Patentability of Life Saving Drugs and Right to Health: A critical review with Indian reference

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Introduction

In India, all drugs were generics before 2005 because there were no product patents for pharmaceuticals. India became fully TRIPS compliant in 2005 through the introduction of pharmaceutical patents, with legislation that included safeguards to protect public health. In particular, section 3(d) of India's Patent Act was included to prevent the extension of patent protection through minor product modifications, unless a 'significant enhancement of efficacy' can be demonstrated. Marred by expensive medicines, disparity with government and the pharmaceutical companies, increased tax slabs, more import duty, threat to pull out of business and growing escalation of unrealistic demands while not bridging the supply chain of essential and affordable drugs is making our mortality rate a number that cannot be ignored or misrepresented for the sake of public relations[1]. The judgment in Novartis AG vs. Union of India[2] is a game changer in these situations. Novartis took legal action against the Indian government to challenge the constitutionality of section 3(d). When this was rejected, the company sought to have *imatinibmesylate* recognized as patentable although it did not have any effective efficacy. The Novartis case is important because it highlights that it's no longer acceptable to the global public that hundreds of millions of people are denied access to life-saving drugs because of monopoly pricing. And the case shows that governments in developing countries with some economic and political clout, such as India's, are prepared to fight the big pharmaceutical companies. The right to life and health is a fundamental right guaranteed to every person living in India and is non-negotiable. India has amended the Patents Act in 1999 and 2002 to comply with the obligations of Trade-related Aspects of Intellectual Property Rights (TRIPS)[3]. The only pending obligation with regard to TRIPS is the introduction of product patents to medicines and agro-chemicals. The product patent prohibits others from making, using, offering for sale, selling or importing the patented product. As a result, the product patent gives a monopoly to the patent owner for the production of patented article during the term of the patent (20 years). Therefore, product patent protection for medicines and agro-chemicals creates monopoly and eliminates competition in the pharmaceutical market. Drug companies often abuse the patent monopoly and fix exorbitant prices for the patented medicines. The introduction of product patent thus reduces accessibility and affordability of drugs[4]. The net result of the TRIPS accord has been high cost of medicines and the consequent denial of access to medicines to the poor across the globe. Further, it has also led to a situation where medicines required to treat diseases that predominantly occur among the poor are not researched at all. Instead drugs that are being researched are drugs used for "lifestyle" diseases like impotence, baldness, obesity, etc. While the pharmaceutical industry claims that high prices are explained by the massive expenditure on R&D, the truth is that drugs they actually research have little relevance to real medical needs. Moreover, the kinds of profits that big pharmaceutical MNCs generate are an indication of profiteering and not just legitimate profit making. Before signing of the WTO agreement, and in the ensuing 10 years till date, globally as well as in the country, diverse contentions have emerged about the impact of TRIPS compliant Patent Laws on domestic industry – especially in developing countries. There is, however, a wide consensus that domestic laws, while being TRIPS compliant, need to make full use of "flexibilities" available in the TRIPS agreement. This was reiterated in unequivocal terms by the WTO Doha Declaration on TRIPS Agreement and Public Health (2001), which, inter alia, commented that countries have the sovereign right to enact laws that safeguard domestic interests. It recognized the gravity of public health problems in developing countries and clearly provided that the member countries had the right to protect public health and to promote access to medicines for all.

Patenting Of Life Saving Drugs: Revisiting the Debate

The relationship between human rights and intellectual property requires elaboration. On the one hand, intellectual property does not provide much guidance concerning its links with other fields of law. On the other hand, human rights treaties show that the interests of the patent holder are recognized but not as fundamental rights and that the interests of the community at large come first[5].TRIPs was adopted as a stand-alone agreement which makes no mention of the impacts it can have, for instance, in the field of health.

[1] Emmanuel Kolawole Oke, Incorporating a right to health perspective into the resolution of patent law disputes, Health and Human Rights Journal 2013, Vol 2, p. 23.
[2] AIR 2013 SC 1311.
[3] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO) (1994), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
[4] G. Dutfield, Intellectual property rights and the life science industries: Past, present and future, 2nd ed. (Singapore: World Scientific Publishing, 2009), pp. 315–316.
[5] G. Dutfield, Supra Note 4.

