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Public Health Open Access
ISSN: 2578-5001

Pharma Patents and Health Care: A Critical Examination of Judicial Response to Novartis Case

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Conceptual Paper

Volume 7 Issue 2

Received Date: September 12, 2023

Published Date: November 09, 2023

DOI: 10.23880/phoa-16000257

Keywords: Pharma Patents; Health Care; Human Rights; Novartis

Abbreviations: ICESCR: International Covenant on Economics, Social, and Cultural Rights; CMMS: Centers for Medicare and Medicaid Services; FTC: Federal Trade Commission; WHO: World Health Organization; EMR: Exclusive Marketing Rights.

Introduction

The right to health as human right paved the way to encourage efforts to optimize the satisfaction of the basic needs of vulnerable people in a sustainable manner and promised to codify as well as to reconstruct them into legal and ethical norms. Health as human right requires that civil society must have democratic participation to capture the essence of the needs and sentiments of people. It conceives the interpretation of health as a judicially enforceable right in every part of the world. At the global level, the institutionalization of health as a human right has found manifestation in international conventions, declarations, and directives. The linkage of health and human rights reference to the understandings that the language 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, and social conditions. This linkage also attributes to the understanding that the status of health is determined in a large measure of the degree to which human rights are enjoyed.

Any attempt to advance health as a human right must start with addressing the cultural, economic, environmental, political, and the social challenges. Rights are meant to empower and mobilize the vulnerable and the disadvantaged, and this should be the main concern of anxiety all over the world particularly in the developing and least-developed countries. Health as a basic and fundamental human right is indispensable for the existence of the other human rights. Both human rights and health are so intrinsically involved with each other that the attainment of the rights is not plausible if an individual cannot take proper care of his/her health. Each and every human being is entitled to the attainment of adequate standard of health conducive to enjoying a life with dignity.

Most countries in the world have become States' parties to one or more international human rights treaties, thus creating an obligation by the State to its people towards the realization of the right to health, which includes access to essential medicines. The question here is to what extent the judiciary has enforced this right in practice.

Issues of human rights affect the relations between the States and their individuals, which in turn generate State obligations and the individual entitlements. The promotion of human rights is one of the main purposes of the United Nations. For example, the WHO Constitution of 1946 points out 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, and political belief, economic or social condition" [1].

Article 25(1) of the Universal Declaration of Human Rights (1948) lays down that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in

circumstances beyond his control" [2].

The right to health is also recognized in many other international [3] and regional [4] treaties, especially the International Covenant on Economics, Social, and Cultural Rights of the (ICESCR) of 1966, an international treaty that is binding on the States Parties [5] and provides the foundations for legal obligations under the right to health. In the ICESCR, States parties "recognize the right of everyone to the highest attainable standard of physical and mental health." In Article 12.2, the treaty lists several steps to be taken by Sates parties to achieve the full realization of this right, including the right to prevention, treatment, and the control of disease, and "the creation of conditions which would assure to all medical service and medical attention in the event of sickness." Article 12 thus constitutes an important standard against which to assess the laws, policies, and practice of States parties. The implementation of the ICESCR is monitored by the Committee on Economic, Social and Cultural Rights, which regularly issues authoritative but non-binding General Comments, which are adopted to assist states in their interpretation of the ICESCR. In General Comment No.3, the Committee confirms that States Parties have a core obligation to ensure the satisfaction of minimum essential levels of each of the rights outlined in the ICESCR, including essential primary care as described in the Alma-Ata Declaration, [6] which includes the provision of essential medicines. ICESCR General Comment of May 14, 2000, is concerned with access to essential medicines and services as included in Article 12.2 (d), which is consistent with the WHO's definition of essential drugs in its Action Program [7].

Essential medicines are those that satisfy the priority health care needs of the population. Essential medicines selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with the assured quality and it a price the individual and community CA afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations, exactly which medicines are regarded as essential remains a national responsibility.

Although the ICESCR acknowledges the limits of available resources and provides for the progressive realization of the right to health including the right to access to essential medicines, States parties have an immediate obligation to take deliberate and concrete steps towards the full realization of Article 12, and to guarantee that the Right to Health will be exercised without discrimination of any kind.

Most countries in the world have acceded to or ratified at least one worldwide or regional covenant or treaty confirming the right to health. For example, more than 150 countries have become States parties to the ICESCR, and 83 have signed regional treaties. More than 100 countries have incorporated the right to health in their national constitution [8]. Some might argue that social, cultural, and economic rights are not enforceable through the courts, and some national courts have indeed been reluctant to intervene in resource allocation decisions of government. Yet accountability and the possibility of redress are essential components of the rights-based approach. Being a State party to human rights treaty that is internationally binding and creates certain state obligations to its people. The question is do governments live up to these binding obligations in practice? If not, do individuals manage to obtain their rights through the judiciary? And if they do, which factors have contributed to their success?

