

## International Legal Obligation of the State with reference to Intellectual Property Rights (Patents) *vis-à-vis* Right to Health: The Indian Case Study

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The problem exists is between the constitutional obligation of the state (India) under fundamental rights, ie. Human rights to health, on one hand and international legal and economical obligations under the trade agreements, ie. WTO, TRIPS etc., on other hand. Intellectual property rights of pharmaceuticals are governed by patent law. India being a signatory of the GATT<sup>1</sup> is governed by TRIPS apart from having its own national Intellectual Property Law. Members are held responsible under the human rights treaties to protect, promote and fulfilled the basic and minimum requirements of an individual in the state. While on the other side, the trade agreements and treaties does not provide sufficient space to protect those human rights. If the state has signed the trade related agreements they are required to protect the interest of the seller and it would be challenging for the signatory state to maintain balance between the interest of a seller and protection of right health.

This article explores the existing constitutional, legal and international provisions pertaining to right to health and patent laws in India. This article analyses judicial decisions passed by the Supreme Court of India on right to health, on TRIPS provisions and its implementations. The article has underlined existing situation and its interplay between human rights and pharma-patents. The article endorse on right to health as human rights and constitutional rights *vis a vis* patent's right under the trade agreements in India. The article explored the practice of pharmaceutical industry and its conflict with idea of right to health by analysis of landmark judgment *Novartis Ag. v Union of India & Others*, decided by the Supreme Court of India on 1 April 2013. The article further deliberates on access to patented medicines under the TRIPS.

**Keywords:** TRIPS, WHO, WIPO, WTO, Doha Declaration, PIL, Sustainable Development Goals

World Health Organization (WHO) has announced annual compilation of health statistics of its 194 Member States.<sup>2</sup> World Health Statistics, 2017 has collected the data on 21 health-related Sustainable Development Goals (SDG), which includes the data on life expectancy.<sup>2</sup> The 2030 agenda for sustainable development is the world's first comprehensive outline for sustainable development.<sup>2</sup> This agenda has framed on both 'health' and 'well-being'.<sup>2</sup> From the health perspective, development can be said to be "sustainable" when natural and manufactured resources are managed by and for all people in ways which support the health and well-being of present and future generations.<sup>2</sup> During the period from 2000–2015, the Millennium Development Goals (MDGs) have been emphasized on programs tailored to specific health conditions including communicable diseases (notably HIV/AIDS, malaria and tuberculosis).<sup>3</sup> The range has been from extreme poverty to right to health (notably HIV/AIDS).<sup>3</sup> Making progress towards Universal Health Coverage

(UHC) as state's effort is to make ensure that all people receive the health services at reasonable price.<sup>3</sup> Certainly, achieving UHC will require health system which supports to deliver effective and affordable medical services to prevent ill-health and to provide health promotion, prevention, treatment, rehabilitation and services as a part of the obligation or a duty of the state.<sup>2</sup> To enable health system strengthen, it requires a harmonized approach for improving health governance.<sup>2</sup>

World Health Organization (WHO) has encouraged countries to amend their national legislations to protect effectively the right to health.<sup>4</sup> Investments in these areas should seek to increase responsiveness, efficiency, fairness, quality and resilience based on the principles of health service integration and people-centered care.<sup>5</sup> In 1983, the Government of India for the first time adopted a National Health Policy (prior to that the actions of the Government in the health sector were guided by the Five Year Plans and recommendations of various committees), and its major recommendations were on 'universal, comprehensive primary health care services which

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have been related to the actual needs and at a cost which people can afford'.<sup>5</sup> However, new health technologies, such as medicines, vaccines and diagnostics, becoming expensive by looking economic backgrounds.