Nevertheless, WTO member-states that are also parties to human rights treaties cannot draft legislation to implement WTO obligations without considering its compatibility with other international obligations, such as human rights commitments. In fact, the UNCESR has specifically indicated in the case of the right to health that states should not agree to measures that are manifestly incompatible with their previous international legal obligations. Even though the formulation of the right to health at the international level is vague, it gives at least a broad framework within which health policies should fall. Thus, it imposes on governments to progressively facilitate access to drugs. Since patents on drugs tend to push prices up, governments have a duty to ensure that the introduction of product patents does not jeopardize access to drugs. Indeed, not only should states refrain from taking any steps that limit access to drugs but also they should also actively pursue better access over time. In this sense, it is doubtful whether the amendment to the Patents Act of 1970 can stand scrutiny under human rights treaties[6]. The 1970 Act introduced a number of limitations on the scope of the rights granted to patent holders with specific public health goals in mind. Dismantling the whole regime amounts to taking several steps back in terms of access to drugs. This seems even truer in the context of the HIV/AIDS crisis, where some of the existing drugs are often available only at prices that are prohibitive for the general public[7].

The patents bill attempts to put India in compliance with its TRIPs obligations. In the process, it sets aside some of the most salient elements of the current legal regime which, together with other instruments such as the Drugs Price Control Order, have generally served well the interests of the country and its inhabitants. It is likely to bring about a legal regime that is less favorable from the point of view of access to drugs for the people of this country. The rationale for introducing the bill in this form was partly that TRIPs does not provide much flexibility in the way it can be implemented. This has now been proved wrong as the examples from South Africa and Brazil indicate. There is today scope for flexibility within TRIPs itself. Further, TRIPs cannot be implemented in isolation[8]. India has a number of other international obligations, particularly in the field of human rights. As interpreted by UN human rights organs, the right to health requires that countries progressively take positive steps towards facilitating access. Dismantling the 1970 regime may constitute a violation of India's obligations under the Covenant on economic, social and cultural rights. There are thus compelling reasons for redrafting the patents bill in a way which neither threatens the country's interests nor constitutes a potential violation of human rights.

The International Perspective

So far we have dealt with arguments, which says as to why patent regime in India should be kept out of the purview of medicines. Now we look at the whole discussion from an International perspective. It can be categorized as follows:

1) United Nations

One key issue at the Special Session of the UN General Assembly (UNGASS) on Social Development was the right of people to essential medicines at affordable prices, and how this right is being undermined by patents and the intellectual property rights regime established by the WTO's TRIPS Agreement[9]. At the end of the 24th Session of the United Nations General Assembly Special Session (UNGASS) in Geneva, governments agreed, after tough negotiations, that they would be allowed to freely exercise options already available to them under international trade agreements to protect and advance access to life-saving and essential medicines. In terms of real progress in addressing the need of developing Countries and poor people's access to life-saving drugs, not much was achieved. In terms of bringing to light the efforts of some of the developed countries in pushing the agenda of pharmaceutical corporations, quite a bit was achieved.

2) Doha Declaration on Health

The Declaration neither amends the TRIPS Agreement nor provides a basis for developing Countries to link their patent and health legislations. The Patents (Amendment) Act, 2002 closely follows TRIPS and in the process does away with provisions of the 1970 Act that constituted India's own response to the challenge of providing exclusive commercial rights in a field concerned with the fulfillment of basic health needs. The provisions of the 1970 act and similar legal regimes in other developing countries have been the source of significant complaints by the private sector pharmaceuticals industry in developed countries. The US pharmaceuticals lobby estimates that it currently loses more $1.7 billion annually because of India's insufficient intellectual property protection[10]. The Doha Declaration is a direct consequence of the multiple controversies concerning patents in the health sector, particularly in the context of the HIV/AIDS epidemics. Its importance is linked to the recognition that the existence of patent rights in the health sector does not stop from taking measures to protect public health.