Judicial Response to Public Health in Developing Countries

Hans et al. identified 71 completed court cases from a total of 12 low-income and middle-income countries, wherein individuals or groups had claimed access to essential medicines with reference to the right to health in general or to specific human rights treaties ratified by the government [9]. Of these cases, 59 (mostly from Central and Latin America) could successfully enforce access to essential medicines as part of the fulfillment of the right to health (e.g., constitutional provisions and the human rights treaties) through courts. Fourteen of these 59 successful cases (24%) made their references to international human rights treaties to which the State is party, while the other 45 made references to the right to health as a matter of the national constitution. Human rights treaties were mentioned as a group and to further substantiate the constitutional provisions. The significance of the international human rights treaties is illustrative in the case of Argentina. Argentina's constitution has no specific provision for right to health, therefore, the Court listed all international treaties that the nation had ratified in support of its ruling for continued life-saving treatment of a child with a blood disease. Most cases were individuals; 27 were public interest cases, and 14 were supported by NGOs. In 61 cases, the social security system or the ministry of health were the defendants. About one-half of the cases were related to potentially life serving treatment of HIV/AIDs. This study demonstrated that access to essential medicines as part of the fulfillment of the right to health can indeed be enforced through the courts. The common success factor remains to be the provisions of right to health in national constitution—that translate as state obligations with regard to health care services and social welfare. Odds of success for those cases have increased when constitutional provisions are combined with international treaties.

From a public health point of view these judgments have both positive and negative implications: on the positive side, judgments in the 59 successful cases increased the availability antiretroviral treatment to patients with HIV/AIDS, as a testimony to courts' commitment to human rights' principles of accountability and redress mechanism; but on the negative side, judgments in the 12 unsuccessful cases, rejection of claims for non-life-saving treatment might have hampered quality of life.

It is not always easy for courts to decide based on individual's right to health. Ideally, every individual is entitled to right to health, but States shall extend an unlimited access to health care services for all of their citizens in order to fully realize such a right. This requires appropriate legislative measures and mechanics of implementing such measures. But, because public budgets are frequently limited, States are forced to make certain choices under certain circumstances, thereby curbing access in certain circumstances to certain individuals for certain health care services. When the access is thus limited or denied, the courts' intervention is sought after, pressurizing them to carefully weigh between the available resources and demands for access to health services. Sir Thomas Bingham described this dilemma in Regina v. Cambridge Health Authority, ex parte B (A Minor) [10].

I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonizing judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this Authority can be fairly criticized for not advancing before the court.

The renal dialysis case in South Africa Soobramoney v. Minister of Health [11] may further elaborate such practical problems for judiciary. In this case, a 41-year-old unemployed male, suffering from chronic renal failure resulting from diabetes, whose life can only be prolonged by an ongoing dialysis treatment, approached a state hospital for his treatment, but the hospital refused him admission to its renal unit following a set policy—that the primary requirement for his treatment was eligibility for a kidney transplant; that the treatment could be administered until a donor was found and the transplant completed. Moreover, a patient has to be free from other significant diseases in order to be eligible for a kidney transplant. Mr. Soobramoney failed to satisfy the requirements for a kidney transplant as he was suffering from other serious diseases such as heart disease. This refusal prompted him to ask for a court order directing the hospital to provide him with ongoing dialysis treatment and restraining the provincial minister of health from refusing him admission to the renal unit of the hospital. The High Court dismissed his application, after which he appealed to the Constitutional Court on the grounds that patients who suffered from terminal illnesses and required treatment to prolong their lives were entitled to be provided such treatment by the State pursuant to Section 27(3) which guarantees the right to everyone not to be denied emergency treatment; and, Section 11, which guarantees the right to life. The Constitutional court refused to order the provision of the treatment arguing that the guidelines had the advantage of allocating scarce resources rationally to ensure that a greater number of patients are cured than would be the case if dialysis machines were used to keep alive persons with chronic renal failures. Justice Sachs opined that [12].

The courts are not the proper place to resolve the agonizing personal and medical problems that underlie these choices. Important though review functions are, there are areas where institutional incapacity and appropriate constitutional modesty require us to be especially cautious … Unfortunately, the resources are limited, and I can find no reason to interfere with the allocation undertaken by those better equipped than I to deal with the agonizing choices that had to be made in this case.

