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THE 3D EFFECT: EXPANDING THE INTERPRETATIVE FRAMEWORK OF INVENTIVENESS FOR PHARMACEUTICAL PATENTS

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INTRODUCTION

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) regime has brought about definitive changes in the dynamics of drug trade, and research and has had a far-reaching impact on drug access, availability, research, prices, disease control, and much else. Until recently, providing patent protection for pharmaceuticals was a choice made by individual governments, in accordance with their development levels. Today, pharmaceutical patents are globalized through the World Trade Organization's (WTO) Agreement on TRIPS, and then further reinforced through bilateral and regional arrangements.[1]

Medical patents constitute an important case study within the broader field of intellectual property rights (IPRs) because this constitutes an area where the industry is highly dependent on patents. One of the perceived advantages of medical patents is that they provide incentive to the private sector to undertake research and innovation of medicines and pharmaceutical products. However, the utility of intellectual property protection - even if that were to be its most powerful defense - cannot be judged solely in terms of the innovation generated. It is important to view patents as a "social contract" [2] between the patent owner and society and that societal health forms the other end of the stakeholder chain. At stake, therefore, is not just the inventive potential of manufactures (arguable in itself)[3] but also the health and

[1] See, for instance, J. Replogle, 'Central American Trade Pact May Limit Access to Generics,' *Lancet* 363, 2004, pp. 1612–1613. Also, for instance, the Free Trade Agreements (FTAs) and TRIPS plus agreements. The FTA process has become the principal process through which the IPR-based industries are able to ensure that the standards of protection and enforcement keep pace with new developments. See, ITAC 15, *The U.S.-Colombia Trade Promotion Agreement (TPA) The Intellectual Property Provisions*, September 20, 2006. For details on FTA and IP protection see, World Bank Group Trade note, Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements February 7, 2005 http://www.cptech.org/ip/health/trade/worldbank02072005.pdf

[2] A term used by Carlos Correa in 'Guidelines for the Examination of the Pharmaceutical Patents: Developing a public Health Perspective', WHO - ICTSD – UNCTAD Working Paper, Jan., 2007. Available at http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf . (Accessed 11Aug. 08)

[3] Refer for instance, Adam B. Jaffe & Josh Lerner**,** *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It,* Princeton University Press, 2004; Michele Boldrin and David K. Levine, "The Case against Intellectual Property," American Economic Review, Vol. 92(2) (2002); Sunil Kanwar and Robert Evenson, *Does Intellectual Property Protection Spur Technological Change*? Center Discussion Paper No. 83, Economic Growth Center: Yale University, June 2001.

lives of millions. If a bulk of the people, that is, a third of the world's population, do not have access to basic drugs,[4] then clearly innovations are not meeting their desired objectives.

While there are many dimensions governing drug access, the *high prices* of patented drugs constitute a significant barrier. Many millions are also denied access because patent protection restricts *availability* of those drugs which have weak monetary demand, i.e. a drug for which there is a low demand because of the low purchasing power of the people in question. [5]The 10/90 gap is instructive in this regard – only 10% of the global pharmaceutical research and development (R&D) expenditure goes towards diseases which account for 90% of the world's disease burden.[6]

COMPULSORY LICENSING AND ITS LIMITS

The Doha Health Declaration (2001)[7] recognized the gravity of public health problems. It provided sufficient lead for the member countries to address relevant concerns in their patent laws. Post the Doha Declaration, a number of countries have used the strategy of "compulsory licensing" implied in Article 31 of the TRIPS Agreement.[8] A subsequent amendment to the article by the August 2003 Decision of the WTO General Council,[9] provided that countries could now also export and import medicines produced under a compulsory license in 'health emergencies', making it the provision useful for countries which lacked domestic manufacturing capacity.

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[4] See, UNDP, Human Development Report 2003, New York: OUP, 2003

[5] Because patents are the primary rewards that provide research incentives it logically follows that the patent system stimulates innovation only where industry sees the opportunity for increasing sales and market share. This is one of the prime reasons why there has been a significant growth in the research and development of lifestyle drugs as there is a strong monetary demand for them. Consider this: Anti-baldness drugs generated $180 million in sales in 1998, the anti-wrinkle drug Botox earned $90 million in sales in 1997, and Viagra's sales approached $800 million in its first year. 'Discretionary Drug Dollars,' *Journal of Business Strategy Publication*, 1Jul, 02 .http://www.accessmylibrary.com/coms2/summary_0286-25645998_ITM (Accessed June 26, 2007)

[6] Global Forum Health 10/90 Report on Health Research 2003-2004. http://www.globalforumhealth.org/Site/002_What%20we%20do/005_Publications/001_10%2090%20reports.php. Also see, Developing New Health Products; (Drugs, Diagnostics, and Vaccines) To Control The Ancient Afflictions of Stigma and Poverty," *The George Washington University Neglected Tropical Diseases Initiative* http://gstudynet.org/docs/The%20GWU%20Neglected%20Tropical%20Diseases%20Initiative.doc Accessed July 13, 2007

[7] Declaration on the TRIPS Agreement and Public Health, WTO 14 November 2001. Available at http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[8] A compulsory license (in the field of health) is an exception to the patent law that is usually justified as an attempt by the government to correct a market failure or negotiate a situation of national health emergency. If patented drugs cost too much, the government authorities can take measures such as issuing a compulsory license to an agency or company to manufacture or import a generic version of that patented drug, which can then be made more available to patients more cheaply. The Doha agreement effectively permits a distribution and use license in countries experiencing a public health emergency and a manufacturing-for-export license in countries possessing appropriate manufacturing capacity.
explain compulsory licensing. Some instances of Compulsory licensing being used to address health emergencies are: Thailand for ARV Efavirenz in Nov.2006 and Kaletra in Feb.2007; Indonesia for manufacture of generic Lamivudine and Nevirapine in October 2004; Malaysia for import from India for ARVs dd1, AZT and Combivir; Taiwan in Nov.2005 for manufacture of Tamiflu.

[9] Decision of the General Council, WTO, 30 August 2003. WT/L/540 and Corr.1

However, the potential role of compulsory licensing in promoting access to medicines is replete with compelling challenges for three reasons. Firstly, it is mired in the politics of bilateral relations – FTAs and other TRIPS Plus agreements – that does not allow weaker states, especially the LDCs, to manoeuvre even the small elbow room provided by TRIPS. [10] The second problem with compulsory licensing is that it is always susceptible to litigation and disputes. Its invocation to address critical public health concerns has , more often than not, remained open to contention. And thirdly, one of CL's critical defects is the stipulation that member countries can make use of options such as the compulsory license mechanism to promote public health *only when a health crisis has arisen,* especially in the form of an epidemic afflicting the populace at large. This limitation clearly weakens their right to utilize the apparent flexibility to take preventive and prophylactic action before a disease becomes a full-blown crisis. Therefore, there arises a vital need to situate health safeguards in provisions other than compulsory licensing. The domain of national laws emerges as an obvious locale for situating public health issues, for it is only in the national domain that public health can be benchmarked in the context of socio-economic-health imperatives. Public health needs to be protected as a principle and as a matter of fundamental right. The core international commitments to health as a human right ought to be guided and located in the national domain to assign a measurable content to the right and to the positive and negative obligations attached to these rights. In the absence of national patent legislations which safeguard public health or the right to health, compulsory licensing may not be the best strategy.[11]

"There is a need to secure a domain for health safeguards outside of global politics, sometimes channeled through the operations of international institutions (like the WTO), and within the sovereign realm of national law. This is simultaneously a task for domestic law-makers and administrators. Relying on existing principles of international law is an inadequate legal strategy
because patent liabilities on health outcomes vary in different countries and different socio-economic domains. There is an increasing link between patent liability and health rights, and this needs to be taken into account at different points in regulatory frameworks of countries. Completely open ended norms, that are often enunciated in the "objectives" sections of international covenants on human or socio-economic rights, perpetuate the image that health rights are imprecise claims that lack content. These rights need to be, therefore, made more "precise" by grounding them in justiciable legal provisions, in sovereign domains of countries, so as to set a level which defines infringement and protection.

