# PATENT EVER GREENING : LAW AND ETHICS

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## ABSTRACT

Today we are living in a 'knowledge economy' which is purely based on information which can be protected and en-cashed. The world is revolving round the potential know-how. The know-how is primarily protected by way of system of patents which is a kind of intellectual property (IP). IP deals with products of human ingenuity and creativity. It relates to knowledge and information which can be incorporated in tangible objects and can be commercially exploited. The expression, 'intellectual property rights' refers to legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields. It is a collective term used to denote independent rights such as patents, trademarks, copyright, industrial designs, geographical indications, confidential information and layout designs.

The discussion in the present paper will be limited to patents with a special emphasis on ever-greening of patents. Patent is an exclusive privilege to reward the true and first inventors of new inventions. To be patentable, an invention must be novel, involving inventive step and of industrial application. Theoretically patents exist to promote the diffusion of innovative knowledge. The patent system provides necessary incentives for investment in research and encourages inventors to engage in new lines of R & D, thus it stimulating further creativity. It is considered as exclusive right and not as a monopoly, because in the scheme of patents there are inbuilt checks and balances to prevent the abuse of patents such as compulsory licensing, permitted use etc.

However, the recent trend in the patent system shows that there is a tendency to evergreen the patent rights, especially in the pharmaceutical sector, by making trivial modifications and changes. Drug companies generally do ever-greening, by filing new patent applications, tweaking existing molecules to show novelty. Ever-greening of patent is a phrase used to label practices that have developed in certain jurisdictions wherein a trifling change is made to an existing product, and claimed as a new invention. The coverage/protection afforded by the alleged new invention is then used to extend the patentee's exclusive rights over the product, preventing competition. Directly or indirectly, it creates private monopolies resulting in patent abuse affecting the human rights of millions of

patients in low income countries. Ever-greening of patents also facilitates giant multinational pharmaceutical companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high. It gives rise to many legal ethical and human right issues including public health crisis. Against this backdrop, the paper will discuss the ethical and legal issues surrounding intellectual property rights with a special emphasis on ill effects of ever-greening of patents. The landmark judicial decision in *Novartis A G* v. *Union of India*[1] will be analysed.

## 1. Introduction

Intellectual property (IP) relates to knowledge and information which can be incorporated in tangible objects and can be commercially exploited. It is a collective term used to denote independent rights such as patents, trademarks, copyright, industrial designs, geographical indications, confidential information and layout designs activity in the industrial, scientific, literary and artistic fields. The nature, scope, content and duration of each right vary from property to property.[2] The main justifications for intellectual property rights(IPRs) are: protection of IP is an incentive to human creativity; it provides necessary stimulation for new Research and Development (R & D); it serves as an instrument for cultural, social, economic and technological development; new creativity helps create sustainable and competitive businesses locally and internationally; IP based industries contribute significantly to national economies and intellectual property right is a catalyst in the information technology development.

## 2. Patents

Patent is one of the strong forms of IPRs. Countries give patent to reward new inventors. The patent law recognizes the exclusive right of a patentee to gain commercial advantage out of his invention. A patent[3] is an exclusive right granted by a country to the owner of an invention to make, use, manufacture and market the invention, provided the invention satisfies certain conditions stipulated in the law. This exclusive right granted on the patentee is only for a limited period of time. Exclusive right implies that no one else can make, use, manufacture or market the invention without the consent of the patent holder.

There are certain statutory criteria to be fulfilled to obtain a patent. Patent is an exclusive privilege to reward the true and first inventors of new inventions.[4] To qualify for patent protection, an invention must fall within the scope of patentable subject matter and must meet the three statutory requisites of novelty, inventive step and industrial application. This means that to be patentable, an invention must be novel,[5] non-obvious by involving an

[1] AIR 2013 SC 1311.

[2] For example, patent creates property rights in respect of novel inventions of first and true inventors for a period of 20 years whereas copyright confers property rights on independent creators of the original works for life time of the author plus 60 years. TRIPs Agreement provides the minimum period for which particular kinds of IPR should be protected in each member country; however, the member countries are at liberty to give longer protection.

[3] Part II, section 5 of the TRIPS Agreement deals with Patents. The Patents Act, 1970 (hereinafter referred to as the Act) regulates this area of law in India.

[4] Under s. 2(1)(j), "invention" means a new product or process involving an inventive step and capable of industrial application.