And Justice Chaskalson saw this case was materially different from that of a decision of a two-judge bench of the Supreme Court of India in Paschim Banga Khet Mazdoor Samity and Others v. State of West Bengal and Another [13].

The Constitution envisages the establishment of a welfare State at the federal level as well as at the State level. In a welfare State the primary duty of the Government is to secure the welfare of the people. Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare State. The Government discharges this obligation by running hospitals and health centers which provide medical care to the person seeking to avail those facilities. Article 21 imposes an obligation on the State to safeguard the right to life of every person. Preservation of human life is thus of paramount importance. The Government hospitals run

by the State and the medical officers employed therein are duty bound to extend medical assistance for preserving human life. Failure on the part of a Government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his right to life guaranteed under Article 21.

Judicial Response to Health Care and Patents

Given the aforementioned difficulty in judicial responses to citizens' right to health under the limited availability of health care services, pharmaceutical patent monopolies further compound the problem of public health. High prices and lack of generics place additional constraints on the access to health care of people, especially who need them the most. Even industrialized countries began seeing it lately. For example, in 2012 the U.S. Supreme Court issued its much-awaited decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc. that claims on methods of determining whether drug dosing levels falls under the "law of nature" because such levels are based on levels of metabolite in a patient's bloodstream, and hence, they were not patent-eligible under Section 101 of the Patent Act of 1952 (35 USC 101) [14]. For a large part, as far as pharmaceutical patents are concerned, judicial response centered around anti-trust laws and patent infringement litigations as a result of certain product modifications and marketing as improvements.

In State of New York v. Actavis plc (Namenda), the Second Circuit became the first appellate court to address product hopping [15], when the State of New York alleged Forest Laboratories, a subsidiary of Actavis plc, for its attempt to remove Namenda IR, an Alzheimer's drug from the market on two occasions after getting patent for the new drug Namenda XR through 2029. This coercive switch, a tactic of product hopping, was designed to avoid generic competition and monopolize the memantine market. When the exclusive patent for Namenda IR expires in July 2015, Forest Laboratories knew that its sales would go to generics within six months—a period called "patent cliff." Therefore, the XR version was introduced in 2013 as a "soft switch," and it was aggressively marketed at discount price through rebates to health plans, and limiting co-payments for the drug. In 2014, the Forest Laboratories faced imminent generic competition for Namenda IR and announced to discontinue the drug beginning August 2014 by serving a notice to that effect to the FDA and the Centers for Medicare and Medicaid Services (CMMS). Production issues caused a delay, and the State of New York sued to enjoin the discontinuation, which prompted Forest Laboratories to agree to a standstill in September 2014. New York also alleged that XR version offered no material benefit to patients over the IR version to justify the switch. The Court, having heard evidentiary hearing from 24 witnesses for five days and reviewed over 1,400 exhibits, found that: (1) withdrawing Namenda IR from the market prior to generic entry forces Alzheimer's patients dependent on memantine therapy to switch to Namenda XR because it is the only available alternative; (2) the generic versions of IR poised to enter the market in July and October of 2015 will not be AB-rated [16] to XR because they are different strengths and dosages; (3) pharmacists will not be permitted to automatically substitute generic IR for XR, since they both are not therapeutically equivalent; (4) if Forest Laboratories forced Alzheimer's patients to switch to XR prior to generic entry, those patients would likely not switch back to IR generic due to high transaction costs associated with patients switching formulations; (5) preventing generic IR from competing under state drug substitution laws (under FDA requirements, the Hatch-Waxman Act) would effectively prevent generic entry into memantine drug market; and, (6) in withdrawing Namenda IR from the market, Forest Laboratories' "explicit purpose" was to impede generic competition and to avoid the "patent cliff"—which occurs at the end of a drug's exclusionary period when generics gain market share through substitution laws [17]. Based on these, the district concluded that New York raised serious question under Sections 1 and 2 of the Sherman Act, showed a risk of irreversible harm, and the balance of equities favored an injunction. Granting the New York's request for injunction until July 2015 (i.e., 30 days after generic IR was scheduled to reach the market), the court required that Forest Laboratories continue to manufacture and supply Namenda IR on the 2013 terms, notify the proper channels of IR availability, and avoid other measures that would inhibit generic substitution of IR. Federal Court of Appeals for the Second Circuit affirmed the lower court and found that the product hop was anticompetitive and exclusionary conduct aimed at unlawful continuation of monopoly and that hard switch is an act of coercion [18].