Rights of innovators and health rights arise from differently weighted considerations and oftentimes require policy tools to balance out the impact they have on each other. It is in this context that the Section 3(d) (or "3d") of the Indian Patent Act (IPA) assumes importance. 3(d), in a sense, is a

[10] Mogha Kamal Smith of Oxfam said that the space given to developing countries by the August 2003 agreement is being taken away by bilateral and regional FTAs with developed countries, especially the United States. For details refer, Martin Khor, *Patents, Compulsory License and Access to Medicines: Some Recent Experiences*, *TWN*, 2007; Sangeeta Shashikant, 'More Countries Use Compulsory License, But New Problems Emerge,' TWN *Info Service on Health Issues* No. 4 Geneva, 19 May 2005.

[11] For an exposition of this position see, Martin Khor, ibid.

minimalist commitment to the right to health – minimalist, for it only seeks to protect a very narrow domain of those health rights that are infringed by incrementally modified drugs (IMDs). However, minimalist commitments are valuable policy tools for they enable a provision like 3(d) to balance out health rights and innovators' rights which, as "full" rights, can become incommensurable and therefore, conflictual entities. The interests that accrue to a medical patient by way of drug access, belong to his right to health. The interests that accrue to the patent holder by way of patent a wards for his innovation, belong to his right as an innovator. Balancing these rights requires the protection of the substance of both rights. 3(d) assumes this complex role of demarcating health rights and obligations in the area of trade and within the domain of TRIPS.

Section 3(d) is reviewed, in this paper, in terms of central themes that it brings to the fore: first, through the stipulation of "efficacy" as a criterion for patentability, 3d expands the interpretative framework and tries to fill out, arguably, the content of the inventiveness criterion mandated by patenting of medicnal formulations . Secondly, Section 3(d), as a part of the national patent law, is an attempt to induce an element of precaution in the grant of medical patents, in recognition of the impact that patents have on drug prices and therefore, on drug access, and in that sense we can also evaluate it as "precautionary principle". Section 3(d) has empowered context-appropriate decision-making by the patent controller and the courts. The decision of both the Madras High Court (date) and the Supreme Court is instructive in this regard. Both judgements engage health related concerns in interpreting the criteria of patentability of a substance. They do not read 3(d) as primarily a scientific subtext but as a text that devolves into the health context of drug access and generic supplies.

It is, in a way, an effort to adapt TRIPS norms to local and national agendas, and in so doing, *reshape* the global agenda embraced in the WTO. The section merits scrutiny for its effort to create the space for addressing national concerns within the framework of the TRIPS, but in doing so it adds another layer – the deployment of a precautionary approach - to the determination of the patentability. Second, It is in this context that the Section 3(d) (or "3d") of the Indian Patent Act is reviewed here, through the impact that it has had on the Novartis patent claim, for its drug Glivec, and for several other patent claims, and through the effect that it has had on expanding the discourse on inventiveness for pharmaceutical patents. The expansion of the discourse would relate to the allocative question of what kind of patents do we allow to go forward in society, which crucially relates to issues of drug availability and access.

This chapter begins with an explanation on section 3(d) of the IPA and the efficacy standards it purports to hold. It discusses some of the impulses and motivation in the formulation of the efficacy clause which have helped shape the primary objective of 3(d) – that of delimiting the criteria of patentability for drugs in order to safeguard supplies of cheaper generics, in India and globally. Section II presents a brief outline of the 'Glivec case', most of which hinged on the veracity of section 3(d), its constitutional validity and issues of its TRIPS compliance. It also draws attention to the court judgement in the case which highlights the need for evaluating the adequacy of a health safeguard in the light of the health imperatives of the country and, perhaps even that of the global civil society. Section III discusses the

implication of the case for drug access and in doing so underscores the importance of generic supplies to secure access to vital, life-saving, life-enabling drugs. Linkages between drug prices, drug access, health rights are drawn to highlight that in enabling health rights a precautionary approach needs to adopted. Section IV then analyzes 3(d) as a precautionary principle, as a principle which aims to limit harm by restricting the grounds of patentability. The chapter concludes by highlighting the broader terms of contradictions that are embedded between any negotiation between health rights and innovators' rights and by asserting that the grounds of adjudication between these two rights ought to be located outside the domain of WTO/TRIPS in order to institutionalize the priority of health rights over innovators' rights.

EXPLAINING SECTION 3(D) OF THE INDIAN PATENT ACT

In March 2005 India enacted an amendment to, the Indian Patent Act (IPA), its 1970 patent law (also amended in 1999 and 2002 in a move to progressively align IPA with TRIPS). The amendment which would have retrospective effect, from January 1, 2005, provided for patent protection for pharmaceutical inventions - thus instating the concept of 'product patents' in this category for the first time since 1970. While the internationally recognized criteria of patentability - novelty, non-obviousness and utility - were retained, the amendment introduced some additional requirements. One, it defines what is required of a patent application to meet the inventive step criteria. To meet the inventive step criteria the patentee will either have to show that the invention includes a technical advance or has economic significance, or both. Two, it defines an invention to include "*any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application…"*. And three, it prescribed a new criterion for patentability - "enhanced efficacy" , embodied in section 3(d) of the IPA.[12] . The fundamental yardsticks to measure and determine an inventive step essentially remain the same as TRIPS. It appears that the intent behind these provisions is to define a 'novelty' standard - which, along with 'non-obviousness' (or 'inventive step') and 'utility' (economic significance), are the three prerequisites for 'patentability'. In essence, therefore, they adhere to the broad norms of patentability.[13] The significant departure seems to be the "efficacy"standard, which adds a nuance to the content of inventiveness

EFFICACY STANDARDS

Section 3(d) of the amended IPA stipulates that a new *form* of a known substance is excluded from patent coverage if it does not show significantly enhanced efficacy, as compared to the known

[12] There is considerable debate on both counts, most of which centers around the ambiguity of various criteria listed and the subjective interpretations and increased litigational impact that they will generate.

[13] For a view that the definition of inventiveness definition dilutes the requirements of an inventive step and broadens the existing provision to the benefit of patent holders, *See, e.g.*, K.M. Gopakumar & Tahir Amin, *Patents (Amendment) Bill 2005*: *A Critique*,40(15) *Economic & Political Weekly*. 1503, 1504 (Apr. 9, 2005)

substance.[14] The enhancement in efficacy is further qualified in the Explanation to the sub-section, which states that derivatives of a known substance ('Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance) shall be considered to be the same substance "unless they differ significantly in properties with regard to efficacy". Efficacy is thus the dividing line between a substance being, or not being, eligible subject matter for the grant of a patent .

