002).
55. U. S. Patent & Trademark Office Guidelines for Examination of Applications for Compliance with Utility Requirements, 66 (4) Fed. Reg. 1,092 (Jan. 5, 2001), *available at* http://www.uspto.gov/web/offices/ com/sol/ notices/utilexmguide.pdf. Although evolved to cater to biotechnology, these guidelines are applicable to all inventions.

that the patent monopoly on a gene sequence is limited to the specific function disclosed and not to all functions.[56]

In much the same way as the above provisions, section 3(d) may be construed as a refinement of patentability criteria to cater to "ever-greening", a specific problem inherent in pharmaceutical innovations.[57] More specifically, the enhanced efficacy criterion can be seen as a refinement of non obviousness principles i.e. most forms of existing pharmaceutical substances are deemed obvious, unless they demonstrate increased efficacy.[58] Or it could be perceived as a refined utility test, where only those new forms that demonstrate substantially different utility than what existed before (in the form of "significantly enhanced efficacy") are patentable.[59]

In short, since patentability criteria have not been defined under TRIPS, a deeming provision such as section 3(d) which caters to a specific technology sector is perfectly compatible with TRIPS. However, care must be taken to ensure that this provision is not interpreted in a manner that no pharmaceutical derivative or incremental innovation is ever patentable; else the provision runs the risk of falling foul of TRIPS.

V. Section 3(d): Constitutionality Analysis

> Under Indian constitutional law, a law made by the Parliament or the Legislature can be struck down by the Court on two grounds and two grounds alone, viz, (1) lack of legislative competence and (2) violation of any of the fundamental rights guaranteed in Part III of the constitution or of any other constitutional provision. There is no third ground.[60]

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56. An amendment approved by the German Parliament in 2004 limits patent protection on human gene sequences to 'disclosed functions' at the time of the patent application i.e. a patent on a human DNA sequence used for a specific function would not cover a second function discovered later by another researcher using the same DNA sequence. *See* sub-section 4 of Section 1(a) of legislation; M. Huenges, *Biotech Directive Implemented*, Managing Intell. Prop. (April, 2005), *available at* www.maiwald.eu/news_d/Umsetzu ng_Biotech-Richtlinie.pdf.

57. Basheer, *supra* note 20.

58. Basheer, *supra* note 20.

59. F.A. Khader, The Law of Patents: With a Special Focus on Pharmaceuticals in India 65 (2007).

60. State of Andhra Pradesh v. McDowell & Co., A.I.R. 1996 S.C. 1627, at 1737-1738 [Supreme Court].

Novartis alleged that section 3(d) violated the fundamental right to equality as enshrined in Article 14 of the Constitution of India. More specifically, it argued that the usage of terms such as "enhancement of known efficacy" and "differ significantly in properties with regard to efficacy" without accompanying guidelines elucidating their scope rendered section 3(d) vague and arbitrary.[61] And such arbitrariness, facilitated in large part by the conferment of uncanalised power on a statutory authority[62] hits at the very root of the concept of equality enshrined in Article 14 of the Constitution of India.

Novartis's second argument, related in many ways with the first one discussed above, stated that the structure of section 3(d) vested the patent office with unfettered discretion to devise its own policy and determine as to what constituted a significant enhancement of efficacy.[63] Novartis urged that this amounted to a delegation of an essential legislative function.

The court, however, disagreed with each of the contentions above. First, the threshold for any statutory provision to qualify as "arbitrary" and therefore violative of Article 14 is considerably high. A paper notes: *"Evidently, to prove that something is arbitrary is very difficult. If the presence of any (legitimate) reason makes an act non-arbitrary, it continues to be an extremely deferential standard of review".*[64]

In order to appreciate this argument better, one needs to have an understanding of the structure of Article 14. Article 14 of the Constitution of India states that: *"The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India".*

The expression "equality before the law" means broadly that except in a very limited class of cases,[65] the court administering justice is not concerned with