Likewise, the Third Circuit court addressed the product hopping allegations in Mylan Pharmaceuticals v. Warner Chilcott, concerning Doryx, an oral antibiotic of the tetracycline class used to treat severe acne. Both the companies introduced in 2005 a new tablet form of Doryx to replace the incumbent capsule version of the product, for which Mylan, the plaintiff, attempted an AB-rated generic. The capsule version was discontinued and removed from Warner Chilcott's website. In 2011, Warner Robins obtained approval of subsequent versions of the drugs by changing dosages and scores, which require a new ANDA demonstrating the bioequivalence and pharmaceutical equivalence between the generic drug and the reformulated branded drug in order for the generic to be AB-rated. In each case, Warner Chilcott discontinued the prior versions of the drug. Mylan sought FDA approval of an AB-rated generic for each tablet

version of Doryx that Warner Chilcott introduced and alleged that Warner Chilcott's product hopping prevented it from obtaining FDA approval of generic version that would benefit from automatic substitution. Mylan obtained ANDA approval for the 2008 version of Doryx tablets in February 2012. By then, Warner Chilcott was already marketing the dual-scored 2010 version. Therefore, Mylan sued Warner Chilcott in July 2012 for monopolizing the Doryx market through a continuous pattern of product hopping. The Eastern District of Pennsylvania gave judgment in favor Warner Chilcott, by stating that Mylan made no effort to market the generic drugs and relied solely on automatic substitution—which is anticompetitive injury. When the decision was appealed the Third Circuit affirmed for lack of sufficient direct evidence of monopoly power based on supra-competitive prices or restricted output [19].

The above two examples show a clear contrast of circumstances on which the United States' judicial response was based. The courts tend to disfavor the hard switch of products or coercion of patients to switch from one version to the other (as in the case of Namenda) while at the same time do not support claims related to anticompetitive injury. The landmark question here is: Can a brand's robust competition in a broader market, such as therapeutic class, overcome the presumption that a branded drug and its generic equivalents comprise a valid market? Modern antitrust law suggests otherwise; that is, pharmaceutical conduct cases alleging anticompetitive conduct targeted at generics typically define the market around the brand regardless of non-brand competition—the position held by the Federal Trade Commission (FTC) [20].

When it comes to the judicial response from the Indian courts, the Novartis case triggered a hugely polarizing discourse around the world about a key feature of India's patent regime. The Court ruling had potential impact on millions of people with critical illnesses such as AIDS and cancer, not just in India but across the developing world. Hence, it deserves a detailed examination.

The Novartis Case and Judicial Response

The high-profile Novartis case was the first of its kind to reach India's highest court, with a history of long and bitter battle over several years, hiring some of India's most eminent lawyers and finally losing its appeal for unlawful evergreening of a product patent under the nation's 2005 Patent Amendment Act. Therefore, it is important to know the Novartis, its role in pharmaceuticals, its evergreening attempts and patent office rulings, its appeals over patent office decisions, and judicial responses to each of those appeals as discussed in the following subsections.

Novartis Beginning and Its Role in Pharmaceuticals

Novartis emerged from two mergers of three of its parent companies—the Basel's Dye factories (CIBA) that specialized in silk-dying works since 1859; Geigy, that specialized in trading materials, chemicals, dyes, and drugs since 1758; and, Sandoz Ltd., that was in operation since 1939 and discovered acid-resistant penicillin for oral administration in 1951, and developed other drugs in later years, such as Sandimmune for organ transplantation, the antipsychotic Clozaril, Mellaril tablets, and Serentil tablets for treating psychotic disorder, etc. The first merger took place in 1971 between CIBA and Geigy to form the Ciba-Geigy. Among its other accomplishments, the CIBA Vision venture in contact lens market is noteworthy. Then, the second merger took place on December 20, 1996 between Ciba-Geigy and Sandoz, to form what is now known as Novartis Company. This was the largest company merger in the history of Basel at that time. The name Novartis is derived from the Latin novae artes, which means new arts or new skills. From the time of this merger, Novartis devoted itself to three business areas: health care, agribusiness, and nutrition. Its pharmaceutical success has been quite impressive, in that the Novartis Company launched some breakthrough drugs such as Gleevec/Glivec for cancer treatment, Diovon for hypertention, and Gilenya for multiple sclerosis [21]. As of 2017, the company's revenue was estimated to be $50.135 billion, with an operating margin of 17.2% [22]. The company boasts its purpose is "to reimagine medicine to improve and extend people's lives" and vision being "a trusted leader in changing the practice of medicine." Novartis products are sold in about 155 countries and they reached about one billion people globally; and, its market capitalization is $195.5 billion in 2017. About 126,000 people of 145 nationalities work at Novartis around the world [23]. Glivec continued to be Novartis' top 3rd product with over $1.9 billion sales, only behind Gilenya (sales $3.2 billion) and Cosentyx (sales $2.1 billion) in 2017 [24]. Despite these phenomenal accomplishments, Novartis could not avoid some critical legal challenges including its 2010 sexual discrimination suit [25] as well as 2001-2011marketing violations investigations in the U.S. [26]; 2009 rejection of a patent application for evergreening in India [27]; 2013 Valsartan data scandal in Japan [28]; 2017 bribery scandals in Greece [29], etc. Of them, the India's Court ruling against Novartis' evergreening has a larger implication, for which it gained global attention.

