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Novartis Verdict: A Boon or Bane

Deepak Kumar
Research Scholar, Faculty of Law
A.M.U. Aligarh

Prof. (Dr.) Saleem Akhtar
Ex.-Dean, Faculty of Law
A.M.U. Aligarh

ABSTRACT:
Before eying on such a most awaited Supreme Court ruling (in Novartis case), I wish to refresh a new and coherent voice which could be justifiable to the momentum for a fundamental reassessment in Socio-legal impact of manufacturing, availability and affordability of drugs. So this ruling is appealing because it asked a question that was the essence of both naïve and salient. The judges wanted to know whether the Novartis patent was a legal tool to prolong an existing monopoly beyond reasonable limits. In court room of Apex judicial body, it was an attempt to question whether India is undervaluing patents or is the rest of the world overvaluing them? That might be one of the more intriguing questions raised by the Supreme Court in its ruling.

Justice Aftab Alam , a judge of the Supreme Court upheld (On April 1, 2013) the Intellectual Property Appellate Board's decision to deny patent protection to Novartis's application covering a beta crystalline form of imatinib, the medicine Novartis brands as Glivec and which is very effective against the form of cancer known as chronic myeloid leukemia (CML). Additionally, the Ever-greening of patents gives the innovators a chance to retain monopoly over its product even after the patent term has expired. The innovators usually bring in small changes and then claim patent rights for 20 years. In the Novartis case, the Supreme Court ruled that there had been no new innovation in the form of new substance used in the drug. In this regard, I realized some queries in my mind those I want to play-on to Government and Judicial Authorities;

How could it be testified that this step is not going to be biased?
Why the Indian Government is not trying to mitigate some well-known loopholes / factors in our International Political Relations, Health Policy and Socio-Economic conditions?
What things Governmental agencies and Public officials are waiting for?

Ironically, I reached at sense of that the above queries are not being answered by the concerned bodies because, here and there, they all are involved in this Blame-Game, so I opined through the Keynotes of my intent pertaining to the Novartis verdict, in analytical attitudes, that this situation may be the demand of the day but not forever. That's why I took my look upon the real scene of this attempt behind the commercial, political & legal game of this Drug-Saga.

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What the Case is?

In present time, a marathon discuss has evolved in incremental place for pharmaceutical products and its proper legal protection (Patenting the Drugs in comparison of Swiss pharma Novartis' new version of Glivec/Gleevec) with all aspects of human touch. As far as the fidelity of human life is concerned, it always needed availability, suitability and recognized resources for making the human life better, so this is the reason for which every effort of every human being is done to minimize the physical inefficiency. On the similar way, they indulge themselves in various innovative work and research tasks and after that they seek some legal protection over there. Since the birth (enforcement) of Patent law in India (1970), a number of Amendments (1999, 2005), Rules (2003, 2010 etc) and International Agreements (PCT, TRIPS, DOHA etc) have taken place to make the human life in its better condition irrespective any geographical or political barriers.

Despite of the above fact, different pharmaceutical matters / cases relating to the Drugs, whether Generic or Life Saving, have enlighten the hope of long and secured lives of every one. From Cipla, Ranbaxy and Natco to Bayer and Novartis, these all played a vital role to easier mode of selection and adoption of affordable and qualitative drugs.

So I tried to analyze and draw an attention of all concerned to this extra-ordinary verdict which enabled Indian Patent Law as Socialization of Indian Pharma Industry with humanity confirmation. Now a nutshell of this case is discussed which shall lead this research paper/article to formulate the opinion of go-through persons whether it is boon or bane.

Recently the Novartis Case[1] of 2013 which is about denying the patent protection by the Apex court has been bone of debate since pronouncements while quoting the question of Ever Greening Patent of Drugs? Actually, Novartis had applied for a patent for imatinib in the United States in April 1994 and later started marketing a derivative of it, viz., imatinib mesylate as an anti-cancer drug under the brand name of Glivec/Gleevec. But Novartis could not apply for a patent for imatinib/imatinib mesylate in India because during 1972 to 1995, India did not recognise product patent protection in pharmaceuticals. The Supreme Court established that the 1994 US patent for imatinib covered imatinib mesylate too.