The efficacy clause, it is important to stress, is not a product of Indian patent law jurisprudence.[15] This provision, interestingly, has been taken from a directive of the European Parliament relating to drug regulation of medicinal products for human use.[16] The provision also relates to a class of patents, known as 'selection patents' in English jurisprudence, where a patentee is granted a patent for selected substances from an entire class of chemical compounds. . To grant a patent to the whole class, comprising several 'related' chemical compounds, may result in a broad monopoly. Patent protection is thus granted only to those members of the class that can demonstrate a new *use* or *form*. Here, the critical insight is that the novelty is derived from the *use*, not the *product*.[17] In other words, for the purposes of a selection patent, the novelty of, or inventive step involved in preparing a substance may be located in the demonstration of a new use.[18]

Section 3(d), locating itself in this interpretative framework, is an endeavour to ensure the 'novelty of use', emphasizing use as an inventive step *in the absence of newness of form*. Section 3(d) makes it clear that those technical creations which are not truly inventive (i.e., are only incremental improvement over existing formulations), are not patentable unless they present a significant increase in efficacy. The IPA, as a statute of India, therefore relies upon utility as the criterion for patentability to transform non-patentable inventions into patentable invention.

Besides serving as a technical requirement delineating grounds for patentability of pharmaceutical drugs, Section 3 (d) also functions as an important public health safeguard. The objective of the 3d patentability criteria is to prevent "evergreening" and tweaking of old medicines to make or extend patent claims. Making patent claims conditional on the novelty or the efficacy of the new innovation is significant for it ensures that patents for drugs are not claimed for mere incremental improvements over

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[14] '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'.

[15] Unlike what Novartis alleged in its application for the Glivec patent in Chennai Patent Office. Refer hearing held on Oct.14, Available at http://www.scribd.com/doc/416824/Patent-office-Order-India-Glivec (Accessed 21 Oct. 2006)

[16] Article 10(2) (b) of Directive 2004/27/EC of the European Parliament states that: 'The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.

[17] For a discussion refer, Catherine Colston and Kristy Middleton, *Modern IP Law*, London: Cavendish Publishing Ltd., 2005. pp-163-4

[18] It does not, therefore, apply to a case where the new form is found to have a completely different use (and not just an increased efficacy vis-à-vis the known use), which are entertained as "Swiss Claims".

existing drugs. The term efficacy is being construed in a `drug regulatory' sense. In effect, 3d delimits claims of patentability thereby ensuring the continued supplies of generics at cheaper prices.

There are two common points of apprehensions expressed vis-à-vis 3d. One, that 3d contravenes the mandate that is contained in Article 27, which states: "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" (emphasis added). The relevant phrases are "in all fields of technology", and "provided they are new, involve an inventive step and are capable of industrial application." 3d allegedly breaches both. For, in consonance with the TRIPS Article 27, it is required that all legislation treat pharmaceutical/biotechnological inventions at par with other technological inventions.[19] Devising efficacy standards only for pharmaceutical patents, detractors argue, is an arbitrary requirement which has manifested itself in an equally arbitrary and nebulous clause, 3d. In fact this line of argument was employed in the petition filed by Novartis in the Chennai High Court, India in defense of its Glivec (Gleevec) patent in 2006. A second reason for discomfiture with 3d is that it severely restricts innovation through incremental steps. As Trevor Jones argues, Section 3d "fails to appreciate that such inventions have utility and value not just in improving therapeutic/clinical efficacy but can also provide significant benefit in terms of patient safety and compliance and in manufacturing efficiency".[20]

There could be two sets of arguments in response. The first would be technical, focusing on TRIPS flexibilities, that is, the room for maneuverability that TRIPS provides in occasional concessions to developing countries. It can be argued that India has taken recourse to the exclusionary aspects implied in TRIPS Articles 27(2) and 27(3) in an effort to keep of the IPA compliant with TRIPS. Article 27(2) provides discretion for Members to exclude subject matter from patentability, where this is necessary, to prevent its commercial exploitation in order to protect *ordre public*, or morality, or human health or the environment. Article 27(3) provides further discretion with respect to the patentability of diagnostics, therapeutic, and surgical methods, for the treatment of humans, animals and plants, and provides for a review. Article 30 of the TRIPS states that members may provide limited exceptions to the exclusive rights conferred by a patent. 3d can viewed as providing for limited exceptions to pharmaceutical patents. These flexibilities have been provided by TRIPS in order to soften the impact of 'free trade' in an unequal world, and they can well provide the mandate required for the legitimacy of the IPA within the TRIPS framework. In any event, 3d is in conformity with the Doha Health Declaration which has been endorsed by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH).[21] The Doha Declaration affirmed that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and in particular, to promote access to medicines for all. [22]

[19] See for instance, Trevor M Jones, India: Innovation at Crossroads. CIEC Working Paper, GWU, May 2007
[20] Ibid, pp. 4-5
[21] CIPIH Report, 'Public Health, Innovation and Intellectual Property Rights,' Geneva, April 2006.
[22] See Para 4 of the Declaration.

The second set of arguments that can be made in favour of this (or similar) legislation, however, would seek to locate the terms of the debate outside the legitimating principles and provisions of TRIPS, so that we do not conceptualize the legitimacy of this legislation in terms of permitted exceptions by TRIPS. This set of arguments would locate the 3d legislation in the rights discourse and argue this legislation derives its legitimacy from the protection that it offers to health victims. There exist a set of moral claims and rights which form the core constituency of government obligations and for which compliance with laws that mainly protect rights of innovators is not a necessary condition. Compliance with TRIPS entails that states delimit economic and social entitlements, like health, to their barest form in order to avoid disruption of intellectual property rights of innovators. Morally speaking, therefore, legislation and safeguards related to health cannot be located within the spaces provided by TRIPS. If states recognize health as a right, either a derivative of the right to life,[23] or a constitutional right ,[24] they needs to move beyond the grants within the TRIPS framework and embrace the many and varied duties that flow from the recognition of these rights. Health-related duties of states cannot expand or contract with reference to rights of innovators. Rather, the rights of innovators must be integrated within the framework of these fundamental human rights.

Foremost in the minds of the drafters of 3d, was not compliance or non-compliance with TRIPS, although some concerns with TRIPS compatibility were expressed[25] in the Indian parliamentary debates, which took place in the context of Patent Amendment Act of 2005. These debates reveal that legislators were mainly concerned about health and related issues. [26] Foremost among these were concerns related to public health, access to generic drugs both in India and globally, the future of generic antiretroviral drugs, and drug prices. Following are two excerpts which echo the concerns expressed in the Parliament on the eve of India becoming fully TRIPS-compliant, and adopting a product patent regime for pharmaceuticals:

> "This is the endeavour of this Government – that this law strikes a right balance between patent holders' rights and earnings and consumers' interests, and economic development to ensure maximum social welfare of the people of the country, who should not be denied access to effective, safe and quality medicines".
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> "If the decree is not changed before the Parliament approves it, it will be very difficult for India to supply life-saving drugs and Indian Parliamentarians must keep in mind that this arcane

[23] For instance India where right to health is interpreted as a derivative right of the right to life enshrined in Art. 21 of the constitution (for court interpretations refer *Bandhua Mukti Morcha case* (AIR 1984 SC 802), *Surjeet Singh v. the State of Punjab* (1966-2-SCC-366), *Paschim Bengal Khet Mazdoor Society* v. State of West Bengal(AIR 1996 SC 2426); For a similar interpretation of courts see the Venezuela case of Cruz *Bermudez et al v. MSAS*, 1999; the Ecuarorian case of *Mendoza & Ors v. Minister of Public Health and the Director of the Nationsl AIDS-HIV-STI Programme.* Case references from COHRE's Litigating Economic, Social and Cultural Rights: Legal Practitioners' Dossier, 2006. http://www.cohre.org/store/attachments/COHRE%20Legal%20Practitioners%20Dossier.pdf

[24] In South Africa for instance. S.Afr.Const. 1996, Art. 27; See also Art. 24.

[25] (XIV-IV Session – 25 Feb-24 Mar, 2005)

[26] Available at http://164.100.47.133/debate14/debtext.asp?slno=1866&ser=WTO&smode=t . (Accessed 10 Aug. 2008)

> dispute is actually a crucial battleground for the health of hundreds of millions of people in India and world-wide."