[6] E. Schiff, Industrialization without national patents: The Netherlands, 1869–1912, Switzerland, 1850–1907 (Princeton, NJ: Princeton University Press, 1971).
[7] B. Lindstrom, "Scaling back TRIPS-plus: An analysis of intellectual property provisions in trade agreements and implications for Asia and the Pacific," New York University Journal of International Law and Politics 42 (2010), p. 917.
[8] E. M. Anderson, "Unnecessary deaths and unnecessary costs: Getting patented drugs to patients most in need," Boston College Third World Law Journal 29/1 (2009), p. 85.
[9] WTO General Council, "Amendment of the TRIPS Agreement," Decision of 6 December 2005, WT/L/641.
[10] H. Brennan, R. Distler, M. Hinman, and A. Rogers, "A human rights approach to intellectual property and access to medicines," Global Health Justice Partnership Policy Paper 1, Yale Law School and Yale School of Public Health (September 2013), p. 1.

More specifically, it affirms that TRIPS should be "interpreted and implemented in a manner supportive of WTO members right to protect public health and, in particular, to promote access to medicines for all". This strengthens the position of countries that want to take advantage of the existing flexibility within TRIPS. In other words, the declaration does not open new avenues within TRIPS but confirms the legitimacy of measures seeking to use to the largest extent possible the in-built flexibility found in TRIPS. The declaration focuses mainly on questions related to the implementation of patents, such as compulsory licensing. Compulsory licensing has long been used as a tool to regulate the exclusive rights conferred by patents. In the case of health, the rationale is to make sure that the existence of a patent does not create a situation where a protected medicine is not available to the public because of non-health related factors. The Patents Act, 1970 provided an elaborate regime that included both compulsory licenses and licenses of right. The TRIPS Agreement has not done away with the notion of compulsory licenses but provides a more restrictive framework than the current regime in force in India. The recognition in the Doha Declaration that TRIPS member-states can use the flexibility provided in the agreement and can, for instance, determine the grounds on which compulsory licenses are granted must thus be understood in the context of a generally increasingly restrictive international patent regime. The declaration has been hailed as a major step forward in the quest for making the TRIPS Agreement more responsive to the needs of developing countries and more specifically to individuals who are unable to afford the cost of patented drugs. In fact, it addresses a number of important issues related to the implementation of medical patents. However, it fails to take up the much more fundamental questions of the scope of patentability and the duration of patents in the health sector. The Doha Declaration remains an important instrument in India for two main reasons. Firstly, at a political level, India was amongst the most vocal developing countries at the ministerial conference in putting forward developing Countries' interests. Secondly, the declaration was adopted while the joint committee of Parliament was finalizing its report[11].

3) Forthcoming WTO Negotiations

At this juncture, the WTO is far from providing a comprehensive response to the needs of developing Countries in the field of health in general. At the most, the Doha Declaration provides a temporary respite in some limited areas. The declaration does not even indicate that negotiations in the new round of trade negotiations will necessarily go towards a relaxation of the TRIPS requirements in this field. In fact, the recent aggressive posturing of the US pharmaceuticals industry seems to suggest that significant lobbying for further strengthening of patent rules is likely to take place in the future. On the whole, the Patents (Amendment) Act, 2002 closely follows TRIPS and in the process does away with provisions of the 1970 Act. Firstly, there has been no official change in the policy underlying the Patents Act to justify such drastic changes. Secondly, India's domestic and international commitments regarding the fundamental right to health of all individuals have not changed in the past decade[12]. Thirdly, it appears that the introduction of product patents in 2005 will adversely affect access to medicines for crores of people. One factor pushing the government in this direction may have been the desire to favour its own private sector pharmaceuticals industry. However, it is striking that there is no unanimity on the part of the industry, which remains today completely or mainly domestic. Some large companies that produce mainly generic drugs have been completely opposed to changes in the 1970 Patents Act, some large companies that have developed significant R and D facilities feel that the new regime may provide them an opportunity to grow overseas while small companies generally seem to have understood that they are not important enough to influence policy-making significantly and must concentrate on surviving either independently or by linking up with bigger domestic or foreign companies[13].