After 1995 when India introduced product patents (in 2005), Novartis could not apply for a patent for imatinib/mesylate because patents are given only for new substances or enhanced efficacy substances but not for known substances. By 1995 information on the drug was in the public domain and it was a known substance and hence not patentable in India. What Novartis did in India after 1995 (in 1998) was to apply for a patent for a new form (**beta crystalline form**) rather than alpha crystalline form of imitanib mesylate.

But in year 2005, India has amended its patent law and it introduced product patent in form of insertion a condition as a Section 3 (d) that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" is not patentable. So those, during 1995 to 2005, as permitted by TRIPS agreement, patent applications were received but were kept in a 'mailbox.' And after 2005, when the examination of patent applications started, the patent application of Novartis was rejected by the patent office on the ground that it did not satisfy the efficacy criterion of Section 3(d).

Novartis AG filed the application (Application No.1602/MAS/1998)[2] for grant of Patent for Imatinib Mesylate in beta crystalline form at the Chennai Patent Office on July 17, 1998. In the application it claimed that the invented product, the beta crystal form of Imatinib Mesylate, has;

(i) more beneficial flow properties,
(ii) better thermodynamic stability, and
(iii) Lower hygroscopicity than the alpha crystal form of Imatinib Mesylate.

The Supreme Court judgment is basically related to the appeal of Novartis against this rejection which was upheld by the Intellectual Property Appellate Board. Then the Supreme Court interpreted the word 'efficacy' to mean therapeutic efficacy. Ultimately, the Supreme Court has rejected the appeal and hence denied the patent to Novartis because Novartis could not demonstrate that the new form enhanced the therapeutic efficacy of the drug. The court has also declined Novartis' claims of better bioavailability and better physical characteristics such as stability of the compound saying that these do not necessarily improve the therapeutic effect. Ultimately, the Indian Supreme Court rejected the attempt by Novartis, the Swiss pharmaceutical company, to patent a new version of the anti-leukaemia drug Glivec or Gleevec**.**

Essence of the Judgment[3]

This legendary horse in race of judicial-pharma arena, the Supreme Court of India has taken a forward step in Novartis case to set a new paradigm regulating the biasness on ground of legume sanctum as socio-legal betterment for the State Welfare. Before eying on the verdict, there are some legal provisions pertaining to the patent law and its variations with pharmaceutical morphology. Here, under the Indian Patent Act, 1970 Section 2(1) (j) "invention" means any new and useful –

(i) art, process, method or manner of manufacture,
(ii) machine, apparatus or other article,
(iii) Substance produced by manufacture and includes any new and useful improvement of any of them, and an alleged invention.

Section 2(1) (l) "medicine or drug" includes –

(i) All medicines for internal or external use of human beings or animals,
(ii) All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals
(iii) All substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals,
(iv) Insecticides, germicides etc.

Country's pharmaceutical industry, helped by the basic changes made in the patent system as Patent Act, 1970 which going from strength to strengthen. Following the Uruguay round of multilateral negotiations under the General Agreement on Tariffs and Trade (GATT), the Agreement on Trade-Related Aspects of Intellectual Property Rights (The TRIPS) was arrived at and it came into force on January I, 1995. India is one of the founding members of the GATT and thus a member of the WTO from its inception, so that India is bound by the obligations under TRIPS Agreement like all other members of the WTO. Apart from this, India with its Domestic patent laws and Human Welfare, it has to be in compliance of International Legal Framework. In this way we have to consider these two specific International provisions viz;

Article 1 of TRIPS Agreement

Nature and Scope of Obligations: In its very basic formulation, the draft of TRIPS Agreement is about the object & obligation in Global spectrum that will help to uplift the standard of Human life and Wild life too.

Article 3 of TRIPS Agreement

National Treatment: This relates to the object as such each Member shall accord to the nationals of other Members treatment no less favorable than that it accords to its own nationals with regard to the protection1 of intellectual property.

So, on the above account, India has to be compliant by international legal framework irrespective of its domestic need.