The parliamentary debates anticipated the fact that the global product patent regime, that India would become part of, would have significant implications for public health and, importantly, for the supply of affordable drugs to the rest of the world. The concern was based on the fact that over a period of time Indian drug companies would lose the opportunity to develop processes for patent protected drugs in the country, and therefore would cease to be suppliers of affordable generic drugs to millions across the world. Consequently, the need was felt for safeguards keeping in mind India's pharmaceutical export potential and public health concerns.

It is in the background of these debates and concern that 3d needs to be evaluated. In focus are two issues: first, the right of a sovereign country to build in safeguards in its patent laws in order to safeguard the interest of its people. Second, the viability and the *de jure* acceptability of the Doha provisions, especially Para 4, which recognizes the right of a state to protect and promote health rights. Both issues relate to drug access, so vital for the realization of health as a human right. Section 3(d), therefore, should not be assessed or gauged in terms of its compatibility with TRIPS, for TRIPS does not have the normative core that can benchmark the realization of fundamental rights like the right to health.

In this context it is important, however, to point out that 3d is at best a health safeguard and is not a proxy for health rights which have not acquired a constitutional status in India, except as a derivative of the right to life. It is only a provision which seeks to delimit the scope of patentability and in the process can ensure the non-exclusion of cheaper generic supplies. The provision needs to be viewed as an attempted health safeguard, both in intent and, as it turned out, in practice during Novartis' fight for a patent claim on its anti cancer drug, Glivec. A brief review of the case will bring out the dynamics of Section 3d.

THE GLIVEC PATENT BATTLE IN INDIA

Glivec (Imatinib Mesylate) is a cancer drug crucial in prolonging the life of patients suffering from Chronic Myeloid Leukemia (CML - Blood Cancer). Since Imatinib Mesylate controls the cellular action that allows the cancer to grow but does not cure the disease, patients must take it for the rest of their lives, unless another type of treatment or cure is available. Glivec is produced and marketed internationally by the Swiss pharmaceutical company Novartis and various Indian generic producers like Cipla, Ranbaxy, Natco, and Hetero. Novartis sells Glivec at 26,000 USD per patient per year. Generic versions of the drug Glivec in the Indian market are priced approximately at 2100 USD per patient per

year.[27] Novartis is charging high prices for Glivec worldwide: from about 25,000 USD to more than 50,000 USD per patient per year (50,000 CHF per patient per year in Switzerland).[28]

PATENT CLAIM BY NOVARTIS

In 1998, Novartis filed an application in the Chennai Patent Office (CPO) for a patent on Glivec. Based on the patent application and a particular provision (92 A) of the Indian Patents Act, in November 2003, Novartis obtained exclusive marketing rights (EMR) for Glivec, pending a final decision on the patent; in case the patent was rejected EMR would be cancelled.[29] The EMR operated like a patent monopoly preventing Indian pharmaceutical companies from producing affordable generic versions of the drug Imatinib Mesylate. Indian courts specifically forbade six out of nine generic manufactures to market imatinib mesylate. Indian generic manufactures had to withdraw production and sale of generic versions of the drug from the domestic market and from export to other developing countries. With an over-10 fold increase in the price of the drug, Cancer Patients Aid Association (CPAA) and some of the non-governmental organizations (NGOs) who provided affordable generic versions to cancer patients had to withdraw their medical support. CPAA even moved the Supreme Court of India against granting EMR to Novartis.[30]

Novartis' patent application on Glivec came up for examination in 2005. Armed with the 3d provision, pre-grant opposition was filed by Natco Pharmaceuticals, Alternative Law Forum (ALF) and Lawyers Collective, acting on behalf of the CPAA. [31] These bodies claimed that this application only concerned a modification of an already existing drug that did not improve its efficacy as required by Section 3(d) of the IPA. In addition, they claimed that the non-availability and non-affordability of any form of Imanitib Mesylate to Chronic Myeloid Leukemia (CML) patients is violative of these patients' rights under Articles 14 (right to equality before law), and 21 (right to life and personal liberty) of the Indian Constitution.[32]

Two points in the Novartis patent claim are particularly worthy of attention, for they are instructive on how the criteria of novelty and non-obviousness are often manipulated. Imatinib as a '*free base*'

[27] Novartis Files Case in India Challenging Patent Controller's Order and Patent Law. Berne Declaration. Available at http://www.evb.ch/en/p25011414.html#note1#note1.

[28] Ibid

[29] India amended her regime in 1999 to provide for exclusive marketing rights. See Chapter IVA of *The Patents (Amendment) Act 1999 (India).*

[30] CPAA also contested the fact that there were only around 7000 CML patients, 99% of who were covered by Novartis GIPAP and provided Glivec free of charge. According to CPAA there are 30,000 CML patients detected every year most of who are not covered by Novartis drug donation program. Quoted from *Times of India*, Sunday Mailbox, April 22, 2007

[31] As did Cipla, Natco Pharma, Sun Pharmaceuticals and Ranbaxy in their own right. Natco Pharma, which launched a generic version of Gleevac under the brand `Veenat', had also challenged the grant of EMRs to Novartis.

[32] Text of the Writ petition No. 24759 OF 2006 in The High Court of Judicature at Madras. Clause16, p.12

molecule was invented by Novartis in 1992, and patented in the US and other countries in 1993.[33] But in 1998, in its application before the CPO, Novartis came up with an application for a *beta crystalline form* of imatinib mesylate, a salt which was claimed to be 'a new form of a known substance'. As this beta crystalline form – Glivec - of Imatinib mesylate, was the most thermodynamically stable, and also the form that the salt normally assumes, it was considered 'obvious'. This was asserted by the opponents to patent application, through evidence of multiple tests performed by the Indian Institute of Chemical Technology, Hyderabad and Indian Institute of Technology, Delhi. Further, this 'new' salt was a beta-isomer of the already disclosed imatinib mesylate and isomers were, as per the Explanation to 3d "*considered to be the same substance, unless they differ significantly in properties with regard to efficacy"*.[34]

Since imatinib mesylate was already known from prior publications, it, therefore, needed to demonstrate enhanced efficacy in order to fulfill the 3(d) patentability criterion. In full knowledge of this requirement, Novartis tried to demonstrate before the Controller that there was an enhancement of efficacy. It submitted that there was an enhanced 'bioavailability' of 30% in studies conducted on rats. Bioavailability is one of the indicators of efficacy of a drug. However, the explanation to section 3(d) requires enhancement be 'significant'. Novartis' case suffered as they had produced a bioavailability study conducted on rats only, even though the drug was admittedly in the market for many years and was consumed by humans. Then again, it was not shown how the 30 per cent increase was critical in the performance of the drug and how this increase made a difference when compared to the known efficacy of other forms of imanitib mesylate.[35]

Following these grounds of pre-grant oppositions, the Assistant Controller of Patents & Designs, V. Rengasamy, in his ruling, said he was not convinced with the contention of Novartis that its patent claim was for a new substance. He ruled, in effect, that Glivec was only a new form of a known substance. In his words, 'It is found that this patent application claims only a new form of a known substance without having any significant improvement in efficacy'. Further, stating that Novartis had failed to prove enhanced efficacy of the beta-isomer over the known substance, the Assistant Controller concluded that, 'the subject matter of this application is not patentable under Section 3(d) of the Patents Act 1970 as amended by the Patents (Amendment) Act, 2005.' Novartis's application to patent the beta crystalline form of imatinib mesylate was thus rejected by CPO in January 25, 2006.[36]

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[33] Invention of the base compound, called as imatinib had already been disclosed in the European Patent publication no. EP-A-056409, published on October 6, 1993, and its equivalent US Patent no. 5521184, etc. [IP-health]... The patent term extension certificate granted by US Patent Office for the 1993 Patent explicitly mentions imatinib mesylate (Glveevec R)as the product. For details see Text of Indian Decisions on Glivec Patent Application http://lists.essential.org/pipermail/ip-health/2006-March/009200.html

[34] Refer 'Explanation' to section 3d.