Human Health vs. Patent Law

Dear Life in good health and free from disease is the foremost human right and is a constitutional fundamental. The humbler the Indian human, the higher the state's duty to protect the person. In this perspective we may have to examine the impact of TRIP S (Trade-Related Intellectual Property Rights) Agreement on Indian corpus juris vis-a-vis the right to life guaranteed under Article 21 of the Constitution, read with Article 14[14]. Public health laws, national drug policy and the patent system are intensely inter-related. This was explained by Prime Minister Indira Gandhi while speaking at the World Health Assembly in Geneva on May 6, 1981. In her words:

"*Affluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process, the drug manufacture has become a powerful industry*."

She added, on the patent system: "My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death." In this historic session, the participating countries unanimously adopted a resolution for "Global Strategy on Health for All". Since then there have been laudable contributions by science and technology to tackle successfully many health problem areas. While there is a substantial unfinished agenda on the health front, new and formidable challenges have been thrown up by an unequal treaty on all-pervasive economic and social aspects by the Final Act embodying the results of the Uruguay Round negotiations. In particular, the TRIPS agreement is the

[11] Ibid.
[12] Supra Note 10.
[13] S. Joseph, "Trade and the right to health," in A. Clapham and M. Robinson (eds), Realizing the right to health, Swiss human rights book series, vol. 3 (Zurich, Switzerland: Ruffer & Rub, 2009), p. 360.
[14] Justice V R Krishna Iyer, Human health and patent law, Frontline, Volume 17 – Issue 21, Oct. 14 – 27, 2000.

most contentious part of the Final Act. The aim of this agreement is to enforce globally tough standards in respect of several forms of intellectual property, which include patents, trademarks, protection of undisclosed information, and so on, forgetting the goals expressed by Indira Gandhi in regard to freeing of medical discoveries from the patent system. A patent is a monopoly right granted by a state to a person to exploit and benefit from the invention patented by him for a particular period. Thereafter, it passes into the public domain. According to Justice Rajagopala Ayyangar's report submitted in 19 59, which report constitutes the basis for the Indian Patents Act, 1970, "The theory upon which the patent system is based is that the opportunity of acquiring exclusive rights in an invention stimulates technical progress in four ways: first, that it encourages research and invention; second, that it induces an inventor to disclose his discoveries instead of keeping them as a trade secret; third, that it offers a reward for the expenses of developing inventions to the stage at which they are commercially practicable[15]; and fourth, that it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously. Manufacturers would not be prepared to develop and produce important machinery if others could get the results of their work with impunity." To the same effect is the decision of the Supreme Court in Vishwanath Prasad v. Hindustan Metal Industries [16](Justice Jeevan Reddy). In a cultural milieu where "knowledge is free", and is transmitted from generation to generation as a duty, it is incongruous to convert discoveries into "cash and carry" vulgarity but that is the perversion under pressure from Western Big Business. "Intellectual Property Rights" conceptually belongs to this money manic bigotry and TRIPS is the parent of this morally indefensible but virtually glorified anathema.

Even so, in human affairs, minor adjustments, without forsaking fundamentals, may be necessary for peaceful co-existence. Even the TRIPS text partially acknowledges this aspect. It is ironic but interesting to recall Thomas Jefferson's words: "If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea… No one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me." In Jefferson's vision, there are no barriers to the acquisition of knowledge. Nobody owns it, everybody partakes of it – and the world becomes richer. Alas, his country is the venal violator of this value. Our cultural cornerstone, the Rigveda mandates: "Let noble thoughts come to us from every side." Patenting intellect or its products is sacrilegious and a social outrage.