Previous and Present Stand

Eying from 1949 to the present time, we have been seeing drastic involvement of Legal tooling in patenting procedure whether various products e.g. Pharma, Food, Fertilizers etc. Here I am taking a brief stand of patent process to this. In early of 1949, a committee was constituted under the chairmanship of Justice (Dr.) BakshiTek Chand[4], a retired judge of the Lahore High Court, to undertake a comprehensive review of the working of the 1911 Act. This committee has made recommendations for prevention of misuse or abuse of patent rights in India and set the standard that Patent Act should contain a clear indication that food and medicine and surgical and curative devices were to be made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee.

And in year of 1957, another committee was also appointed under the chairmanship of Justice N. Rajagopala Ayyangar to take a fresh look into the law of patent and to completely revamp. Justice Ayyangar conclusively collected valuable data as the Bakshi Tek Chand report and compiling them into a number of reports which showed the share of Indians giants in the field of patents. Justice Ayyangar examined the nature of the patent right and considered the arguments advanced as justifications/rationalizations for grant of patents. Justice Ayyangar's report specially discussed in these points;
(a) patents for chemical inventions, and
(b) patents for inventions relating to food and medicine.

Justice Ayyangar submitted a comprehensive Report on Patent Law Revision in September 1959 and the new law of patent, namely, the Patents Act, 1970, came to be enacted mainly based on the recommendations of the report, and came into force on April 20, 1972, replacing the Patents and Designs Act, 1911. After being passed by the Lok Sabha, the Bill was presented in the Rajya Sabha where it was passed on March 23, 2005. It received the assent of the President on April 4, 2005, and was published in the official gazette of April 5, 2005. Patents Act, 1970, as it stands today after its amendment by the amending Act of 2005, we must refer to clauses (ac), (j) and (ja) of section 2(1) of the Act, as far as this issue is concerned:

Section 2. Definitions and interpretation. — (1) In this Act, unless the context otherwise requires,—
(ac) "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry;
(j) "invention" means a new product or process involving an inventive step and capable of industrial application;
(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;"

Therefore, until 2005, India had only allowed 'process patents' which meant processes in drug making could be patented, but not the products but in 2005 there was an Amendment in compliance with the WTO TRIPS Agreement and India has started granting product patents. Although it has started accepting applications from 1995 which were 'patent mailbox provisions' meant that any applications from that period would be considered against the knowledge present until the point of application. Fatefully this amendment in 2005 was mainly focused on Section 3(d) of the Indian Patent Act, 1970 which prevents the patenting of 'new forms of known substances unless they show enhanced efficacy'. Although this provision is a relatively stringent requirement for 'non-obviousness' and it is compliant with India's international obligations and remains unchallenged at the international level. In between, a number of Patent Applications have been filed / pursued and some prepared their mind & effort to do so. For example; Cipla, Wockhardt, Cadila, Roche, Ranbaxy, Bayer, Natco etc.

Nonetheless, the Apex Court has shown its path to determine the real efficacy for India patent law and its industrial policy with mature resonance of International behavior. And eventually in 1998, Novartis applied to the Indian Patent Office for the 'beta crystalline' form of imatinib mesylate. One year earlier, its US patent application for the same was granted on appeal. Imatinib mesylate, which received FDA approval in 2001, is the salt form of imatinib, patented in the US in 1992. So Novartis has processed at many stages as litmus taste basically at Indian Patent Office, IPAB, other related committees and finally at the Supreme Court of India. Presently, Indian apex judicial body has declined the commercial interest of this pharma giant (Novartis) and settled the question regarding survival of public at large. So the court has made happier to the Indian people by upholding the judgment of IPAB and founded a so called mile stone in generic version of drugs, its manufacturing, proper availability and affordability etc.

Novartis verdict: A Boon

As and when Indian Supreme Court rejected Novartis' patent application over a leading leukemia drug Gilvec/Gleevec[5], it has become a boon to Indian citizen. Many assumed it as a victory for patients while others denounced it as a regressive step for pharmaceutical innovation. With money on one end of the scale and lives on the other, perspectives are easily polarized. However, innovation and access are supplementary when it comes to improving health, because of its nature as hope of the least pessimist seeking a panacea. The output of this verdict became resultant as;

(i) The imatinib mesylate was in fact a 'known' substance,
(ii) It is just an 'efficacy' referred to 'therapeutic efficacy' and
(iii) It presented evidence of increased bioavailability and better storage ability.