[35] Technical challenges were submitted to the Controller about the enhanced efficacy of the new compound by Natco Pharma Ltd. C.R. Sukumar, 'Novartis Loses Patent Claim On Cancer Drug — Patents Controller upholds Natco contention', *Financial Daily, The Hindu*, Jan 26, 2006

[36] Decision of the Controller available at http://www.scribd.com/doc/416824/Patent-office-Order-India-Glivec

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THE NOVARTIS CHALLENGE [37]

On 17th May 2006, aggrieved by the order of the Controller, Novartis filed two cases before the Madras (Chennai) High Court. It not only appealed the patent office decision, but, in a rather controversial move, it also challenged 3d on the grounds of lack of TRIPS compatibility and unconstitutionality. Its writ petition[38] alleged the following:

1. That section 3(d) of the Patents Act is unconstitutional on the ground that it violates Article 14 of the Constitution of India, that is the right to equality, as it discriminates against the pharmaceutical sector vis-à-vis other technology sectors.
2. The 'new Section 3(d)' is in violation of India's obligation as a signatory to the TRIPS under Article 1(1), Article 27 of the TRIPS
3. Section 3d is vague and arbitrary. Its formulation, that a discovery becomes an invention if the substance in question results in enhancement of known efficacy is a very "ingenious concept"…and "defies logic". [39]

On February 23, 2007, the Chennai High court, in accordance with the IPA, converted one part of its case – the challenge to the patent office's decision to not grant a patent for Glivec – from a writ petition to an appeal and transferred it to the Intellectual Property Appellate Board (IPAB).

The case, at this stage, got divided into 3 parts: patentability of Glivec; 3d's compliance with TRIPS; and constitutional validity of 3d.

Part 1 of the case rests with IPAB. It is believed to be likely that the patent rejection by the CPO will be upheld. To win, Novartis must convince the IPAB that: (a) in relation to 3d the 30% increase in bioavailability is an enhanced efficacy and so the beta crystalline form is patentable, and (b) the beta crystalline form of the mesylate salt is not an obvious form of the free base form.

For *part 2*, the Court considered the WTO's Dispute Settlement Board a more appropriate forum. It further stated that it was outside the purview of the Court to adjudicate in this matter.

Consequently the decision in the Court hinged on *part 3* - Section 3 (d) and its constitutionality. The Chennai High Court on 6th August, 2007**,** upheld the validity and constitutionality of 3d. The Court stated that 'India, being a welfare and a developing country, which is pre-dominantly occupied by people below poverty line, has a constitutional duty to provide good health care to its citizens by giving them easy access to life saving drugs. In so doing, the Union of India would be right to take into account

[37] Writ Petition No. 24759 0f 2006 in the High Court of Madras
[38] Writ Petition No. 24759 0f 2006 in the High Court of Madras
[39] Refer, Novartis petition at The High Court of Judicature at Madras (Special Original Jurisdiction) w.p.no.24759 of 2006

the various factual aspects prevailing in this big country and prevent "evergreening" by allowing generic medicine to be available in the market'.[40]

It further ruled that there is no ambiguity or vagueness in the expressions under attack as found incorporated in the amended section and the explanation attached to it. Also, 3d is an "obviousness" standard, and member states are free to define the same in a manner consistent with their national policy. It added that while one of the fears of the petitioners was that the amended 3d could lead to arbitrary interpretations and misuse, 'no law can be declared illegal because there is a possibility of its misuse' and 'the Legislature has a duty to safeguard the economic interest of the country.'

The court held that the amended section is not in violation of Article 14 of the Indian Constitution. 3d does not "discriminate" against the pharmaceutical sector, it only makes a "justified differentiation", given the specificity of salt forms in the sector. Other technology sectors such as mechanicals, electronics, etc., do not face such issues.

Several important issues emerge from the judgment. First, the judgment clearly views the pharmaceutical sector as a sector which merits a justified "differentiation" for its ability to impact human life. In doing so it draws an order of priority amongst competing claims and entitlements and rules that the constitutional obligation that the state has towards providing good health overrides the imperatives of TRIPS obligation. In referring the matter of TRIPS compliance to the dispute settlement board of the WTO it clearly demarcates issues of patentability and health entitlements. It thus, provides a framework for evaluating the adequacy of a health safeguard in the light of the health imperatives of the country and, very significantly, the health imperatives of the global civil society, implying that there is need to conceptualize health rights in non-citizenship terms also.

Second, The 3(d) provision provided a useful scheme for the courts to catalyze decisions, relating to drug patents, with added criteria of, what appears to be, a set of scientific, technical requirement. The intent of 3(d) was, quite clearly, to prevent evergreening of drugs, for furthering patent claims. It was this intent which got reflected in the court's decision. It is this intent, more than the actual framing and conceptualization of the provision (which has been quite widely adjectivized as "vague", "arbitrary", "nebulous", "shoddy drafting"), which has functioned as a defense against internationally imposed mechanisms that constrain access rights. The court has been able to harness the full potential of this section in order to read in health related concerns into the very determination of patentability of a substance. The court's role thus goes beyond the merely judicial, into the administrative – by making a policy matter – health outcomes– a part of its concern. It consciously adopted adjudicating on grounds of socio-economic (health) entitlements, and in doing so the court, in many ways, provides a lead and presets the grounds of future adjudications, both nationally and internationally. As a galvanizer, this judgement may lay the basis for health safeguards to prefigure in actual legal-institutional outcomes, .

[40] *Novartis AG & Anr. v Union of India & Othrs.*, (2007) 4 MLJ 1153.

The judgment has effects beyond the immediate refusal to grant the patent. The judgment, not only affects other and similar patent claims, but also has the potential to expand the global discourse on inventiveness for pharmaceutical patents. It provides a framework for balancing arguments to proceed, whereby justifications for limitations of property rights and for their narrower construal are available. The judgement thus lays the case open to generalization and application.. It is this aspect of the provision and the judgement that the case study highlights

IMPLICATIONS OF THE GLIVEC CASE FOR DRUG ACCESS

At stake in the Glivec case was, and in many ways still is, not just the fate of the Indian drug industry but the life and well-being of hundreds of millions of users of generic drugs the world over. 'We have opposed patent applications for crucial AIDS drugs', says Elango Ramchandar, president of Indian Network for People with HIV/AIDS. 'Our survival depends greatly on winning these patent oppositions. Novartis is a test case for us.'[41] This case also has huge implications for the supply of affordable medicines not just in India, but in African countries and other parts of the developing world that rely on medicines exported from India. The ramifications of this case are wide and multidimensional.