### **Problem under the Patentability of Drugs and Medicines**

In recent years, the patentability of health-related innovations has become under debate world-wide. Billions of dollars are invested each year in pharmaceutical research, but the percentage of people who can afford potentially life-saving drugs remains minuscule.<sup>6</sup> The development of drugs is costly for pharmaceutical companies, and without intellectual property law protection, the formula for the drugs can be easily duplicated and the drugs can be synthesized at a cheaper cost.<sup>7</sup> Thus, intellectual properties laws often allow companies to monopolize the synthesis and sales of drugs. Unfortunately, this exclusive right to manufacture and sell drugs provides the necessary monetary incentive for drug discovery.<sup>6</sup>

### **Trilateral Cooperation**

The idea of cooperation of these three international organizations is missing in spite of given proper agreement in spirit. The specific roles, mandates and functions of the WHO, World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO), which cooperate within the general international framework on issues related to the interface between public health, intellectual property (IP) and trade concerning innovation in, and access to, medical technologies.<sup>8</sup> World Health Organization (WHO) collaborates with key partners including the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) and other relevant intergovernmental organizations on public health, intellectual property, trade-related issues (TRIPS) and in particular on the key role of intellectual property rights in promoting innovation and its impact on access to medicines.<sup>8</sup> Wherever possible, local industry is included to encourage capacity building and sustainability.<sup>9</sup> The adoption of the Doha Declaration was a landmark occasion for the issues that intersect public health, intellectual property (IP) and trade.<sup>8</sup> Since 2001, the principles enshrined in the Doha Declaration have shaped the framework for multilateral cooperation in joint publications and mutual participation in training programs.<sup>8</sup> Based on the adoption of the development agenda by the

WIPO General Assembly in 2007 specifically Recommendation Number 40, WIPO was requested to strengthen its cooperation on IP-related issues with relevant international organizations and in particular with the WHO and the WTO, in order to support the coordination required to achieve maximum efficiency.<sup>10</sup> Explicitly requested to the WHO "to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD to effectively implement the global strategy and plan of action".<sup>11</sup> In addition, in the case of more than 20 activities detailed in the plan of action<sup>11</sup>, the three organizations along with other international organizations are listed as the stakeholders responsible for the implementation of these activities.<sup>11</sup> This includes efforts to increase transparency in the patenting of essential medicines and to promote access to medicines through different means including through the use of TRIPS 'flexibilities' and de-linking the cost of developing technologies from their market price.<sup>2</sup> The Doha Declaration on the TRIPS Agreement upholds the right of developing countries regarding flexibilities which protect public health and in particular provide access to medicines for all.<sup>2</sup> This article may be helpful to the government draw a guidelines or rules in future to balance between the right to health and obligation of the state.

### **Premise: The Idea**

The reasons for the lack of access to essential medicines are manifold but in many cases the high prices of drugs are a barrier to needed treatments.<sup>12</sup> Ensuring universal access to free or affordable essential medicines is one of the core obligations for fulfilling the right to health.<sup>13</sup> High-priced drug are often the result of strong intellectual property protection. Governments in developing countries that attempt to bring the price of medicines down have come under pressure from advanced countries and the multinational pharmaceutical industry.<sup>13</sup> The WTO and TRIPS have set out the minimum standards for the protection of intellectual property including patents for pharmaceuticals.<sup>8</sup> While TRIPS does offer safeguards against patent abuse, it is undefined whether and how countries can make use of these safeguards when patents remaining barriers to medicine access.<sup>12</sup> This unclear ground has resulted in to un-followed obligations of the state in terms of protection of right to health. Public health supporters welcomed the Doha Declaration as an

important achievement because it gave primacy to public health over private intellectual property and clarified WTO Members' rights to use TRIPS safeguards.<sup>12</sup> But the Doha Declaration did not solve all of the problems associated with intellectual property protection and public health. The recent failure at the WTO to resolve the outstanding issue to ensure production and export of generic medicines to countries that do not produce.<sup>12</sup>

#### **Patents and Affordable Medicines**

When a pharmaceutical company has a patent in a country, it means it has a monopoly in that country for a certain amount of time.<sup>12</sup> This means it can prevent other companies from producing, selling or importing the medicine in that country for the duration of the patent term which according to WTO rules is a minimum of 20 years.<sup>14</sup> This in turn allows companies to charge high prices because there are no competitors in the market.<sup>14</sup> In the absence of patents, multiple generic producers produce medicines which makes the price down. Competition among different producers is the way to bring prices down. Competition among generic manufacturers have helped to bring the cost of HIV and AIDS treatment down from over US\$10,000 per patient per year in 2000 to \$150 today. The absence of patents in India has also helped in the development of three-in-one HIV/AIDS.<sup>14</sup>