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61. *Novartis AG*, (2007) 4 M.L.J. 1153, at ¶ 14.
62. *Novartis AG*, (2007) 4 M.L.J. 1153, at ¶ 14.
63. During the course of oral arguments before the Madras High Court, Novartis also challenged section 3(d) as violating the fundamental right to practice one's business, as enshrined in Article 19(1)(g) of the Constitution. However, at a later stage, they dropped this specific challenge. *See Novartis Update*, 29th Jan 2007, *available at* http://www.lawyerscollective.org/ content/novartis-update-%3A-29th-jan-2007.
64. *See* T. Khaitan, *Anuj Garg v Hotel Association of India* – Equality Jurisprudence Coming of Age? (Draft on file with authors).
65. E.g. public servants cannot be prosecuted for certain offences without the sanction of the appropriate authorities: *see* Criminal Procedure Code, Sections 164 and 197.

the status or position of the parties appearing before it; the law is no respecter of persons.[66]

The second part of Article 14 dealing with the *"equal protection of the laws"* implies that amongst equals, the law is to be applied equally.[67] Therefore Parliament is free to differentiate between different classes/categories. However, for such differentiation/classification to be valid:

i) the classification must be based on "intelligible" criteria, and;

ii) such classification must bear a rational nexus to the object that the Act seeks to achieve.

Reasonable classification is, thus, the cornerstone of Article 14.[68]

Novartis might have argued as below:

i) That by discriminating against pharmaceutical patentees, section 3(d) violates the equal protection clause. In other words, by creating an extra efficacy hurdle for pharmaceutical applications, the law created two classes of patentees.

ii) There is no intelligible differentia between the two classes of patentees above.

iii) There is no rational nexus between this classification (pharmaceutical patentees v. other patentees) and the object sought to be achieved by the Parliament.

Surprisingly, Novartis never pursued this argument.[69] Perhaps the fact that the level of judicial review under Article 14 is abysmally low and the courts have

66. H.M. SEERVAI, CONSTITUTIONAL LAW OF INDIA: CRITICAL COMMENTARY, Vol. I, 225, 438 (4th edn., Universal Law Publisher 1999).

67. Seervai notes that the Equal Protection Clause was borrowed from the 14th Amendment to the U.S. Constitution which provides *"Nor shall any State...deny to any person within its jurisdiction the Equal Protection of the laws"*.

68. *See* M.P. JAIN, INDIAN CONSTITUTIONAL LAW 1000-1002 (5th edn., Wadhwa and Company 2003).

69. Since Novartis never raised this issue, the court did not delve into it. Although there is no express bar on an Indian court delving into issues/points not raised by the parties, at least one judgment (albeit a minority decision) seems to suggest that this is not good practice. In NMDC v. State of Punjab, (1997) 7 S.C.C 339 [Supreme Court], Justice Ahmadi of the Supreme Court came down strongly against the practice of certain judges dealing with issues which had not been raised by either party. His rationale was that the law requires that both parties should be given an equal opportunity to be

rarely struck down legislations on this count may have caused Novartis to strategically eschew this line of attack.[70]

Had Novartis advanced such a challenge, the Court could have easily addressed it, stating that the nature of pharmaceutical/chemical innovation called for such a classification. Illustratively, the problem of salts, polymorphs and other derivatives that potentially have the same function as the parent compound is, to a large extent, specific to the field of chemical/pharmaceutical technology. Therefore, a rule that such derivatives would need to show enhanced efficacy over their parent compound in order to be patentable encapsulates:

1. An intelligible differentia between chemical/pharmaceutical patent applications and others.
2. A rational nexus to the object sought to be achieved by the Patents Act, i.e. preventing ever-greening.

As mentioned earlier, Novartis did not pursue this line of attack and the discussion is, to that extent, academic. Rather, Novartis alleged that section 3(d) was arbitrary and therefore violated Article 14.

The concept of arbitrariness was first introduced into Article 14 through a judgment of Justice Bhagwati in Royappa v. State of Tamil Nadu.[71] While deciding whether an administrative order was violative of the equality clause in Article 14, Justice Bhagwati held that:

> Equality is a dynamic concept with many aspects and dimensions and it cannot be "cribbed, cabined and confined" within traditional and doctrinaire limits. From a positivistic point of view, equality is antithetic to arbitrariness. In fact equality and arbitrariness are sworn

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heard on all issues that affect them. And if the Court dealt with certain issues/ arguments on its own volition at the stage of judgment, this would mean that the party against whom such issues went would have been denied a fair hearing on the respective issue.