The Background of Novartis Challenge in India

Dr. Jürg Zimmermann, global head of oncology and exploratory chemistry at Novartis sought and obtained patent from the United States (Patent No. 5,521,184) for a

number of derivatives of N-phenyl1-2-pyrimidineamine, one of which is CGP 57148 in free base form, which was later given the international nonproprietary name, Imatinib, by the World Health Organization (WHO) on May 28, 1996. These Zimmermann compounds were also granted a European patent (No. EP-A-0 564 409) subsequently [30]. Novartis filed the application for grant of patent for Imatinib Mesylate in beta crystalline form at Chennai Patent Office on July 16, 1998, claiming that the product has (a) more beneficial flow properties; (b) better thermodynamic stability; and, (c) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate—which collectively make the invented product "new" and "superior!" [31]. The application also had the priority date of July 18, 1997—indicating that Novartis applied for grant of patent on that date for the subject product in Switzerland; but at that time, Switzerland was not one of the 'Convention Countries [32].' Also, India was in the process of revising its patent law at the time of the application, as such all applications for product patent, including this one, would lay dormant under an arrangement called "the mailbox procedure."

Before the "mailbox" applications were taken out for consideration, several amendments were introduced to the Indian Patent Act of 1970 that fundamentally shifted the nation's patent law. The new patent law came into effect from January 1, 2005. In the meantime, Novartis made an application on March 27, 2002, for grant of exclusive marketing rights (EMR) under section 24A (which was later deleted) and the Indian Patent Office granted it on November 10, 2003. When the Novartis application for product patent was reviewed, the Assistant Controller held that the invention claimed was: (a) anticipated by prior publication, i.e., the Zimmermann patent; (b) obvious to a person skilled in the art, given the information disclosed in the Zimmermann patent; and, (c) disallowed by Section 3(d) of the Act. In addition, the application was found to have wrongly claimed the same priority date in India as it was in Switzerland, though Switzerland was not a convention member as of July 18, 1997 [33]. Therefore, the application was denied.

Appeal Procedures

At the time of the rejection of Novartis' application for product patent, the appellate authority under the new 2005 Patent Amendment Act had not yet become functional. Therefore, Novartis challenged the Assistant Controller's orders by filing writ petitions directly before the Madras (former name of Chennai) High Court, along with filing two additional writ petitions (one by the Novartis and the other by its Indian power of attorney holder) seeking a declaration that Section 3(d) of the Act was unconstitutional, by claiming that: (i) it violates Article 14 of the Constitution of India; and, (ii) it was not in compliance with TRIPS. Following the formation of the IPAB (Intellectual Property Appellate Board), the writ petitions were transferred from the High Court to IPAB on April 14, 2007, where they were registered and numbered as TA/1 to 5/2007/PT/CH. The Division Bench of High Court heard the other two writ petitions assailing Section 3(d) and dismissed them on August 6, 2007. Novartis did not take that matter any further.

Nearly two years later, on June 26, 2009, the IAPB heard the five writ petitions filed by Novartis and dismissed against the orders of the Assistant Controller concerning novelty, non-obviousness, and the priority date applicability in India. However, the IAPB held that Novartis product was not patentable in India under section 3(d) for the following reason [34].

Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substance.

This ruling was consistent with the judgment of Madras High Court, wherein Novartis writ petitions challenging the constitutional validity of section 3(d) were dismissed, by stating [35].

We have borne in mind the object which the amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens.

Additionally, Novartis enjoyed its exclusive marketing rights (EMR) on Gleevec by charging Rs. 1,20,000 per month for a required dose of the drug from cancer patients—creating a havoc to the lives of poor people and their families affected with the cancer—which caught the eyes of IAPB and caused to conclude that [36].

[the Novartis'] alleged invention won't be worthy of a reward of any product patent on the basis of its impugned application for not only for not satisfying the requirement of section 3(d) of the Act, but also for its possible disastrous consequences…

Then, Novartis appealed the IAPB decision under Article 136 of the Constitution to the Supreme Court and urged that the Court might itself decide the appeals instead of directing to move it to the High Court, given the importance of the matter. As unprecedent as it is for an appeal on IAPB decision to bypass the High Court, the Supreme Court proceeded to

decide the case on its merits.