#### **The Problem of Access of Medicine and Intellectual Property**

A number of new medicines that are vital for the survival are expensive.<sup>15</sup> Developing countries, where three-quarters of the world population lives have less than 10% of the global pharmaceutical market.<sup>15</sup> The implementation of TRIPS is expected to have a further rising effect on drug prices while increased R&D investment whose aims is to address health.<sup>15</sup> *Médecins sans Frontières* (MSF) together with other non-governmental organizations (NGOs) formulated the concerns related to TRIPS and increased patent protection which leads to higher drug prices.<sup>16</sup> It said that the number of new essential drugs under patent protection is increased so the drugs will remain out of reach to people because of high prices.<sup>16</sup> As a result, the dissimilarity between developed and developing countries will widen. Application of WTO rules may have a negative effect on local manufacturing capacity and it may remove a source of generic, innovative, quality drugs on which developing countries are dependent.<sup>16</sup> It is dubious that TRIPS will encourage

adequate 'Research & Development' (R&D) in developing countries for diseases such as malaria and tuberculosis because poor countries often do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry.<sup>16</sup> Developing countries are under pressure from manufacturing countries and the pharmaceutical industry to implement patent legislation that goes beyond the obligations of TRIPS.<sup>16</sup> This is often referred to as 'TRIPS plus'. 'TRIPS plus' is a non-technical term which refers to effort to extend patent life beyond the twenty-years.<sup>17</sup>

#### **India and Pharmaceutical Industry in Transition**

In order to conform the TRIPS requirements, amendments to the Patents Act were enacted in 1999, 2002 and 2005.<sup>18</sup> The 2005 amendment has introduced the exclusive provision on the patentability of pharmaceuticals. There were serious concerns that the introduction of product patents for pharmaceuticals would lead to a downpour of applications and that patents might be granted for minor and frivolous inventions.<sup>18</sup> There were further fears that this could lead to 'ever greening' of patents, ie. continuation of a patent's monopoly beyond the stipulated 20 years based on minor revisions in the medicines.<sup>18</sup> The 2005 amendment has however restricted the scope for the granting of patents on frivolous claims by clarifying that, '*the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy*' is not patentable.<sup>18</sup> At the same time, however, Indian law has defined the step (one of the three criteria for patentability) as a feature of an invention that 'involves technical advances as compared to the existing knowledge or having economic significance or both'.<sup>18</sup> It has been argued that this step should apply only to technical advances as it defines the innovative content in an invention. Thus, the incorporation of *economic significance* would seem to dilute the criteria for what is an invention. It is yet to be seen how this clause will be interpreted in practice.<sup>18</sup>

#### **Patent Protection Duration, Terms and Rules**

The TRIPS Agreement requires WTO Members to provide protection for a minimum term of 20 years from the filing date of a patent application for any invention including for a pharmaceutical product or process.<sup>19</sup> Prior to the TRIPS Agreement, patent duration was significantly shorter in many countries.

For example, both developed and developing countries provided for patent terms ranging from 15 to 17 years,<sup>20</sup> whilst in certain developing countries, patents were granted for shorter terms of 5 to 7 years.<sup>20</sup> The TRIPS Agreement also requires countries to provide patent protection for both processes and products, in all fields of technology.<sup>19</sup> Before TRIPS, many countries provided only process but not product patents. Product patents provide for absolute protection of the product, whereas process patents provide protection in respect of the technology and the process or method of manufacture.<sup>19</sup> Protection for process patents would not prevent the manufacture of patented products by a process of reverse engineering, where a different process or method from that which has been invented (and patented) is used. For example, national legislation requiring only process patent protection which is enabled manufacturers in certain countries to make generic versions of patented medicines. These countries have opted to make use of the transition period that permitted countries to delay, until 2005, patent protection in the areas of technology that had not been so protected before the TRIPS Agreement.<sup>19</sup>