70. A paper notes

> ...the standard of judicial review has traditionally been perfunctory. Under its 'reasonableness' standard of judicial review, all that the S.C. demands is any 'rational nexus' between the restriction and the state interest sought to be furthered. This only addresses the 'suitability' aspect of the standard of review constituents. The courts have bent over backwards to find some rational basis in the classification.

See Khaitan, *supra* note 64.

71. Royappa v. State of Tamil Nadu, A.I.R. 1974 S.C. 555 [Supreme Court].

> enemies; one belongs to the rule of law in a republic while the other, to the whim and caprice of an absolute monarch.[72]

Therefore, apart from cases that fall foul of what is now commonly referred to as the "reasonable classification" test, cases involving arbitrary acts were also likely to violate Article 14. With the introduction of this new dimension of arbitrariness into Article 14, the Supreme Court increased its powers to review laws and executive actions.[73]

This expansion in the scope of judicial review has not been without criticism. Seervai, a leading constitutional law jurist, labels this new doctrine as logically fallacious and one that hangs in the air, as it propounds a theory of equality without reference to the language of Article 14.[74]

Another jurist points out that while every inequality amounts to an arbitrary action, the converse is not necessarily true, i.e. an arbitrary act may not necessarily violate the equality clause.[75]

> For example, if only red-haired students in a school are expelled without any cause, the action is arbitrary as well as unequal *vis-à-vis* non red-haired students. If however all students in the school, whatever the colour of their hair, are expelled without any cause, the action is simply arbitrary without any question of inequality. It is simply incorrect to say that arbitrariness necessarily results in inequality.[76]

To the credit of Indian Courts, they have been restrained in deploying this doctrine to invalidate statutory provisions.[77] For a statutory provision to be struck down on the ground of arbitrariness, the arbitrariness must amount to "manifest

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72. *Royappa*, A.I.R. 1974 S.C. 555, at ¶ 85.

73. For other cases applying this doctrine, *see* Maneka Gandhi v. Union of India, (1978) 1 S.C.C 248 [Supreme Court] and more recently, Bidhanagar Welfare Association v. Central Valuation Board, (2007) 6 S.C.C 668 [Supreme Court], where the Supreme Court struck down a legislation on the grounds of arbitrariness.

74. SEERVAI, *supra* note 66, at 438.

75. A.P. DATAR, DATAR ON CONSTITUTION OF INDIA 37 (Wadhwa and Company, 2001).

76. T.R. Andhyarujina, *The Evolution of Due Process of Law by the Supreme Court* in SUPREME BUT NOT INFALLIBLE: ESSAYS IN HONOUR OF THE SUPREME COURT 193 (B.N. Kirpal ed., Oxford University Press 2002).

77. *Id.*

arbitrariness".[78] An enactment cannot be struck down on the mere ground that a particular court thinks it unjustified.[79]

Not surprisingly, the Madras High Court also followed this trend of judicial circumspection and highlighted that merely because legislation is skeletal and does not contain definitions or guidelines, it does not necessarily mean that it is arbitrary. Rather, one has to look into factors such as the wording of the statute, the amount of discretion conferred, the possibility of appeal to correct any wrong decision and the object of a statute. Further, a determination of when a new form demonstrates a "significant" enhancement of efficacy under section 3(d), when compared with the old substance is not amenable to a uniform formula, but is to be based on the facts of each specific case.

Therefore, it is extremely difficult to qualify section 3(d), a section brought in to prohibit a phenomenon widely known as "ever-greening" as "arbitrary" or vague.[80] The Madras High Court correctly notes that:

> The argument that the amended section must be held to be bad in Law since for want of guidelines it gives scope to the Statutory Authority to exercise its power arbitrarily, has to be necessarily rejected since, we find that there are in-built materials in the amended section and the Explanation itself, which would control/ guide the discretion to be exercised by the Statutory Authority. In other words, the Statutory Authority would be definitely guided by the materials to be placed before it for arriving at a decision.[81]

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78. Bombay Dyeing & Mfg. Co. Ltd. v. Bombay Environmental Action Group, (2006) 3 S.C.C 434, 511 [Supreme Court]. *See also* KHADER, *supra* note 59, at 96.

79. *"It is one thing to say that a restriction imposed upon a fundamental right can be struck down if it is disproportionate, excessive or unreasonable and quite another thing to say that the court can strike down an enactment if it thinks it unreasonable, unnecessary or unwarranted."* State of Andhra Pradesh v. McDowell and Company, (1996) 3 S.C.C 709, 738-39 [Supreme Court].