The Supreme Court Observations

The Supreme Court of India made the following observations in the Novartis AG case:

(a) This case falls in the transitional period between two fundamentally different patent regimes; that is, when the application for patent product was made in 1998, it was under Section 5 of the Patent Act 1970 (Inventions where only methods or processes of manufacture patentable) that barred grant of patent to substances intended for use, or capable of being used, as food and medicine or drug, or prepared or produced by chemical process. The application was then put in the "mailbox" and was taken out for consideration when many changes had been made in the Patent Act of 1970, with effect from January 1, 2005, to make the patent law compliant with the terms of international agreement entered into by the Government of India. Accordingly, the new Patent (Amendment) Act of 2005 adopted large scale changes in three stages. Section 5 of Patent Act, 1970, under which the application was filed, was altogether deleted from the statute book. Additionally, clauses (j) and (ja) of section 2(1), apart from some other ancillary clauses of section 2(1) as well as section (3) were amended to the extent of redefining the concepts of invention and patentability. Finally, as it stands today after major changes were brought about in the Patents Act, 1970 in 2005, the Act is fully TRIPS compliant. The Doha Declaration and the TRIPS agreement insist that the Indian law must be judged and interpreted on its own terms, and not on the basis of standards of patentability prescribed in some countries of western world [37].

(b) India had learnt from experience the inverse relationship between product patents and the indigenous pharmaceutical industry, and its effects on the availability of essential drugs at affordable prices. It is also seen that after the patent system in India barred the grant of patents for pharmaceutical and chemical substances, the pharmaceutical industry in the country scaled great heights and became the major supplier of drugs at cheap prices to a number of developing and underdeveloped countries. Hence, the reintroduction of product patents in Indian patent system through the TRIPS agreement became a cause of alarm not only in India but also for some international agencies, as detailed in a letter of the HIV/AIDS Director of the WHO, dated December 17, 2004, to the Ministry of Health and Family Welfare, Government of India. In this letter, Dr. Jim Yong Kim explicitly stated that [38].

As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take necessary steps to continue to account for the needs of the poorest nations that urgently need access to antiretrovirals, without adopting unnecessary restriction that are not required under the TRIPS Agreement and that would impede access to medicines.

Likewise, Achmat Dangor, the Director of Advocacy, Communication and Leadership for UNAIDS, wrote on February 23, 2005, to the Minister of Commerce and Industry, Government of India, urging India [39]:

…to consider all appropriate legal means to protect and scale up access to essential affordable medicines. The Doha Declaration, in which India played an important role, makes clear that the interests of public health and equitable access to medicines for all should be primary concerns in the application of the TRIPS Agreement and related trade and intellectual property rules.

And the above concerns were factored in the Patent (Amendment) Act, 2005—which explains the "why" and "how" of the law.

(a) The current meaning of "invention" should be derived from clauses (ac), (j) of section 2(1) of the Patent (Amendment) Act, 2005 . Section 2(1)(j) requires a product to satisfy three conditions to qualify as an invention: (i) it must be "new", that is to say it must not have been anticipated; (ii) its coming into being must involve an "inventive step"; and, (iii) it must be "capable of industrial application," that is to say it must be capable of being made or used in an industry [section 2(1)(ac)]. "Inventive step" as defined in section 2(ja) involves technical advance as compared to the existing knowledge, or economic significance or both and that makes the invention not Obvious to a person skilled in the art [40,41].

(b) Invention and patentability are two distinctly separate concepts. For example, Section 4 prohibits the grant of a patent to inventions related to atomic energy falling within sub-section (1) of section 20 of the Atomic Energy Act, 1962. Therefore, it is essential that for grant of patent the subject must satisfy the twin tests of "invention" and "patentability." Otherwise, even if something that qualifies an invention for the purposes of the Act, may be denied patent for other larger considerations that are stipulated in the Act. For the purpose of the appeal being considered, only section 3(d) was relevant, as it was "on the Government's assurance that the proposed section 3(d) (besides some other changes in the Act) would take care of the apprehensions about the abuse of product patents in medicines and agricultural chemical substances that the Bill was passed by the Parliament [42]."

Novartis Argument

Novartis argued that section 3(d) has no application to the case of the subject product, since it satisfied the tests of invention as provided in sections 2(1)(j) and 2(1)(ja); that the primary purpose of section 3(d) is to prevent evergreeing, and yet to encourage incremental inventions; that section 3(d) contradicts with sections 2(1)(j) and 2(1)(ja); that an invention cannot be characterized by the word "mere"; and, that the word "invention" is distinct from the word "discovery)—all of which suggest that section 3(d) operates only as ex major cautela [43].