#### **International Standards and Right to Health**

The right to health is a fundamental of right to life with dignity. There is a foundational rationality for health concerns to be addressed by rezoning the human rights. The right to the enjoyment of the highest attainable standard of physical and mental health<sup>21</sup> even if professional ethics in the medical profession have retained an individual-centric focus on curative treatment.<sup>21</sup> The evolution of international human rights norms pertaining to health has created a normative framework for governmental action.<sup>22</sup> Internationally, the right to health was first articulated in the 1946 constitution of the WHO, whose preamble defines health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'.<sup>23</sup> The preamble further states that 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.'<sup>24</sup> The 1948 Universal Declaration of Human Rights also mentioned health as part of the right to an adequate standard of living.<sup>25</sup> Since then, the right to health has been enshrined in international<sup>26</sup> and regional<sup>27</sup> human rights treaties as well as national Constitutions all over the world.<sup>27</sup> The right to health was again

recognized as a human right in the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR). Specific reference can be made to the provisions in the convention on the Elimination of all forms of Discrimination against Women (CEDAW), the Convention on the Rights of the Child (CRC) and the International Convention on the Elimination of all forms of Racial Discrimination (CERD).<sup>28</sup> The right to health is relevant to all states. Every state has ratified at least one international human rights treaty recognizing the right to health. Moreover, states have committed themselves to protecting this right through international declarations, domestic legislation and policies, and at international conferences.<sup>29</sup>

#### **Constitutional Obligation of India and Right to Health**

Good health and free from disease is the foremost human right and is a fundamental. In this perspective it may have to examine the impact of TRIPS Agreement on Indian corpus juries *vis-a-vis* the right to life guaranteed under Article 21 read with Article 14 and Article 39<sup>30</sup> and of the Indian constitution.<sup>30</sup> Certain principles to be followed by the state like health of workers, children are not abused and are given opportunities & facilities to develop.<sup>31</sup> Article 47 is a duty of the State to raise the level of nutrition and the standard of living and to improve public health. The State shall look the raising level of nutrition and the standard of living of its people. The improvement of public health as among its primary duties.<sup>31</sup> The Constitution of India has provisions regarding the right to health. The duty of the State is to ensure and satisfy the conditions of good health by implementing Articles 38<sup>32</sup>, 39 (e)<sup>33</sup> (f), 42<sup>34</sup>, 47<sup>35</sup> and 48 (A)<sup>36</sup> in Part IV of the constitution of India.<sup>37</sup>

#### **Judicial Approach on Right to Health in India**

In *Bandhua Mukti Morchav Union of India*,<sup>38</sup> the Supreme Court held that the right to live with human dignity enshrined in Article 21 is derived from the directive principles of state policy and therefore includes protection to health. In *Vincent Panikulangarav Union of India*,<sup>39</sup> the Supreme Court of India on the right to health care observed and said that '*Maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community. Attending to public health in our opinion, therefore is of high priority*'. In *Mahendra Pratap Singh v State of Orissa*,<sup>40</sup> a case pertaining to the failure of the government in opening a primary health care center in

a village and the Court had held 'In a country like ours it may not be possible to have sophisticated hospitals but definitely villagers within their limitations can aspire to have a Primary Health Centre. The government is required to assist people get treatment and lead a healthy life. Healthy society is a collective gain. Primary concern should be the primary health center and technical fetters cannot be introduced as subterfuges to cause hindrances in the establishment of health center.' It was also stated that 'great achievements and accomplishments in life are possible if one is permitted to lead an acceptably healthy life.' Thereby, there is an implication that the enforcing of the right to life is a duty of the state and that this duty covers primary health care. The Supreme Court<sup>41</sup> has addressed the epidemic of HIV/AIDS. In a case where the court had to decide whether an HIV positive man should disclose his condition to the woman he was to marry? The Court held that 'the woman's right to health is priority over the man's right to privacy'. *Sahara House and Sankalp Rehabilitation Trust*<sup>42</sup> filed Public Interest Litigation (PIL) in the Supreme Court for access to equitable treatment for PLHIV (Patient Living with HIV, AIDS). In this PIL, the Supreme Court of India reviewed the steps taken by National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India to combat HIV/AIDS and the services being provided to PLHA's. In this regard, the Supreme Court issued various directives for enhancing the extent and efficacy of treatment administered to PLHAs.