80. Novartis also argued that all derivatives (polymorphs, metabolites, salts and combinations) need not necessarily be the same "substance" and therefore the deeming fiction created by the Explanation is bereft of any guidelines and is bad in Law. The court however appeared to agree with a Supreme Court judgment (M/s. J.K.Cotton Spinning & Weaving Mills Ltd. v. Union of India, A.I.R. 1988 S.C. 191 [Supreme Court]) which held that *"the Legislature is quite competent to enact a deeming provision for the purpose of assuming the existence of a fact which does not really exist"* . *Novartis AG*, (2007) 4 M.L.J. 1153.

81. *Novartis AG*, (2007) 4 M.L.J. 1153, at ¶ 16.

Regarding the second line of attack on the grounds of excessive delegation of power, the Supreme Court has ruled in several cases that while Parliament may delegate some functions to administrative bodies, it ought not to delegate an "*essential legislative function*".[82] In other words, it is permissible for the legislature to lay down broad policy and delegate powers of rule making to the statutory authority to implement the policy. Delegated legislation is particularly common in areas of specialised knowledge, where the legislature lacks the knowledge and expertise to frame detailed rules. In Jyoti Pershad v. Union Territory of Delhi,[83] the Supreme Court held:

> So long as the Legislature indicates, in the operative provisions of the statute with certainty, the policy and purpose of the enactment, the mere fact that the legislation is skeletal, or the fact that a discretion is left to those entrusted with administering the law, affords no basis either for the contention that there has been an excessive delegation of legislative power as to amount to an abdication of its functions, or that the discretion vested is uncanalised and unguided as to amount to a carte blanche to discriminate. If the power or discretion has been conferred in a manner which is legal and constitutional, the fact that Parliament could possibly have made more detailed provisions, could obviously not be a ground for invalidating the law.

Drawing on the above proposition, the Madras High Court correctly hinted that section 3(d) is an example of delegation of a non-essential legislative function. And that merely because it is "skeletal" or that it does not define terms such as enhancement of known efficacy" does not mean that "uncanalised discretion" has been vested on the patent office.[84]

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82. *See* In re Delhi Laws Act, A.I.R. 1951 S.C. 332, 516 [Supreme Court], where the court stresses that, "*in the absence of express powers of delegation allowed by the Constitution, the Parliament has no power to delegate its essential legislative functions to others, whether State legislatures or executive authorities, except, of course, functions which really in their true nature are ministerial.*"

83. Jyoti Pershad v. Union Territory of Delhi, A.I.R. 1961 S.C. 1602 [Supreme Court].

84. It bears noting in this regard that Indian Courts have demonstrated a great reluctance to strike down legislations solely on the ground of 'excessive delegation'. A commentary on constitutional law has pegged the ratio of success at 4:41. *See* DATAR, *supra* note 75.

It is significant to note that although section 3(d) is constitutional, its drafting leaves much to be desired. Beset with crudities, it is currently a litigators' El Dorado.[85]

VI. Conclusion

The Madras High Court was right in defending the constitutionality of section 3(d). Its findings were consistent with earlier Supreme Court precedents which had observed that the mere absence of guidelines or definitions in a section ought not to mean that the section is arbitrary or vague or that it confers uncanalised discretion on a statutory authority.

However, in so far as TRIPS compatibility is concerned, the Madras High Court wrongly relied on a "contractual" framework to "duck" the issue. Furthermore, it buttressed its analysis with a US court decision handed down more than a century back![86] Although, it correctly alludes to the lack of a "direct effect" doctrine in India by citing an English precedent on the point, it never follows through on its analysis. More glaringly, it ignores earlier Supreme Court decisions on this point and reveals a penchant for foreign case law, even when there is more "direct" Indian precedent available.

Lastly, it is important to appreciate that the Madras High Court ruling does not settle the TRIPS issue but only shifts the jurisdictional venue. Assuming the matter were to come before the WTO, this paper argues that it is very unlikely that the panel will rule against India.

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85. For a discussion on these various crudities and how best to refine them, *see* S. Basheer and T. P. Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)* 5 S.C.RIPT-ED 2 (2008).

86. Edye v. Robertson, 112 U.S. 580 (1884) [United States Supreme Court].