By virtue of Indian patent amended law in 2005, Novartis did not present any evidence that the 'beta crystalline' form presented any 'enhanced efficacy' over the known substance imatinib mesylate. And no doubt another issue was the high price of Novartis' drugs. In its decision, the Court was not required to define the therapeutic efficacy threshold required by Section 3(d), so the case can only be viewed as limited precedence. In spite of that actual scene of intention behind this Novartis case was that such huge amount of investment (about $38 – 96 million dollars) in its pharmaceutical innovations must be utilized by the needy people irrespective of any legal, political or territorial barrier. And majority need public i.e. patient, they be facilitated by public funds without any gross profits because human life comes first. If Novartis pharma lands a new standard to its availability and to considering the enormous profit margin as well as the importance of human life so that consequences of Novartis case cannot be accepted to exclude hundreds or thousands of patients. Moreover these patients can never been left on mercy of some commercial gaining. They are equal entitled to afford specific (LSDs) just like as any generic. I pointed out this verdict as a boon in numerical steps viz;

Firstly, India is not prejudiced to protecting or prohibiting patents on new forms of known substances whether it's about Novartis or any other Pharma giant but India following the legal framework of International character of IP laws and IP industries. Rather to receive patent protection, products must show enhanced efficacy and there must be front phase transparency regarding the costs involved in bringing these drugs to the market, sometimes it may be difficult to tailor laws which allow the recoupment of these high costs**.**

Secondly, pharmaceutical companies make most of their revenues from US, EU and Japanese markets. As such, they direct their business models around these countries. It is very unlikely that sales in developing countries like India would cause net losses on the same drugs being sold as generics in poorer countries. At the same time, India's buzzing generic industry has ensured that patients across the developing world are able to access otherwise expensive medicines**.**

Thirdly, the rich countries can pay more for 'frivolous' medicines than poor countries and their people can afford for life saving medicines irrespective of high costs and absolutely stronger patent rights can increase this

inequality. So the pharmaceutical market must signal to the poor indicators of where limited inventive resources are to be directed and it becomes necessary to ensure the legal and Health policy concerns redirect it in more Socially beneficial directions to all kind of lives. And finally, another fact on this issue of Novartis verdict was that the government says it can't permit ever-greening of patents because such an act would diminish the actual purpose of this boon-oriented judgment[6].

This latest Novartis verdict follows previous rulings that granted compulsory license to an Indian generic drug manufacturer Natco Pharma in place of German pharma giant Bayer's Nexavar, a drug used to treat kidney cancer. In this segment of pharma arena, India has provided due process for foreign companies and patent holders comparable to those in advanced democracies. Indian Patent offices have decided on patents and compulsory licensing granted to Indian companies yet their verdicts have been challenged before an independent appellate body, whose verdicts have, in turn, been contested in the courts. Though, drugs manufacturers seem to be disappointed by such kind of ruling if outcomes have gone against foreign firms and its R & D. Nevertheless, this spirit imbuing all the recent patent cases in India has been to strike a balance between the legitimate returns to inventors and investors against the concerns of consumers in a country where the affordability of drugs is of paramount political and social concern. That is unavoidable if the prices charged by a drug company exceeds the income of more than 90 % of households in a country and if generic alternatives are available at one-tenth or even one-thirtieth the cost. But balance and fairness towards foreigners and to the demands of IP rights must not be ignored, for example, the Supreme Court decided to take on the Novartis case instead of waiting for the lower courts out of concern that delays could cut into the life of the patent. This is also a factor, when deciding on the compulsory licensing fee that generic drug makers should pay Bayer (the German maker of the anti-cancer drug Nexavar), the Indian patent office opted for the highest end of the range recommended by the World Health Organization.

Similarly, it must be collaborated by this latest Novartis verdict. This well-wisher mindset of Indian Apex court on Novartis verdict reflects the strength of the generic drug industry and of consumer groups, advocating affordable health care. Nevertheless, the challenge for India will be to ensure the law does not get out of step with the demands of a country that needs foreign investment and new technologies and definitely it shall give a positive attitude to WTO and WHO in terms of Doha Declaration on Public Health.

To some extent, Novartis was hoist by its own petard. In a rush to file patents, drug companies make very broad claims to maximize the scope of their monopoly. A consequence is that subsequent patents' claim to novelty getsundermined.