The Supreme Court Ruling

The Supreme Court disagreed that section 3(d) is a provision ex majore cautela, instead it pointed out the Novartis' inability to see the vital distinction between the concepts of invention and patentability, which is the heart of the Patent Act of 1970 and reinforced in section 3(d). The Court further emphasized that [44].

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

The Supreme Court also gave numerous examples to show that the drug Gleevec directly emanates from the Zimmermann patent and comes to the market for commercial sale; that Zimmermann coauthored a publication in the journal of Cancer Research, as early as in January 1996, which included a detailed discussion about the antitumoral properties of Imatinib and its methanesulfonate salt; i.e., Imatinib Mesylate—all indicating that Imatinib Mesylate was not a "new" product and it does not qualify the test of "invention" as laid down in sections 2(1)(j) and 2(1)(ja) [45]. Also, because the beta crystalline is the beta crystal form of Imatinib Mesylate, it is a "known substance" with "known efficacy" and failed to stand up to the test of section 3(d). The Court also pointed out that Novartis failed to show the "enhanced efficacy" of the beta crystalline form of Imatinib Mesylate over Imatinib Mesylate (non-crystalline); and, clarified the meaning of "efficacy" in the case of medicine that claims to cure a disease is "therapeutic efficacy," which must be judged strictly and narrowly in the genesis of section 3(d) [46,47]. In other words, the physio-chemical properties of beta crystalline form Imatinib Mesylate such as: (i) more beneficial flow properties; (ii) better thermodynamic stability; and, (iii) lower hygroscopicity have nothing to do with therapeutic efficacy for the test of section 3(d). Thus, the Court found [48].

…in whichever way section 3(d) may be viewed, whether as setting up the standards of "patentability" or as an extension of the definition of "invention," it must be held that on the basis of the material brought before this court, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of section 3(d), too, of the Act. Hence, the appeals filed by Novartis AG failed and were dismissed with cost.

Judicial Response: A Critique of Novartis Case

The judicial response to the appeals filed by Novartis AG attracted both accolades and criticism. Some viewed that the Novartis decision clearly raised the bar for granting a patent in India [49]; helps immensely to generic companies like Cipla to produce low-cost versions of Gleevec which enhance the accessibility to essential drugs not only in India but in other developing and least developed countries [50]; the purpose of preserving public health and ensuring access to medicines at reasonable prices would probably be better served by refocusing upon traditional standards of patentability, or by a comprehensive reform of section 3(d) or through the grant of market exclusivity for innovations that neither pass the threshold of section 3(d) nor constitute evergreening; [51] the Supreme Court left open the interpretation of "enhanced efficacy" and the Novartis decision was detrimental to innovation and would likely to harm India's own growing pharmaceutical industry [52]; the Court in Novartis AG manifested poor understanding of evergreening when it compare the beta crystalline form of imatinib mesylate to distant free-base imatinib because free-base imatinib was not capable of administered as a drug to humans and therefore lacked evergreen potential [53]; and the like.

Drawing lessons from the Novartis court ruling for the Southern African Development Community (SADC), Prof. Ndlovu, faculty of law at the University of South Africa affirmed that [54].

Although the rejection of Novartis' claims was met with criticism from the pharmaceutical industry as shifting the balance too much in favor of the protection of public health, the fact that the decision gave prominence to public health issues over IP must be celebrated as relevant to the current SADC situation in which law reform is still possible. In the judgment itself, in the course of describing the history IP law in India the Supreme Court said that the Committee under the chairmanship of Justice N. Rajagopala Ayyangar "took a fresh look at the law of patents to completely revamp and recast it to best subser the (contemporary needs of the country……. The decision in Novartis relating to the interpretation of section 3(d) was well reasoned and concluded [55].

The case provides a good example of how to take maximum advantage of one of the TRIPS flexibilities, namely setting national criteria for patentability. In identifying the source of lessons for SADC from outside the region, it is important to select lessons from countries with socio-economic conditions similar to that prevail in the SADC. India is therefore appropriate as a source of lessons, based on the fact that it is a developing WTO member which most SADC members are likely to use as a source of generic drugs.

In fact, some developing countries have already considered (or considering) adopting patent restrictions similar to those in section 3(d) of India to prevent evergreening and increase accessibility of patients to drugs at reasonable prices. To cite a few examples, Philippines proposed to amend its laws on identical clauses [56]. Brazil Patent Office drafted similar guidelines to restrict patentability on known substances. The Brazilian Patent Reform Report clearly states [57].