[5] As per s. 2 (1) (l) 'new invention' means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent

inventive step[6] and must be of industrial application.[7] The novelty requirement is, by and large, satisfied as long as the patent applicant was the first to invent the claimed invention.[8] The concept of novelty jurisprudence lays down that only what is new at the time of filing of the application for a patent is patentable. Novelty can be anticipated either by prior publication or prior use. Mere discovery is not an invention. Patent is not granted for an idea or principle. To be the subject matter of a patent right, the article must be material and capable of being manufactured.[9]

The requirement on industrial application suggests that the invention must be useful to the industry and it must serve some minimal human need. The condition on inventive step (non-obviousness) requirement denies patentability if the differences between the claimed invention and the relevant prior art are such that the claimed invention would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

The invention may be a product or process and its scope extends to all fields of technology.[10] The inventor, in order to obtain protection, has to disclose the invention and also describe the method of performing it. The patent confers on the patentee the right to exclude others from, among other things, making, using or selling the invention.

Countries may exclude from patentability certain inventions to protect *ordre public* or morality or to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by such countries' municipal laws.[11]

The object of patent law is to encourage scientific research, new technology and industrial progress.[12] The patent system is premised on the reasonable assumption that the public will enjoy additional benefits when the government takes additional steps to encourage the creation, commercialization, and disclosure of new inventions. The basic argument is that the society benefits when people conceive of new inventions, develop and commercialize new products incorporating these inventions and publicly disclose information about their inventions, so that others may learn from and improve upon these inventions. Inventing something new often requires a substantial investment of intellect, time and capital. The technology disclosed serves to stimulate ideas for further invention and innovation. The economic value of patent information is that it provides industry with technological information that can be used for commercial purposes. If there is no protection, there may be

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application with complete specification, *i.e.,* the subject matter has not fallen in public domain or that it does not form part of the state of the art.

[6] Under s. 2(1)(ja), (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.

[7] S. 2(1)(ac) defines the phrase 'capable of industrial application'. In relation to an invention, it means that the invention is capable of being made or used in an industry.

[8] *M/s Bishwanath Prasad Radhey Shyam* v. *Hindustan Metal Industries*, AIR 1982 SC 1444 at 1448.

[9] In *Diamond* v. *Chakrabarthy,* 447 U.S. 303 (1908) it was held that the touchstone of patentabilty is not whether an invention involves living or inanimate subject matter but whether it involves a human made invention.

[10] Article 27. 1 of TRIPS.

[11] See, article 27. 2 of the TRIPS Agreement and section 3 of the Indian Patent Act, 1970.

[12] Peter G. Groves, *Source Book on Intellectual Property Law*, Cavendish Publishing Ltd., London, 1997

a substantial incentive to take a free ride on someone else's investment. This potential for free-riding reduces the incentive to invent something new because the inventor may be unable to recoup the investment.

Patents are also meant to correct a market failure. The market failure leads to sub-optimal levels of investment in innovative activities and arises because producers that can use an innovation without incurring research and development costs will always have a competitive advantage over firms that innovate and incur those costs. As a result, there will be no incentive to innovate. Patents reward innovators with a temporary monopoly on the intellectual property that they have created.[13] The patent holder is required to disclose the scientific knowledge that underlines the innovation to the public in order to promote knowledge dissemination. Making the scientific information available instead of allowing it to remain proprietary has the objective of reducing information costs for other innovators.

Thus, Patent confers property rights on inventors of new inventions. Among all forms of IPRs, the patent is considered to be the most economically potential form of IPR which has direct impact on scientific and technological development of a country and which considerably influences the public health policy of a nation.[14]

As the discussions above reveal, an invention *per se* may not be patentable notwithstanding it satisfies the triple test of patentability.[15] The invention must not have been excluded from patentability, *i.e.*, the subject matter of the patent must not be a non-patentable invention in the country concerned. TRIPS Agreement provides enough flexibility for its member countries under clauses 2 and 3 of article 27 to exclude certain inventions form patentability *inter alia* to protect *ordre public* or morality or to protect human, animal or plant life or health. Every country has thus the right to exclude from patentability certain inventions on these permissible grounds. In India, section 3 of the Indian Patent Act has been amended to provide for non-patentable inventions. It enlists the inventions that are not patentable though otherwise they may fulfil the pre-requisites for patents.

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[13] In *Raj Parkash* v. *Mangat Ram Chowdhry and Ors.*, AIR1978 Delhi1, it was observed that the grant of patent, no doubt, creates a monopoly in favor of the patentee but then law throughout the free world recognizes that an inventor must first get the benefit of his invention, even if it means creating a monopoly.

[14] N. Rajagopala Ayyangar Committees' Report – 1957 unequivocally stated thus: "It would not be an exaggeration to say that the industrial progress of a country is considerably stimulated or retarded by its patent system".