Whether Indian law and the recent rulings are deviant can only be tested through impartial, international adjudication by the WTO. As I said earlier in my opinion the testimony to the US Congress recourses the WTO's dispute settlement process may be necessary and desirable to settle the competing claims of foreign pharma companies and needy people of India.

In addition to above, Mr. Saurabh Chandra[7], Secretary, Department of Industrial Policy and Promotion (DIPP) said that after the Supreme Court's decision in the Novartis case, the government couldn't permit ever-greening of patents. He further said, "There has been a lot of debate about a judgment given by the Supreme Court and I suppose it's not an issue of law because Section 3(d) is embedded in the Indian Patent Acts which are TRIPS (Trade Related Aspects of Intellectual Property Rights) compliant. Despite of the fact, I also suppose everybody agrees that ever-greening should not be permitted because it could affect the quality of drug and the interest of patients suffering from cancer / leukemia". Mr. Chandra was speaking at an event on Intellectual Property Rights (IPR) organized by industry body i.e. FICCI while the verdict was welcomed by the Indian government and NGOs as a means for cheaper cancer drugs benefiting thousands of cancer patients, multinational companies had expressed their concern at the order. Ultimately, my first attempt, to lifting the veil over Novartis verdict, has tremendously satisfied as a positive step or boon to the forerunner of Anti-Favoring the Public Health on cost of their commercial benefit, though R & D can't be overlooked.

Novartis verdict: A Bane

Though the Supreme Court decision is consistent with TRIPS agreement and has been arrived at transparency and internationally accepted legal processes, yet there are many factors which seem as wrongdoer to the concerned Research & Development of drug-maker's fight. We can easily understand when a company invests about $38 – 96 million dollars in its pharmaceutical innovations. As well as a majority of the product discovery and development costs have been paid for by public funds and non-profits, then it can not be ignored that the said company is not entitled to get return in terms of its net-profit. In 2012, Novartis spent almost $4.7 billion on Glivec sales, considering the enormous profit margin, how a one can say that Novartis does not deserve to make some profit which is a paramount reason to investment. It may be, sometimes, exclusion of thousands of patients only able to afford generics, but still they set to go on so as to receive a small increase in revenues from the few patients in India able to afford the branded product. The Apex court of India has quoted India's status as "the pharmacy of the world" in its judgment of this latest case. But I am totally dissent to such kind of improper buttering to please Indian big bulls. Even this verdict has taken harsh steps into the horizontal nexus of R & D at a Global level. It is just like that a person put his all labor and effort to cultivate the field and yield the grains while another has thrashed out the first person and started to enjoy the whole.

There are some points to this;

- Unni Karunakara[8], International President of Medicines Sans Frontiers states, "instead of seeking to abuse the patent system by bending the rules and claiming ever longer patent protection on older medicines, the drug industry should focus on real innovation, and governments should develop a framework that allows for medicines to be developed in a way that also allows for affordable access". And this is a dialogue that needs to happen as a panacea for both, patent seekers and patients.
- It seems wherein access to medicines increasingly depends on the use of what are known as "TRIPS flexibilities" and its legal measures enshrined in countries' laws to safeguard the right to health. That is why the Doha Declaration of 2001 emphasizes "that the [TRIPS] Agreement can and 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 in general." India's patent law has been commended as a success story by the World Health Organization and health activists, doctors, and patients across the world in widening access to HIV drugs and saving millions of lives. India is often called the "pharmacy of the developing world" because of its generic drugs industry the recent ruling is therefore important.
- Meanwhile, the issue of "ever-greening patent" is a most-must strategy being used by drug companies to prevent losses from sale of cheaper generic drugs and protect their market share, and no doubt this an important factor to investment. A government or judiciary can not ignore the efforts of tactics such as chemical tricks, reformulations, fixed dose drug combinations, changes in dosage regimen, and brand promotion among others etc. Because it could be a setback for drug-manufacturer, doctors, health systems and international commercial relations, so that the government and judiciary have to wake up to these factors. And I am sure it will be helpful identify similar pharmaceutical tactics, the way they affect the prescribing decisions, and as a direct offshoot whether a patient can afford these life saving drugs[9].