The Glivec/Novartis case has implications beyond the provisioning of Glivec at affordable prices. There are 150 pre-grant oppositions before the Indian Patent Office which are likely to be affected by the Glivec ruling. [42] Prominent among these oppositions are some that involve an AstraZeneca's lung cancer drug and a cholesterol-lowering medicine; a Pfizer treatment for fungal infections; Roche's Tamiflu bird flu medicine; Eli Lilly's erectile dysfunction drug; Merck's Efavirenz, Gilead Sciences's Tenofovir and Amprenavir; and also Roche's hepatitis drug Pegasys.[43] Now under threat are drugs that are not truly innovative.[44]

It is in this context that the Glivec case assumes a global significance and it is for this reason that it became the face of the global campaign to save generic production of drugs in India. Ninety-one

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[41] Quoted from Praful Bidwai, High Stakes in Attack on Indian Patent Law, *One World,* *http://www.commondreams.org/headlines07/0202-08.htm* (Accessed 12-11-2007)

[42] There have been very few cases where Section 3(d) of the Patent Act, 2005 has been used as the basis for the rejection of a patent application. After the Glivec case, Delhi patent office rejected the claim for an anti HIV Nevirapine composition, as falling short of satisfying the increased efficacy hurdle under section 3(d). Details available at http://www.lawyerscollective.org/sites/default/files/Patent%20Decision%20-Pg%208-14.pdf. A recent court case, where the Delhi High Court declined to grant a temporary injunction to Roche, who sued CIPLA for infringement of its patent covering its anticancer drug, Tarceva. CIPLA counterclaimed invalidity, citing section 3(d) as one of the grounds. See *F. Hoffman-La Roche Ltd. & Anr. v Cipla Ltd*., CS(OS) 89/2008, Delhi High Court.

[43] Ed Sliverman, "India's Gleevec Ruling Is Bad News For Other Drugmakers Too," *Pharmalot.* http://www.pharmalot.com/2007/08/indias-gleevec-ruling-is-bad-news-for-other-drugmakers-too/. Also see, Lawyers Collective and their AMTC campaign reports at http://www.lawyerscollective.org/^amtc/^Patent_Oppositions/introduction.asp

[44] For a view that the majority of research conducted by industry is for higher-priced and similar versions of existing medicines, See H. Mintzberg, 'Patent Nonsense: Evidence tells of an industry out of social control," *Canadian Medical Association Journal* 175 (4), 15 August 2006. Only 15 per cent of the new drug applications approved by the US Food and Drug Administration (FDA) from 1989 to 2000 were identified as clinical improvements over products already on the market.NIHCM, 'Changing patterns of pharmaceutical innovation', May 2000. See http://www.nihcm.org/finalweb/innovations.pdf.

organizations and personalities from around the world had made calls to Novartis to drop the case in an open letter, in October 2006, to Daniel Vasella, Chairman and CEO of Novartis.[45] India has, over the years, become a very large player in the production and exports of generic medicines the world over, justifiably earning the designate "the pharmacy of the developing world". The following figures compiled by Médecins Sans Frontières (MSF) highlight the importance of India as a crucial player in access to affordable medicines.

1. 67 % of medicines produced in India are exported to developing countries.
2. 75-80% of all medicines distributed by the International Dispensary Association (IDA) to developing countries are manufactured in India.
3. In Zimbabwe, 75% of tenders for medicines for all public sector health facilities come from Indian manufacturers. 90% of the ARVs used in Zimbabwe's national treatment programme come from India.
4. The state procurement agency in Lesotho, NDSO, states it buys nearly 95% of all Anti Retrovirals (ARVs) from India. [46]
5. India ranks second on the list of countries from which UNICEF purchases medical supplies. Belgium only ranks first because of vaccines (e.g. combination vaccines are not yet being produced in India).
6. 80% of ARVs MSF uses are purchased in India and are distributed in treatment projects in over 30 countries.
7. Over 90 %of all patients using AZT/3TC in MSF projects are on generic versions of the drug.
8. Globally, 70% of the treatment for patients in 87 developing countries, purchased by UNICEF, IDA, the Global Fund (GFATM) and the Clinton Foundation since July 2005 has come from Indian suppliers.
9. The US President's Emergency Plan for AIDS (PEPFAR), also purchases ARVs from India for distribution in developing countries, thus resulting in cost-savings of up to 90%. 89% of the generic ARVs approved by the US Food and Drug Administration for PEPFAR are from India.[47]

Globally, life-saving drugs remain beyond the reach of the majority of people with HIV/AIDS. For instance, of the 6 million people worldwide who needed ARVs in 2003, fewer than 8% were receiving them.[48] Many millions of people still cannot access existing vaccines and drugs for tuberculosis, malaria, cancer, neglected diseases and many others. By excluding generic versions, essential-drug patents have the potential to undermine access to medicines for HIV/AIDS, for heart disease, for diabetes, in fact for every new medicine needed by the poor in developing and poorer countries. In every

[45] Available at http://www.evb.ch/en/p25011413.html

[46] Source for (1) to (4): Campaign for Access to Essential Medicines. Examples of the importance of India as the 'Pharmacy of the World' http://www.accessmed-msf.org/documents/Overview%20Jan%202007%20FINAL.doc

[47] Source for (5) to (9)Campaign for Access to Essential Medicines. Available at http://www.accessmedmsf.org/documents/Overview%20Jan%202007%20FINAL.doc. (Accessed 19 Jan.2007)

[48] K. Attawell, and J. Mundy, 'Provision of Antiretroviral Therapy in Resource-Limited Settings: A Review of Experience up to August 2003,' Health Systems Resource Centre, Department for International Development, London, 2003. Available at: http://www.who.int/3by5/publications/documents/en/ARTpaper_DFID_WHO.pdf. (Accessed April 4 2005)

case generic prices present an opportunity for cost savings. A PEPFAR report states that in some cases, the branded price per pack of a drug is up to 11 times the cost of the approved generic version. [49]

Table 1: Price Differentials between Branded and Generic Drug Prices

Brand Name -- Generic Name		
Note: Generics have an asterisk		
Mean Pack Price US$		
Stocrin-- Efavirenz*	**FY04**	**FY05**
Stocrin 600mg (30 TAB)	32.50	32.76
Efavirenz 600mg (30 TAB)*	n/a	23.30
Retrovir-- Zidovudine*		
Retrovir 300mg	21.67	34.78
Zidovudine 300mg*	n/a	14.48
Zerit-- Stavudine FY04 FY05		
Zerit 15mg (60 CAP)	4.88	9.22
Stavudine 15mg (60 CAP)*	n/a	5.18
Zerit 1mg/ml	10.73	8.71
Stavudine 1mg/ml*	n/a	7.15
Zerit 20mg (60 CAP)	6.36	5.99
Stavudine 20mg (60 CAP)*	n/a	5.64
Zerit 30mg (60 CAP)	6.48	6.20
Stavudine 30mg (60 CAP)*	n/a	3.83
Zerit 40mg	6.60	6.14
Stavudine 40mg*	n/a	4.32
Viramune-- Nevirapine*		
Viramune 10mg/ml	24.81	24.30
Nevirapine 10mg/ml*	n/a	7.50
Viramune 200mg	50.23	59.86

[49] 'Bringing Hope: Supplying ARVs for HIV/AIDS treatment,' PEPFAR, May 2006

Nevirapine 200mg*	n/a	5.79
Viramune 50mg/5ml	26.19	34.79
Nevirapine 50mg/5ml*	n/a	7.50
Epivir-- Lamivudine		
Epivir 150mg	7.22	13.56
Lamivudine 150mg*	n/a	4.93
Epivir 10mg/ml	7.34	9.12
Lamivudine 10mg/ml*	n/a	5.35
Combivir-- Zidovudine/		
Lamivudine*		
Combivir 300/150mg	24.87	24.23
Zidovudine/		
Lamivudine 300/150mg*	n/a	17.51

Source: PEPFAR Report on Antiretroviral Drugs for HIV/AIDS Treatment. [50]

Besides price differentials, generics also impact pricing structures of patented drugs. Take the case of Cipla's aggressive pricing of its ARV drug, *Triomune*. This encouraged Merck, a US pharmaceutical company, to reduce the price of *Crixivan*, a protease inhibitor, to about the same price, which in turn caused Bristol Myers Squibb and Glaxo SmithKline to follow suit. Moreover, Abbott Laboratories, holder of patents over *Kaletra*, another HIV drug, came to an agreement with the Brazilian government reducing the price by 30 per cent – a saving of US$10 million per year.