Appreciating the Pro Health Right Scenario in Developing Countries

There are five reasons why it is important for courts in developing countries not to ignore the right to health when adjudicating pharmaceutical patent cases. One, the courts have to be more vigilant when scrutinizing legislation aimed at granting stronger protection to patents. Several bilateral and regional trade agreements currently pressure developing countries to adopt legislation providing stronger patent protection, but possibly significantly impeding access to medicines[17]. Courts should be vigilant and careful when interpreting such laws to ensure that the right to health of poor patients is not trampled upon. The Kenyan Anti-Counterfeit Act is just one example of the current expansionist trends in international patent law which, among other methods, seeks to use border and customs control measures to prevent the movement of counterfeit goods across international borders[18]. While such measures might actually be helpful in protecting people from harmful fake products, such measures can equally restrict access to low-cost generic medicines. The failure of the Kenyan Anti-Counterfeit Act to clearly distinguish between counterfeit drugs and generic drugs demonstrates this danger. Thus, where a country has been compelled to include a similar provision in its patent law by means of a trade agreement, the provision can be held to be unconstitutional on the basis that it can potentially impede the enjoyment of the right to health. Similar arguments can also be made with respect to any other provision incorporated into the domestic patent law framework that might impede the enjoyment of the right to health[19]. For instance, where a trade agreement requires a country to provide patent protection for new forms (or new uses) of known drugs, a court could rule that such a provision in the patent law would impede the enjoyment of the right to health by permitting pharmaceutical companies to extend the length of their monopoly rights on essential medicines. In other words, the fundamental and critical need of providing access to essential medicines would not be served by extending the lifespan of the instrumental (monopoly) rights of pharmaceutical companies on essential drugs. Two, incorporating a right to health perspective into pharmaceutical patent cases enables a court to properly construe and apply the flexibilities already contained in the domestic patent law such as provisions on compulsory licenses and parallel importation. For instance, as seen from the analysis of the Kenyan cases, the tribunal in the Pfizer case failed to recognize the tension between patent rights and access to medicines; it is therefore not surprising that it also failed to properly construe and apply the provisions on parallel importation in the Kenyan patent law. However, in its decision in the Ochieng case, the Kenyan High

[15] M. V. Hristova, "Are intellectual property rights human rights? Patent protection and the right to health," Journal of the Patent & Trademark Office Society 93/3 (2011), p. 356.
[16] 1979 (2) SCC 511.
[17] T. Bazzle, "Pharmacy of the developing world: Reconciling intellectual property rights in India with the right to health: TRIPS, India's patent system and essential medicines," Georgetown Journal of International Law 42 (2011), p. 795.
[18] Ibid.
[19] M. V. Hristova, "Are intellectual property rights human rights? Patent protection and the right to health," Journal of the Patent & Trademark Office Society 93/3 (2011), p. 356.

Court incorporated a right to health perspective into its decision and properly construed the provision on parallel importation. The Kenyan High Court noted that until the passage of the Industrial Property Act in 2001, it was not possible for poor people infected with HIV/AIDS to access anti-retroviral medication as the only ones available were expensive branded medicines. Generic anti-retroviral drugs were not available in Kenya as the existing legislation did not allow parallel importation of generic drugs and medicines. Section 58(2) [of the 2001 Act] allowed the parallel importation of generic drugs. It is on the basis of this legislation that availability and access to anti-retroviral drugs has increased and greatly enhanced the life and health of persons such as the petitioners who have been living with HIV/AIDS. The incorporation of a right to health perspective can therefore also assist a court in construing patent laws and flexibilities in a manner that serves the fundamental and critical need of securing access to medicines. In addition, a right to health perspective can be quite helpful when a court is considering the balance of convenience in a case where a pharmaceutical company is trying to obtain an injunction to prohibit or delay the production of cheaper generic drugs[20]. For instance, in the Indian case of Hoffmann-La Roche Ltd. v. Cipla Ltd., the Delhi High Court refused to grant an injunction sought by Roche against Cipla for the latter's production of the former's patented drug.77 The Delhi High Court noted that:

"The Court cannot be unmindful of the right of the general public to access life-saving drugs which are available and for which such access would be denied if the injunction were granted. ... The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. ... Another way of viewing it is that if the injunction in the case of a life-saving drug were to be granted, the Court would in effect be stifling Article 21 [of the Indian Constitution, which provides for the right to life and which forms the bedrock of the right to health in India] so far as those [who] would have or could have access to Erloticip are concerned."