Justice Aftab Alam has also derived his opinion in this verdict while quoting Sudip Chaudhury's book, to the fact that India considers its people's health concern but it has to maintain the international commercial relations and India as signatory to most of the Treaties or Conventions (WTO, TRIPS, PCT, Doha Declaration etc), there must be a coherence between the public interest and commercial interests.

The Supreme Court judgment (pages 22 -26) quite extensively quoted from **Sudip Chaudhuri**'s book "The WTO and India's Pharmaceuticals Industry (Patent Protection, TRIPS, and Developing Countries", which highlighted the adverse effects of product patents and positive effects of its abolition in the pharma industry in India. Professor of Economics at the Indian Institute of Management Calcutta, Chaudhuri has done extensive

research on products patents pharmaceutical industry, industrial policy and the like. In an interview to rediff.com **Indrani Roy**[10], he talked about why Novartis ruling is a landmark, what effect will it have on research and development and the positive and negative effects of product patents among other issues. He further told that patent is given for a limited time period, currently under Trade Related Intellectual Property Right (TRIPS) for 20 years. Thus after the expiry of the patent, other firms can and do enter the market and that results in a fall in the prices and hence of profits of the company which had the patent. The MNCs often try to block or delay this competition by getting new forms of the old drug patented. But the objective of the patent system is not to encourage or permit patenting of new forms of old drugs to basically extend the patent term. This is what the Supreme Court is saying is that consumers should not be forced to pay higher prices just because it is chemically a new drug unless there is a therapeutic benefit involved. It may be, undoubtedly, a happy moment for a section of people and surely, is not an anti-patent judgment but requires a crystalviewtodrug-makers'interests.

Some countries such as the Unites States, Brazil and South Africa which have stricter patent regimes can introduce similar provisions in their patent laws to make drugs more affordable but it could be failure of international legal framework. Thus the judgment should be significant as far as international implications are concerned. Drugs may become more affordable but it must not adversely affect innovation as Novartis**.** The principal economic rationale for granting patents is indeed that it will stimulate investment for research for innovation. This is the positive effect. But, patent rights which exclude others from producing and marketing it, lead to inhibition of competition and hence high prices and hence less access. This is the negative effect. As the judgment has reiterated and highlighted it is fundamentally important to balance these two divergent effects**.** Finally, what is remarkable about the judgment is that the matter has been has been dealt with not just in technical and legal terms. It has placed it in a much larger context. The judgment in fact traces the history of the pharmaceutical industry in India to note that before 1972 when India recognized process (now product) patent protection, the country suffered because no innovation took place but had to pay high prices for patented products. The judgment is not saying that the innovation impact is unimportant. What it is saying is that where the innovation impact is absent or trivial or limited, as in the beta crystalline form case, consumers should not be forced to pay a higher price and hence patents should not be granted. In spite of that the Parliamentary debate, the names of the appellant company (Novartis) and the drug (Glivec/Gleevec) being the subject matter of this case were repeatedly mentioned, and the excessively high price fixed for the drug after the grant of "exclusive marketing rights" to the appellant was expressly cited as the likely result of bringing in the product patent regime in pharmaceuticals.

In my own words and the subsequent review, the Hostility to foreign companies would translate into weaker protections than this verdict if such a practice keep go on. India is transitioning from a development stage of being a net user of technology (which favored weak IP protection) to one of being both a user and producer of technology (which favors stronger IP protection). The drug industry, too, has evolved from exclusively comprising generic manufacturers to one with greater representation of R&D-based companies. So India has obligation to implementing the World Trade Organization's TRIPS agreement for the sake of domestic patent regime which has been strengthened from virtually no protection for pharmaceuticals to some protection. But recent rulings and the underlying Indian Law and Judiciary tend to favor weaker rather than stronger protection of IP.