### Discussion

#### Whether Government of India should Grant Patents on Medicines?

As a member of WTO, India has to comply with trade rules set by the WTO. One of these is the Agreement on TRIPS which obliges member countries to grant patents on pharmaceuticals.<sup>43</sup> To comply with this international obligation, India amended its patent law in 2005 and started to grant patents on medicines. As a result, when patents are granted in the country, Indian generic manufacturers are not able to produce cheaper generic versions of these medicines. This is already a beginning to have a significant impact on access to affordable medicines. New medicines which are invented after 1995 are likely to be patent protected in India, such as 'raltegravir' (for HIV) and 'PEGylated-interferon' (for hepatitis C).<sup>43</sup>

#### Novartis Case: Landmark Judgment

Novartis's patent application was rejected in part because of Section 3(d) of India's Patents Act. When India amended its patent legislation in 2005 to comply with international trade rules, the Indian Parliament included provisions to protect health and access to medicines. 'Imatinibmesylate' (Gleevec) is the salt form (mesylate) of an older medicine 'imatinib'.<sup>43</sup> Novartis claimed that it deserves a patent on 'imatinibmesylate' based on the fact that there is a 30% increase in the bio-availability of the medicine in this new form. But according to the guidelines for the examination of pharmaceutical patents developed by the WHO, the selection of a salt of the active ingredient with the purpose of improving bio-availability is well known in pharmaceutical art and is an often-used form of what is known as 'ever-greening'. Ever-greening is a practice followed by multi-national pharmaceutical companies to extend their patent terms by making minor changes in their existing medicines and claiming the medicine is then patentable.<sup>43</sup> The Indian Parliament introduced Section 3(d) to give explicit guidance on what did deserve a patent and what did not. When Novartis's patent application on 'imatinibmesylate' was first rejected by an Indian Patent Office, the company decided to challenge this part of the Indian patent law.<sup>43</sup>

The entire debate was based on judgment pronounced by Supreme Court of India in the case of *Novartis AG v Union of India & Others* decided on 1 April 2013. The battle between the Government of India against the global pharmaceutical industry was derived when officials withdrew patent protection for an 'emphysema' drug marketed by Germany's 'BoehringerIngelheim GmbH'.<sup>44</sup> India's refusal to recognize patents on some of Western drug makers' most profitable medicines had been the cause of considerable acrimony between New Delhi and Governments in the U.S. and Europe, alleged India is failing to adhere to global intellectual-property rules.<sup>44</sup>

The country's pharmaceutical sector was expected to grow to at least \$48.8 billion in sales by 2020 from \$11 billion in 2012 according to 'Price-Water-House-Coopers'. Novartis AG, the Swiss company, had said that it would reconsider launching new drugs in India after losing a court battle in 2013 to get a patent approved. 'Pfizer Inc.' assumed at the time that it concerned about the environment for innovation and investment in India."<sup>44</sup> The fact of the matter is that

Indian Law is strict in limiting what can and cannot be patented.

#### *Facts of the Case*

The Indian Supreme Court on 1 April 2013 delivered a landmark judgment rejecting Novartis's Indian patent application for beta-crystalline form of 'Imatinib Mesylate' a drug used to treat 'chronic myeloid leukemia' (CML) a type of blood cancer marketed under the names 'Glivec' or 'Gleevec'. This case has ended 'Novartis' eight year battle with various Indian legal forums to get its drug patented. The following were the issues with the case:

1. What is the true importance of Section 3(d) of the Patents Act, 1970?
2. How does Section 3(d) interplay with clauses (j) and (ja) of Section 2(1)?
3. Does the product for which the appellant claims patent, qualify as a "new product" which comes by through an invention that has a feature that involves technical advance over the existing knowledge and that makes the invention "not obvious" to a person skilled in the art?
4. In case, the appellant's product satisfies the tests and thus qualifies as "invention" within the meaning of clauses (j) and (ja) of Section 2(1), can its patentability still be questioned and denied on the ground that Section 3(d) puts it out of the category of "invention"?

The Supreme Court for the first time has interpreted Section 3 (d) of the Indian Patent Act, 1970 (Act) which attempts to curtail 'ever-greening' of patent.<sup>1</sup> The Supreme Court in its 112 page judgment traced the history of Indian Patent Law starting from the Justice 'Tek Chand Committee Report', 1949 to the 2005 amendment of the Act. The Supreme Court laid down particular emphasis on (i) Justice Ayyangar Report on Patent Law Revision, 1959 ( the 1970 Act was enacted based on the recommendations in this report) (ii) effect on the Indian pharmaceutical industry due to the changes in the Patent Law (the SC looked at statistics relating to Market share of *Indian Pharmaceutical companies v MNC pharmaceutical companies* pre 1970 and post 1970) (iii) why pharmaceutical chemical and food product patents were not permitted till 2005 (iv) how India had to retrospectively introduce product patent regime after having lost at the WTO wherein the WTO panel and the appellate body had ruled that India had failed to meet its TRIPS obligations

(v) relevant provisions of the TRIPS Agreement and flexibilities under the Doha Declaration (vi) the facts and the background leading to introduction of Section 3(d) including parliamentary debates and the letters received from various organizations like WHO and UNAIDS . After extensive deliberation on these points the SC proceeded to apply the law to the facts of 'Novartis' patent application.