Three, courts in developing countries should equally be aware that courtrooms are now forums for shaping and reshaping global health diplomacy. While multinational pharmaceutical companies can successfully lobby for stronger patent protection in international trade forums, poor patients and civil society groups usually rely on domestic courts to ensure that their interests are protected at the local level. Consequently, in a situation where more courts in developing countries are adopting a right to health perspective in pharmaceutical patent cases, it will encourage litigants in other developing countries to seek the assistance of local courts to protect their right to health. These local courts may also decide to follow the example of other countries by incorporating a right to health perspective in pharmaceutical patent cases[21]. Four, as the impact of non-communicable diseases such as cancer continues to increase in developing countries, it is obvious that more patients will require access to expensive but essential drugs in order to sustain a healthy lifestyle. A right to health perspective will therefore ensure that courts are mindful of the importance of the availability of cheaper generic drugs in the market. The Kenyan High Court in the Ochieng case was mindful of the need to ensure that generic antiretroviral drugs remained affordable and accessible. The court noted that "[m]any of those who are infected with the virus are, like the petitioners, unemployed and therefore financially incapable of procuring for themselves the anti-retroviral branded medication that they need to remain healthy. They are therefore dependent on generic anti-retroviral medication which is much cheaper and therefore more accessible to them." If the Kenyan Anti-Counterfeit Act had been implemented in the form in which it was enacted, it would have jeopardized the lives of the petitioners and other patients who rely on the availability of cheaper generic drugs[22]. Finally, it is important to note that, unlike the situation in industrialized countries where there are sophisticated mechanisms such as antitrust laws that can be used to curb the excesses of pharmaceutical companies, in several developing countries the legal framework to curb anti-competitive activities is either undeveloped, underutilized, or non-existent.80 In several developing countries, the right to health is the only potent weapon that can be effectively used to ensure that pharmaceutical companies do not abuse their patent rights. It is essential for developing countries to devise strategies to curtail the current expansionist trends in international patent law. In the midst of growing demands for stronger patent laws, the right to health can be utilized to reclaim some policy space for developing countries to design their national patent laws in a manner that facilitates access to medicines[23]. Domestic courts have a major role to play in this regard: when they are adjudicating disputes involving patents on pharmaceutical products, they can recognize the tension between patent rights and the right to health and resolve this tension by distinguishing between the instrumental nature of patent rights and the fundamental nature of the right to health.

Novartis AG vs. Union of India: A Review

In early April, India's Supreme Court rejected an application by the Swiss multinational pharmaceutical company Novartis for a patent on a modified version of the leukemia medication imatinibmesylate[24]. Naturally, the outcome of the case affects the affordability of the

[20] R. M. Hermann, "Developing countries are not making the most of TRIPS flexibilities because of political pressure," British Medical Journal 343 (2011), p. 45.

[21] P. Yu, "Reconceptualizing intellectual property interests in a human rights framework," UC Davis Law Review 40 (2007), p. 1073.

[22] Ibid.

[23] Supra Note 2.

[24] Novartis AG vs. Union of India, AIR 2013 SC 1311.