Future Perspectives

Now a big question comes to the knowledge why the Supreme Court is not trying to restore the balance between the foreign Drug-manufacturers (Bayer, Novartis etc) and the Consumers (Indian patients) and the MNCs who are upset with the verdict will they not stop innovating and investing in the country such as India? For answers there are some reasons given below**;**

Firstly, when product patents are denied, they cannot charge high prices and hence their profits go down, in result their R & D and commercial interest will suffer. And they will be disappointed to invest**.**

Secondly, one of the ways they try to resist such a fall in profits is to try to influence particularly developing countries by issuing threats of dire consequences. When India abolished product patents in 1972, similar threats wereissued**.**

Thirdly, actually not only the pharmaceutical industry in India developed, the MNCs as a whole too contributed much more to the economy than they did earlier as I have reached to this opinion by virtue of my analytical approach about this verdict. As I came to know while going through a paper published in the Economic and Political Weekly (March 24, 2012), they are more keen on importing patented products and selling at high prices rather than innovating or manufacturing in the country but they, in realty, wanted to satisfy a human face of their R & D**.** And in Novartis case, it has spent a large sum of money for developing this drug. By denying it the patent, India is effectively not contributing to the financing of R&D by these organizations. India is free riding. Is this fair? No, not at all. Though it is not an anti-patent judgment, but the Indian law needs to be more practical. Most developed countries adopted pharmaceutical product patent protection after they had reached a highdegreeofeconomicdevelopment**.**

Thus, it is actually morally and historically unfair for the developed countries now to deny the developing countries the privileges which they enjoyed at the corresponding stages of their development. Western governments and MNCs often put pressure on developing countries to change their Intellectual Property laws**.** Such a financially and otherwise powerful organization as Novartis fighting a long legal battle backed by Western governments could not have its way. The judgment does show that pressures even when it comes from very influential circles can be successfully resisted. The civil society, particularly the Indian civil society has to play a very important role in this case. With such a vibrant civil society and such an impartial and independent judiciary, the environment will definitely change for the better. Another point is whether a result of this judgment will, in terms of prices of drugs in general, be more affordable**?** We can say, yes, this particular anti-cancerdrugwillbecomemoreaffordable.

Apart from this, all the drugs which are under product patents and will be so in future will be high priced unless compulsory licenses are given to non-patentees to manufacture and sell these. It is important to note that if rather than in April 1994, Novartis had filed the patent in the Unites States a few months later after 1 January, 1995 when TRIPS came into effect, the anti-cancer drug would have been eligible for a patent in India and section 3 (d) would not have been applicable (till that patent expired). Hence to make patented drugs more affordable, other steps, including and most importantly compulsory licensing, is necessary. In India, there is also the very critical problem that because of factors like low incomes, poor public health and inadequate insurance facilities, access to essential drugs, including those which are not patented, is very low.

In future concern, I would like to give 50-50 marks to this judgment and the simple but strict criterion of efficacy; it will be more difficult to get patents for new forms of old drugs. Hence it should be more affordable and quality product. Thus to ensure proper health care much more needs to be done.

Apart from the observed situation, no matter where we start, the saga has come to an end, and the key lesson seeping through is that good sense won. Firstly, the Supreme Court decision was not about the patentability of the imatinib compound as such: that patent, having been instituted in 1993, is excluded from the purview of the Indian patent system, which is only obligated to consider patents filed in 1995 or after. The case the Supreme Court heard whether Novartis' beta crystalline form of imatinib was worthy of patent protection and even its judgment was that this modification by Novartis did not satisfy the standard of inventiveness required under Indian patent law. Secondly, Indian patent law is as yet unchallenged at the WTO; Novartis's earlier challenge to the constitutionality and TRIPs compatibility of Indian patent law was rebuffed by the Madras High Court in

2007 and no appeal was pursued. Thirdly, the Supreme Court judgment effectively recast Indian patent law as being nuanced and original in its meshing of domestic political economy concerns with the integrated global economy it participates in. Sometimes it doesn't seem the above situation generally, so what the outcome of this nuance and originality? Imatinib will continue to be available to patients in India from multiple suppliers at a price 10 times less than the current cost of Glivec; approximately 27,000 cancer patients in the country who pay for their imatinib will continue to have access to the medicine in the public and private sectors at the lowest cost possible; and should Novartis ever suspend its charitable programme, all 15,000 of the cancer patients who currently receive imatinib free from Novartis will have similarly equitable access to the medicine[11].