The evergreening 2013 Novartis case in India, in which the Indian Supreme Court rejected the grant of a patent for a new form of known substance, evidences how important the implementation of the TRIPS Agreement safeguards can be to a country, and indeed to the world, for India has become the major international provider of affordable generic medicines to the world's population.

Argentina's new patent guidelines, as amended in May 2012, exclude treatment methods, new dosages and combinations, polymorphs (as well as pseudo-polymorph—hydrates and solvates) that are considered to be intrinsic property of the substance—therefore mere discoveries and not inventions, single "known" substances such as salts, esters, amides, enantiomers and other derivatives, and new formulations and compounds that do not meet the "non-obviousness" requirement—all from patentability [58].

Mexican Industrial Property Law (IPL) 1991, as amended in June 2010 stipulates that polymorphs must produce extraordinary technical effect compared to already known in order for them to be considered as inventive. Article 19 (VIII) of the law states that the following are not considered inventions [59].

Juxtaposition of known inventions or mixtures of known products, or alteration of the use, form, dimensions or materials thereof, except wherein reality they are so combined or merged so that they cannot function separately or where their particular features or functions have been so modified as to produce an industrial result or their use is not obvious to a person skilled in the art.

Even some of the developed countries, as Linda Lee found, which have no direct counterpart to section 3(d) of India Patent Act, apparently exercise similar constraints indirectly. For example, the U.S. Federal Circuit invalidated a patent on the metabolite of antihistamine drug because the metabolite "necessarily and inevitably" formed upon ingestion of previously patented antihistamine under normal conditions. U.S. also prohibits double patenting, where a patentee cannot hold more than one patent with identical claims; and, under 35 USC 103 nonobvious doctrine, U.S. courts can invalidate certain pharmaceutical claims, as in the case of Pfizer, Inc. v Apotex Inc. where the Federal Court invalidated Pfizer's patent on hypertension drug on non-obviousness grounds because the active ingredient of the drug was merely a salt form of a known substance [60].

Japan's patent legislation allows new use of drug to be patented, provided it is absolutely novel over the original with clearly differentiable medical use. For example, if the original medicine is used in the treatment of malady "A" and, after the discovery of a new use, the medicine begins to be employed in the treatment of malady "B", it characterizes innovation, and therefore, the medicine will have its new legal protection— "clear legal gymnastics and artifices [61]."

Shamnad Basheer, a law professor at Oxford University, notice some differences between section 3(d) and the patent laws of the United States and European Union, despite some broad similarities in terms of technology-specific non-obviousness standard. First, this standard under US and EU laws is not limited to therapeutic advantages alone and other advantages may qualify as well, unlike section 3(d). Second, the unexpected results framework under US and EU laws is not dispositive of the issue of whether the derivative is inventive or nonobvious, but a mere presumption. In other words, it could be dislodged upon the production of evidence by the inventor. On the other hand, section 3(d), while not a presumption, is a conclusory legal standard—once it is established that the derivative is not significantly more efficacious than existing substance, it fails the test of patentability. Thus section 3(d) is more of a patent eligibility than a patentability—a requirement that a subject matter for which a patent is sought is inherently suitable for patent protection [62,63].

Conclusion

The judicial response in Novartis AG has a reverberating effect on patent laws around the world. This would also avoid monopoly by US corporations charging exorbitant prices. While US patent law supports the grant of patent over a new form of uses or combination of known compositions as they have lower level of patentability standards, when compared to Indian patent law, many developing nations have begun raising their patent grant standards similar to those in section 3(d) to safeguard against evergreening and increase

patients' access to life-saving drugs at reasonable prices by increasing opportunities for generic manufacturers to enter the market. As Basheer pointed out, section 3(d) succeeded its toughest litmus test in the aftermath of Novartis' patent challenge. Indian judiciary endorsed the legality of section 3(d) and upheld the rigorous therapeutic efficacy threshold. The judiciary, while complimenting the efforts of legislature, refused to co-opt into a cozy patent construct engineered by the allegedly more sophisticated patent regimes of developed nations; and, set the trend to other developing nations in a new direction of patent law and intellectual property rights. Professor A. Lakshminath, the former vice-chancellor of Chanakya National Law University, India, summarized this view.

Indian Judicial system has again proved its ability and strength to block all attempts from multinational pharmaceutical gains to cash upon the life of thousands of patients those who have been fighting for their life either in hospital bed or at home. The decision to provide free of cost medicine regardless the company withdraw its charity is another landmark in this direction. Innovation and patent are two separate things. Innovation should be for serving humanity, especially whatever in the field of medical science, patents should not have only one objective to amass profit.

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