drug. But the core issue was the right of the Indian government to take account of public health in designing intellectual property rights (IPR) legislation. In India, Novartis charges about US$26,000 per patent per year for the drug, marketed as Glivec (Gleevec in the United States)[25]. But generic versions produced by local companies are available for less than US$2,500. Novartis's price excludes all patients except the extremely rich, although the company supplies Glivec for free to some patients. The Indian government and civil society groups see this situation as health policy being held hostage to corporate charity. And to them that is unacceptable. The Novartis case confirms the right of India's parliament to implement public health safeguards available under the Agreement of Trade-Related Intellectual Property Rights (TRIPS). These include the definition of patentability criteria, the central issue in this case. Such 'flexibilities' mostly revolve around the conditions for market entry of alternative generic brands — the term generic drug refers to a copy of an original product whose patent has expired[26]. In India, all drugs were generics before 2005 because there were no product patents for pharmaceuticals. India became fully TRIPS compliant in 2005 through the introduction of pharmaceutical patents, with legislation that included safeguards to protect public health. In particular, section 3(d) of India's Patent Act was included to prevent the extension of patent protection through minor product modifications, unless a 'significant enhancement of efficacy' can be demonstrated. Novartis took legal action against the Indian government to challenge the constitutionality of section 3(d)[27]. When this was rejected, the company sought to have imatinibmesylate recognized as patentable. But it did not even purport to demonstrate enhanced efficacy. Novartis aimed to put a stop to generic competition in the imatinibmesylate market. And it was also attempting to prevent the export of locally produced, more affordable brands to other developing countries. In its judgment, the court determined that imatinibmesylate is not patentable as it 'fails the test of section 3(d)'. The Supreme Court judgment has given rise to an enormous amount of global commentary. Public health advocates and patients greeted the outcome with great relief. Médecins Sans Frontières, Joseph Stiglitz and various media outlets hailed the decision. They see it as a good precedent for drug affordability in developing countries in general. In contrast, Novartis and fellow corporate giants such as Pfizerreacted with dismay. For example, Novartis is reported to have 'threatened to stop supplying India with new medicines'. This overwrought reaction points to a crisis in their traditional business model. The industry is being reshaped due to issues such as steadily falling R&D productivity and political mobilisations for access to medicines for all[28]. The Novartis case is important because it highlights that it's no longer acceptable to the global public that hundreds of millions of people are denied access to life-saving drugs because of monopoly pricing. And the case shows that governments in developing countries with some economic and political clout, such as India's, are prepared to fight the big pharmaceutical companies. But Novartis and its peers will not abandon the Indian market in reaction against measures to make drugs more affordable. India is too important an economy and continues to offer plentiful opportunities for international pharmaceutical companies. And Indian firms are large-scale suppliers of low-cost generics to Western markets as well. These firms have an impact on global industry dynamics, and many collaborate with the international companies. India has changed a lot in regards to its pharmaceuticals market. Between independence in 1947 and the 1970s it was highly dependent on imports of expensive medicines. But between 1970 and 2005 India abolished product patents on medicines. The Indian government also put in place industrial policy measures and public sector research institutions to collaborate with local producers. The result was a strong and vibrant Indian generic industry. The entry of generics lowers prices and widens access to medicines. And it is much more effective in achieving these outcomes than philanthropy or the model of tiered or differential pricing strategies preferred by multinational companies. The patenting of trivial modifications, known as 'ever-greening', is one of a host of 'life-cycle management' techniques employed in response to generics competition[29]. Nevertheless, the Indian government will continue to face challenges from international pharmaceutical companies seeking to stifle generic competition. Bayer recently sought to overturn a precedent-setting compulsory license on another cancer drug awarded to Hyderabad-based Natco Pharma in 2012. An appeals court in March this year rejected Bayer's application. The Novartis and Bayer cases suggest that India is well placed to defend and extend pharmaceutical and IPR policies aimed at balancing economic development with public health[30].

Conclusion

The Doha Declaration on TRIPS and Public Health has set a firm foundation upon which developing countries can protect their public health needs against the WTO's intellectual property policies. The preamble of this declaration addresses the fundamental concerns purported by developing member states, including a need for broad recognition of medical goods and diseases where the circumvention of patent protection rules for matters of public health is expected and necessary. The Declaration clarifies the right of poorer nations to act outside the market to avoid higher commodified drug prices by way of drawing on pertinent flexible mechanisms, including compulsory licensing and

[25] Hans Lofgren, Novartis vs. the government of India: patents and public health, 26 April 2013, East Asia Forum Journal.
[26] Supra Note 24, para 34.
[27] Ibid.
[28] Ibid, Para 39.
[29] A Chapman, "Approaching intellectual property as a human right: Obligations related to Art. 15(1)(c)," Copyright Bulletin 35 (2001), pp. 10–11.
[30] E. R. Gold, "Patents and human rights: A heterodox analysis," Journal of Law, Medicine & Ethics 41/1 (2013), pp. 186–187.

parallel imports. Therefore, it is concluded, in principle, that developing countries are adequately equipped with special provisions to protect their right to public health and promote access to medicines. While the TRIPS flexibilities denoted in the Doha declaration have well-guided intent, the abilities of developing countries to utilize these flexibilities for public health concerns face onerous internal and external barriers. Many developing countries continue to lack local production capabilities and experience difficulties in achieving economies of scale. There is also a lack of efficient technical expertise to create the needed legislative reform to implement TRIPS flexibilities, as well as a lack of regulatory and registration capacity for drug patents and generics. TRIPS flexibilities and the Doha Declaration have set the stage; however, a greater effort is needed to overcome internal and external constraints. Without such an effort, the health of the developing world will continue to suffer at the hands of economic concerns.