#### *Background of the Case*

The Supreme Court had made an exception and admitted the SLP side-stepping the jurisdiction of the Madras High Court in view of the importance of the case and the number of inspiring issues that were involved in the case. The Supreme Court did not have any guidance from the Act in interpreting Section 3 (d). Hence, it referred to the parliamentary debates and the circumstances surrounding enactment of Section 3 (d) to a great extent to give a purposive interpretation. Further, considering that Section 3 (d) is very unique to India, it was very important both for the pharma industry and the patent office to have guidance on its interpretation. Though, Supreme Court has attempted to clarify certain aspects however some issues are still open.<sup>45</sup>

One debate that was laid to rest was whether efficacy under Section 3(d) for pharmaceuticals is therapeutic efficacy. The Supreme Court has made it clear that efficacy for a pharmaceuticals refers to only therapeutic efficacy. The Supreme Court ruled that enhanced therapeutic efficacy should be interpreted strictly and properties such as improving storage process ability and inherent pharmacological properties do not amount to enhancement of therapeutic efficacy. Thus, there were some guidance on parameters that do not amount to enhanced therapeutic efficacy but there was no guidance as to what parameters amount to therapeutic efficacy. The Supreme Court stated that increase in bio-availability can amount to enhancement of therapeutic efficacy if it established by research data. One can take a signal from this that appropriate research data needs to be provided to show enhancement of therapeutic efficacy but the question was, what kind of research data would suffice to meet this requirement was been kept open.<sup>45</sup>

Another important aspect highlighted in the judgment is the need to identify exact prior substance against which the invention should be compared. The practical difficulty in obtaining comparative data needs to be resolved once it is clear as the nature of

data that will be accepted to prove therapeutic efficacy. One puzzling issue prior to this judgment faced by patent applicants was whether the evidence required establishing enhancement of therapeutic efficacy or external evidence would suffice? This issue seems to have been laid to rest since the Supreme Court has relied on external evidence i.e. expert affidavits to decide enhancement of efficacy in this case. The Court has clarified that the judgment in this case should not be understood to mean that Section 3(d) bars all incremental inventions of chemical and pharmaceutical substances. However, the bar that has been set by the Supreme Court to surpass the hurdle of Section 3(d) is very high.

As a matter of principle if prevention of ever-greening of patent is the real mischief that is sought to be remedied by Section 3(d) then it is important to take into consideration whether prior substance was indeed commercialized. The reason being often the prior substance is in free base form and not the salt form.<sup>45</sup> A free base form generally cannot be administered to humans whereas a salt form can be administered thus the free base form cannot be commercialized. In a drug discovery cycle it is the free base form which is discovered first, thus generally pharma companies file for a patent for the free base form encompassing all salt forms in order not to lose the priority, at this stage the pharma companies are not generally aware as to what salt form of the free base would have most therapeutic efficacy. This discovery is generally made after conducting extensive human or animal clinical trials.<sup>45</sup> This point becomes very important because if a salt form cannot be claimed separately due to Section 3 (d). Then in order to stop a patent infringer from using the salt form of its drug, the pharmaceutical company has to rely on its patent covering its free base form. However, the first argument raised by the defendant in its counter claim is that the salt form is not covered under the free base patent and a broad claim which claims all salt forms is not enabling. Thus, the defendant is not infringing the patent. This is a big dilemma for pharmaceutical companies and needs to be addressed. The purpose of Section 3(d) is to prevent pharmaceutical companies from extending their period of monopoly i.e. ever-greening of patents but it should not stifle inventions. Hence, the Parliament and judiciary should revisit the provision so that it is only the new form of the known “commercialized” substance may

not be granted patent unless enhanced therapeutic efficacy is shown.<sup>45</sup>

*India's Solution to Drug Costs: Ignore Patents and Control Prices - Except For Home Grown Drugs*<sup>46</sup>