My Opinion/Suggestions

First of all I do not favor this verdict as because it is not followed properly the International character of IP laws and Pharma sectors reason being Pharmaceutical companies spend billions of dollars on its Research. Most of the time it is estimated that, of every thousand patented drugs screened and only 4-5 % reaches in clinical trials and only one is actually availed this necessary drug for diagnose. Pharmaceutical companies patent the drugs that they develop and thereby obtain exclusive marketing rights; the costs of research and the profits due to the shareholders are recovered through appropriate pricing mechanisms from the patients who receive the patented drugs. Our Government (**Government of India**) has also, I will urge it robust fully, not intended to rope the Health-Care in root of Indian groups of actual needy. It is due to the lackness of willpower and gross corruption in its Health & Drugs Policy as we saw in NRHM scam where all efforts of domestic and international parameters have been slapped down.

Internationally, drug patents and the exclusive marketing rights associated therewith are awarded for a period of 20 years, during this time, no other drug company is allowed to manufacture or market the same drug. After the patent expires, other companies are permitted to manufacture and market the drug; their brands are known as generic versions.

So far as Indian public is concerned the Novartis verdict is actually an Anesthesia to their Health problems despite the fact that substantial progress in the popular understanding of the place of patents in a developing country like India, a hackneyed narrative has emerged, especially in the pink press, warning us that this judgment will have a negative impact on innovation in the long run. As it happens, one of the most useful outcomes of the Supreme Court judgment is a renewed focus on what innovation is and how it should be rewarded? Behind the headlines foretelling various levels of doom such as the death of innovation in the country and the end of research for diseases which matter to us, is the popular idea that patents are a proxy for innovation. After all, patents are widely understood as short-term monopolies enshrined in the law and provided as incentive to inventors on the evaluation of publicly disclosed innovation. It would seem as if patents are synonymous with innovation in R & D.

In the last three decades, the global gold rush for patents has been dominated by filings for minor and mostly inconsequential innovations at the expense of breakthrough innovation. In large part, this is because weak standards in the patent laws of developed countries (led by the U.S. and Europe) have explicitly encouraged such kind of tactics. A British Medical Journal[12] report from 2012 succinctly summarizes the global research situation for new medicines: "This is the real innovation crisis about pharmaceutical research and development which turns out mostly minor variations on existing drugs and most new drugs are not superior on clinical measures." So, if the patent regimes of developed countries are dominated by minor patents, many or most of which have no demonstrable innovation to show, why are they so avidly pursued by global pharmaceutical companies? A Public Library of Science[13] study from 2012 also points to the answer that secondary patents extend the patent life (and thereby, the monopoly pricing) of pharmaceutical products long beyond their designated life span, adding, on average, between six and seven years to the patent life of the original compound. Any patent regime which stands for incentives in case of secondary patents with weak laws will only serve to extend commercial monopolies at low levels of innovation and will no longer provide the incentive for genuine innovation. The genius of the Supreme Court judgment on Novartis's patent application

lies in restoring the connection between patents and innovation by upholding and legitimizing a regime with a higher threshold of inventiveness.

In the present day, India comprises 1.3 per cent of the global pharmaceutical market by value. That figure, in itself, is why changes to Indian patent law will not help global pharmaceutical giants break free from the incentive model they are prisoners of. At most, they might have to learn how to compete in a crowded market for some of their less original products. In other side, the symbolic opportunity presented by the Supreme Court's backing of Indian patent law, however, is a real threat and pharma CEOs in New York, London and Basel get it. In the long run, as more countries understand the Indian model, appreciate its legitimacy, and reflect on its benefits to both public health and innovation, they might want the same. And if that happens, we may begin to see real and positive changes in the way pharmaceutical innovation works.

Eventually, the new empowered scenario has most vividly illustrated this phenomenon during the peak of the HIV/AIDS treatment crisis in the first decade of the 21st century, when countries like Brazil, Thailand, and South Africa and of course India, took health security into their own hands and legitimately moulded their domestic interest to respond to the crises within. This time, however, the change might come more slowly; the hell the Indian government was dragged through has not been lost on anyone. The lengthy trials, the frequent challenges, the full-scale vilification, and every other scare tactic thrown our way by a public-relations juggernaut (along with the implicit support of many developed country governments) was not for nothing. And the Supreme Court judgment is all the more important as a result, for it shows a new way may be hard and tiresome, but is ultimately possible. So, ultimately I can say that this verdict may have a Human Face but it has not Uniformity in its nature.

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