Table 2: The Price War (2001)

Drug (Company)	US Price	Cipla	Hetero	Company Offer in Africa
Zerit (Bristol-Myers)	3,589	70	47	252
3TC (Glaxo)	3,271	190	98	232
Crixivan (Merck)	6,016	N.A.	2,300	600

[50] Available at http://www.state.gov/documents/organization/66513.pdf . Also available in this report are data and figures on the increasing role that generics have come to play in providing access to ARV drugs in LDCs and developing countries. And India plays a vital role in generic supplies.

Combivir (Glaxo)	7,093	635	293	730
Stocrin (Merck)	4,730	N.A.	1,179	500
Viramune (Boehringer)	3,508	340	202	483

Note: Prices are for AIDS drugs per patient per year in the US and Africa offered by drug TNCs and two Indian generic drug companies. Prices are in US dollars.

N.A. – not available.

Source: Wall Street Journal – Available on the TWN website http://www.twnside.org.sg/title/twr131c.htm

Tables 1 and 2 are instructive in ascertaining the role that generic drugs play in assuring access to essential drugs. They have come to play a vital role in public health agendas with the realization that access can be affected at the practical level by the introduction of patents on medicines. While the world today, and least of all the developing world, is not at the liberty to discard patents in pharmaceutical products, measures like 3d are attempts to induce a balance between intellectual property rights of the innovators and human rights like the right to health.

3D AS A "PRECAUTIONARY PRINCIPLE"

One of the core issues concerning access to medicines is the stipulation of the scope of patentability specifically in relation to pharmaceutical substances. Though the usual test for patentability requires that the innovation be new, not-obvious, and useful; some modern scientific sectors, among them the biochemical-pharmaceutical sector, have made it more difficult to clearly demarcate between the fulfillment of the first and second criteria.

The amended Section 3(d) was clearly intended to make the criteria for patentability of pharmaceutical products more restrictive. Courts' refusals to grant injunctions against patent infringements,[51] court proceedings, depositions, the judgement in the Glivec case,[52] civil society debates, the initial exclusion of pharmaceutical drugs and food from the purview of patentability in the IPA, etc., are all pointers that India is a reluctant signatory to pharmaceutical patents. The right to health (though only a derivative of the right to life), public interest, access to drugs and irreparable injury are important considerations which shape the wisdom that access rights to drugs need to be protected vis-à-vis rights of innovators. The amended section makes it amply clear that just about any improvement made to a known substance shall not merit protection. Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall

[51] The Roche case, refer note 38.

[52] See *Novartis Update*, 29th Jan 2007: http://www.lawyerscollective.org/content/novartis-update-%3A-29th-jan-2007.

be considered part of 'prior art' unless they exhibit, clearly, novelty in use by way of 'enhanced efficacy,..

Section 3(d) therefore needs to be viewed more as a "Precautionary Principle" (PP), than a mere technical requirement for patentability. This principle, formalized at the 1992 United Nations Conference on Environment and Development, emphasizes that the discipline of precaution be carefully exercised to avoid potential harm and unforeseen and unintended consequences. The principle requires that precaution should prevail whenever questions of human and environmental health are involved and mandates restraint until cause and effect relationships are properly understood.[53] While largely debated and deployed in the context of genetic modification in foods and environmental degradation, the PP may legitimately be used to create exceptions to patentability. The argument here being that if there is a risk or uncertainty of a health emergency, and there is a likelihood of large scale potential harm, precautionary measures ought to be taken to prevent the damages before they come to be real. A precautionary principle can, in other words, be legitimately developed to prevent health emergencies. This is where this principle scores over the compulsory licensing provision implied in Article 31 (c) of TRIPS, which provides a measure for addressing health emergencies, but not preventing them.

Chronic diseases like hypertension, heart disease, diabetes, and asthma, infectious diseases like tuberculosis, HIV/AIDS, neglected diseases like sleeping sickness, leishmaniasis, dengue are diseases that threaten poor populations. Clearly, if we reduce access to drugs that reduce this threat, through patents and the concomitant rise in prices, we are only precipitating the threat. Recognizing the objectives of science, the precautionary principle is intended to enable and encourage precautionary actions that serve underlying values of scientific endeavour: health and right to dignified existence being one of them. It is the classical liberal duty of restrain from harm.

An observational study of brand and generic supply based on a dataset of 2,162 orders of AIDS drugs for Sub-Saharan Africa reported to the Global Price Reporting Mechanism at the WHO from January 2004-March 2006 was performed. Generic companies supplied 63% of the drugs studied, at prices that were on average about a third of the prices charged by brand companies. 96% of the procurement was of first line drugs, which were provided mostly by generic firms, while the remaining 4%, of second line drugs, was sourced primarily from brand companies. *85% of the generic drugs in the sample were manufactured in India*, where the majority of the drugs procured were ineligible for patent protection.[54] The 3d safeguard was introduced keeping in mind India's pharmaceutical export potential and public health concerns. To this extent there was perhaps a conflation of interests of the consumers with the domestic drug industry. Drastic levels of poverty and problems of drug access related to drug pricing warranted a reduction in the scope of patent grants.

[53] Wingspread Statement, 1998

54 World Health Organization (2006) AIDS Medicine and Diagnostic Services. Available: http://www.who.int/3by5/publications/briefs/amds/en/index.html. Accessed 16 August 2006.

3d, viewed as a precautionary principle, forms a legitimate ground for reviewing patentability of specific pharmaceutical products. It is based on a recognition that patent claims for incrementally modified drug ought to be disallowed, by stringently interpreting and adhering to patentability criteria, in light of the 'potential harm' it can cause to public health by reducing generic supplies and seriously hampering drug access, especially for life-threatening or life-altering diseases. It views accessibility of medicines as a key element of public health policy. It is based on the understanding that narrow novelty standards lower the bar to assess inventive step. A greater number of grants made on the basis of low standards of patentability may lead to unnecessary limitations on competition, especially from generics, "without any significant trade-off in terms of more innovation to address society's needs".[55]

3d is an assertion that TRIPS Agreement should be interpreted and implemented in a manner supportive of countries' right to take measures to protect public health and promote access to medicines. Precaution is at the heart of medical and public health practice, as embodied in the 'first do no harm' tenet of medicine. It can be used as a tool to redirect innovation towards
Supply of affordable drugs to meet human needs The field of medicine and public health urges research agendas, and public policies related to them, to support examination of broader hypotheses which includes the cumulative and interactive effects of patented drugs and risks to vulnerable sub populations.

The term "efficacy", which forms the core of the PP implied in 3d, emerges as a useful policy lever. As Shamnad Basheer discusses in his paper, it can be defined restrictively to mean "therapeutic" efficacy, or widely to include "all kinds of advantageous properties exhibited by the new form including heat stability, enhanced bioavailability, humidity resistance, new drug delivery mechanisms etc."[56] Like most instances of PP, even 3d continues to be a controversial provision. Restrictive interpretations, Basheer and Reddy argue, would stifle innovation and affect R&D incentives in relation to diseases of specific concern to India, such as malaria, tuberculosis and other neglected diseases. A wide interpretation, on the other hand would lead to expanding the scope of patentability with the expected trade-off with drug accessibility.