Drug pricing is a major issue in India. The Indian Government believes that the prices of lifesaving drugs shouldn't be set by market forces.<sup>46</sup> In a country where very few people have health insurance, 70% of Indians pay for healthcare expenses out of their own pockets.<sup>46</sup> When it comes to cancer drugs, the problem is even more acute. There is no way that people in India can pay even a fraction of the cost for drugs that can be priced at \$50,000/year in the West.<sup>46</sup> The ‘Glivec’ situation is not unique. India has granted compulsory licenses to other cancer drugs including Bayer's ‘Nexavar’, Roche's ‘Tarceva’, and Pfizer's ‘Sutent’. These licenses allow Indian generic drug manufacturers to make these drugs with impunity.<sup>46</sup>

*Actions justified by India's Pharmaceuticals Department*<sup>47</sup>

‘We need to ensure that expensive drugs are available at affordable rates to the poor.’ It is hard to argue with that philosophy. However, India is expanding this policy beyond expensive cancer drugs. Again the Indian Supreme Court refused to prevent an Indian generic manufacturer, ‘Glenmark’ Pharmaceuticals, from manufacturing and selling Merck's diabetes drug, ‘Januvia’, in India. Merck will likely appeal this decision. While it is an important drug, Januvia does not carry an expensive price tag.<sup>46</sup> In fact, when it was launched in India, Merck charged \$0.86/tablet, one-fifth the US cost. Nevertheless, despite recognizing the need to make Januvia affordable in India, Merck's intellectual property for this drug will be ignored in this country for the foreseeable future. In addition to not granting patents for new drugs, the Indian government sets prices for drugs that are patented, but this is not just for expensive medications. There are now 348 drugs that have price caps. However, India has now introduced a new element to this policy. Drugs that have some form of innovation that can be attributed to Indian researchers can be immune from price controls for five years. Three types of innovations can qualify for this benefit: 1) drugs that arise from indigenous R&D; 2) improvements by an Indian company on a process for making an existing drug; 3) development of a new drug delivery system by Indian R&D.<sup>46</sup> The rationale for this policy was explained by a Government Official, “This would spur innovation and make sure

price-control regime doesn't dissuade pharma firms from research and development". It can also envision that these new rules could be used by Indian generic companies to circumvent pharmaceutical company patents.<sup>48</sup> For example, what is to stop an Indian company from developing a new process for making an important new drug developed by a non-Indian pharma company? It would not be surprising for the Indian Government to allow a patent on this process and again the innovative company would be out of luck in protecting their commercial rights for this medicine in India. If all of this wasn't galling enough, a *New York Times* Editorial came out in support of the Indian decision on Glivec, "This decision could help poor patients get drugs at prices they can afford while preserving an incentive for true innovation."

### Conclusion

The effect of Patent Law on drug prices and availability is an issue that is of crucial importance not just for India but for a large number of developing countries. Medicines already in the market before 1 January 1995 would not be affected by the new rules but for other more recently developed medicines, it may now take much more time for Indian companies to launch generic versions (unless they request and obtain a compulsory license). The TRIPS Agreement necessitates that all WTO member countries provide for pharmaceutical patents in their domestic laws. It also incorporates elasticity that can be used to defend the public health interest and to fit different national contexts. Subsequently, as mentioned in the report of *"Intellectual Property Rights and Access to Medicines: A South-East Asia Perspective on Global Issues"*, by WHO Regional Office South East Asia in 2008, the Doha Declaration clarified that TRIPS safeguards can indeed be used to protect public health, and allows LDCs to postpone the implementation of pharmaceutical patents until 2016. Access to essential and needed medicines is a human right and a key element of a well-functioning health care system. Thus, the public health interest should be taken into account when trade agreements are negotiated and patent laws enacted. International laws and treaties provide room for maneuvering but it is up to each country to make use of that flexibility and to safeguard it. Also, India has to see and consider that global population uses traditional medicines at some point in their lives. There is also today a growing demand for traditional and alternative medicines in the developed world and an awareness that traditional

knowledge needs to be protected if access to traditional medicines is to continue. Protection of traditional knowledge can include IP-related measures as well as non-IP related mechanisms.

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  - 35 Duty of the State to raise the level of nutrition and the standard of living and to improve public health.—The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health.
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