[55] Carlos Correa, 'Guidelines for the examination of pharmaceutical patents: developing a public health perspective.' ICTSD — UNCTAD, January 2007 l

[56] Shamnad Basheer & T. Prashant Reddy, 'The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)'. Available at http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.asp (Accessed Sept. 11, 2008)

There is ,therefore, a fine line to be tread in determining grounds of "efficacy", balancing both innovation in pharmaceutical R&D and protecting and promoting the health security of vulnerable sections of the population.

The issue of what constitutes "enhanced efficacy" of a drug is not in general settled. As Srinivasan states, nor is "the means to establish the validity of a claim for enhanced efficacy. Is it bioequivalence or bioavailability? How much difference should be there in each to show that 'they significantly differ in properties with regard to efficacy?' What indeed is the definition of efficacy?"[57] This may not even be an issue which can be settled under a global juridical rubric because of the number of variations that subsequent cases may present, such that factors like "bio-availability", "bioequivalence", and "efficacy" will necessarily imply different measures in different contexts. There cannot be mathematically derived parameters which can be applied with any degree of consistency or uniformity.

Moreover, the debate on what constitutes "invention", "novelty", "prior art", etc., is likely to get further aggravated, for other countries are planning to incorporate 3d-type precautionary principles in their patent legislations. Maldives, Pakistan, Sri Lanka, Vietnam, Indonesia, Malaysia and Bangladesh are actively considering adapting Section 3(d). According to an official of the Indian Ministry of Commerce and Industries: "We get a lot of enquiries from a host of countries about the provision. The Philippines[58] has already amended its law on similar lines." The Indian Pharmaceutical Alliance Secretary-General, DG Shah, adds that the nations that provided for patents for finished pharmaceutical products in 2005 now want greater flexibility in honouring their WTO commitments.[59] The prevailing socio-economic conditions of these countries would determine and influence, to a large extent, their policyformulations. There are huge variations in the socioeconomic settings of different countries, varying their concerns and interests and thus, leading to different policy and interpretative trajectories for each economy.

The value of 3d is not in settling the debate on "what constitutes invention", "what is novel", and "what is useful". If at all, it perhaps complicates the issue by adding a nebulous dimension, of what could be described as 'novel'. However, a more important function of 3d, and indeed of the Glivec judgement based on this section, is to incorporate a precautionary principle into the current dialogue on ways to protect human health. This could be stated in more express terms, and "efficacy" and "significant enhancement" could develop into more precise guidelines, [60] but as answers these can only be

[57] S. Srinivasan, 'Battling Patent Laws,' *Economic and Political Weekly*, Sept. 15, 2007, p. 3687

[58] *See* P Ollier, *Philippines plans to follow India in limiting patentability*, May 6, 2008: http://www.managingip.com/Article/1927492/Philippines-plans-to-follow-India-in-limiting-patentability.html (Accessed Aug, 18, 2008).

[59] See, GC Prasad, *Copycats Popping Patent Law Pill*, *Economic Times*, August 13, 2007. *http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Pharmaceuticals/Copycats_popping_patent_law_pill/articleshow/2276358.cms*. (Accessed 13 April, 2007)

[60] For useful suggestions as to how to make 3d 'work more "efficaciously" and to help lend more certainty to the law' see, Shamnad Basheer & T. Prashant Reddy, 'The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d),' *Scripted,* Volume 5, Issue 2, August 2008.

successful if we know the full component of questions that need to be asked. The questions need to locate the debate outside the spaces provided by WTO and TRIPS.

CONCLUSIONS

This paper uses the imagery of the '3d effect' on the Glivec case to make two fundamental points. First, that there is a need to expand the interpretative framework through which "inventiveness" is defined for the purpose of granting pharmaceutical patents, so as to safeguard access to essential drugs. TRIPS provisions do not automatically become national laws, they must be enacted in individual countries and therefore must be in consonance with the exigencies of those countries. Patent laws ought not to run counter to health guarantees, whether these are concretized in the form of constitutional imperatives (as in South Africa) or read into the right to life (as in India). Every country has a sovereign right to protect the right of access of vulnerable sections of the society to affordable drugs. Section 3(d) of the IPA needs to be evaluated in this light. It is crucial that in the decision to grant a patent, the "inventiveness" or "non-obviousness" of a substance are carefully determined, for a patent, once granted, serves as a limitation on competition. Pharmaceutical patents in particular eliminate competition from generic drug manufactures, thereby raising issues of drug prices and access. Carlos Correa argues that as the TRIPS Agreement does not define these concepts of inventiveness and novelty, member countries ought to be free to determine whether they want a system under which a myriad of incremental innovations are patentable, or one aimed at rewarding more substantive departures from the prior art. Patent offices and courts can apply more or less lax or stringent criteria to determine non-obviousness/inventive step.[61]

The second point relates to devising rules which define the relationship between intellectual property, the proprietary knowledge system that it advances, and public health. It is morally incumbent to base these rules on an understanding that pharmaceutical patents (as also biotechnological patents) constitute a special field, with the ability to critically affect lives. Since pharmaceutical products are vitally linked to the preservation of life, they cannot be treated like other consumer products. Health rights are, in a sense, prior rights of people, deriving their fundamental status as a derivative of the right to life itself. A connection between health and life is useful, because it focuses in the most urgent steps necessary for the satisfaction of these rights. Health rights are - as Henry Shue terms them - "basic rights", because they precondition the enjoyment of all other rights.[62] As Rochelle Dreyfuss discusses in an earlier chapter of this volume, the WTO and the World Intellectual Property Organization are not untouched by this realization, but they remain – at least foremost - institutions that promote intellectual property rights. In trying to achieve a balance between interests of inventors and the health rights of the consumers, within the framework of IP rights, they end up stripping human rights claims to their bare minimum so as to ensure a satisfactory consonance.[63]

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[61] Carlos Correa, 2007

[62] Henry Shue, Basic Rights: Subsistence, Affluence and U.S. Foreign Policy 23 (2d ed) 1996

[63] The text DD is instructive in this regard. It is important to underscore the point that DD does not restrict patentability in the field of health even in the context of national emergencies, as Cullet points out. It only reaffirms the flexibility in the TRIPS

The TRIPS does not provide much guidance concerning its linkages with other rights, and hardly envisages patents in relation to other fields of law. There is, for instance, no attempt in TRIPS to delineate the relationship between patents and the right to health. The relationship between intellectual property and public health is fraught with tension and one that does not provide easy resolution. This tension emerges not out of competing moral claims but out of competing institutional claims. The institutional apparatus of health rights needs to be bolstered, as Ellen t'Hoen states, in order to "outweigh full protection of intellectual property."[64]

3d assumes importance in this regard. It is an attempt to cull out a negotiating ground between patents and health rights. An attempt which would make a trade-off, from patent rights to health rights, possible. In adopting the "precautionary approach" – which implies that if patenting some drugs has the potential to cause harm, then there is a case for exercising greater caution in the grant of that patent – it has galvanized an idea that reads health concerns in the very criteria of patentability. Experimentalist as it may be, 3d has reached out to transnational actors and is beginning to set the terrain which will produce actual legal- institutional outcomes, in other parts of the world. It takes forward the discourse that legal provisions, national or international, ought to engage with exigencies of human plight and that these concerns ought to devolve into provisions that shun the either-or dichotomy of innovators' rights or health rights. A "dual operation" will always run the danger of health rights being jettisoned in favour of innovation rights: for that not to happen the turf needs to be broadened to include constitutional rights and remedies to bolster the right to health.

agreement. It specifically focuses compulsory licenses as a means to improve drug access. See for a discussion, Philippe Cullet, *Intellectual property Protection and Sustainable Development*, New Delhi: Butterworth, 2005, p.85

[64] Ellen t' Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha,' *Chicago Journal of International Law*. Vol. 3, No1 (Spring 2002), p. 46