[15] Arts. 27.2 &27.3 of TRIPS Agreement provide thus:

> 27. 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
>
> 3. Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

## 3. Real objective of patents

Section 83 of the Patent Act makes it crystal clear that the patents are not granted merely to enable patentees to enjoy a monopoly. The section reads that:

> a. that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
>
> b. that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
>
> c. that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
>
> d. that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
>
> e. that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
>
> f. that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
>
> g. that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public. They are not granted to impede protection of public health but the patent should act as instrument to promote public interest especially in sectors of vital importance for socio- economic and technological development of India.

While going by section 83, one can understand that there are many practices primarily being practiced by developed nations in order to obtain patents which are against the interest of the developing and least developing world. Such practices include bio-piracy, traditional knowledge misappropriation, ever greening etc. In the past decades the patent system has been subjected to different types of misuse such as patent ever-greening, patent trolling, patent thicketing etc., all these practices have caused serious damage to innovators, technology producers, and of course, the general public.[16] The remaining part of the article shall focus on ever greening and its impact on poor countries.

[16] Nagaraj Mannikeri and Vidya Bhaskar Singh, *Patent Trolling And Evergreening: Unethical Acts Or Malpractices?*; at http://www.foxmandal.com/wp-content/uploads/2015/06/Malpractices-in-the-Patent-system-final-June-15-21.pdf

## 4. Patent ever greening

Ever-greening of patent is an abuse and misuse of patent system. It is the perpetual renewal of patents. It denotes lifecycle management the practice of pharma companies seeking extra patents on minor variations of the original drug – new forms of release, new dosages, new combinations or variations, or new forms, changing a drug from a tablet to a capsule etc. In this process, a trifling change is made to an existing product and later it will be claimed as a new invention. Drug companies generally do ever-greening, by filing new patent applications, tweaking existing molecules to show novelty. Ever-greening of patent is a phrase used to label practices that have developed in certain jurisdictions wherein a trifling change is made to an existing product, and claimed as a new invention. The coverage/protection afforded by the alleged new invention is then used to extend the patentee's exclusive rights over the product, preventing competition. These changes are typically made to blockbuster drugs shortly before their patents expire. Ever-greening is possible in many countries like Australia and US because their legal standard required to get a patent is very low. Different methods of delivering drugs (such as extended release, for example) have been known for decades. But when one of these known delivery methods is combined with a known drug, the patent office considers this sufficiently inventive to grant a new 20-year patent. [17] New use' patents directly or indirectly supports ever-greening in the developed nations. Low standard benchmark set by the US for inventive steps and utility, allows trivial drug patents. National Institute of Health Care Management on Pharmaceutical Innovation reports that over 75% of the patented drugs are new forms of known substances, thus eliminating competition, extending monopolies, making drugs unaffordable and adversely affecting the right to health.[18]

The negative impacts of ever-greening are many. Ever-greening extends the period of market exclusivity. It forces the generic manufacturer to wait indefinitely for all the patents to expire and delays the introduction of generic competition. It adversely impacts public health and plays a detrimental role in driving out the domestic generic medicine market which provides access to vital medicinal or life saving drugs at affordable prices to lower section of the society. For example, the patented drug 'Gleevec' costed in India Rs. 4,115/- per tablet. Its generic version is being sold in India by Resonance and Indian generic drug company at Rs. 30/- per tablet. While the annual cost of the Gleevec is Rs.15,00,000/-[19] in India its generic versions costs just Rs.10,000/- annually. On the expiry of patents for a widely used drug, the price falls up to 95%.[20] Allowing patents for new use of pharmaceuticals directly or indirectly encourages ever-greening in the developed nations.

## 5. Public Health *vis-a-vis* patents

Right to health is a fundamental right of every human being. WHO Constitution encourages the member states to achieve highest attainable standard of health. The human right to health implies that everyone has the right of physical and mental health, which includes access to all medical services, sanitation, adequate food, decent housing, healthy working conditions, and a clean environment. It is not an utopian notion of right to be

[17] http://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623
[18] 2002 Report.
[19] Novartis ranked in a total turnover of US $ 1.69 billion from US alone in 2012 from the drug, Gleevec.
[20] http://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623

healthy. On the contrary, it means that the state has to generate conditions in which everyone can be as healthy as possible. These conditions include ensuring availability of health services, healthy and safe working conditions, adequate housing and nutritious food.

The right to health contains four elements:[21] *Availability* - Adequate functioning public health care facilities, goods and services, as well as programmes should be available in all geographical areas and to all communities; *Accessibility* - Access to health facilities, goods and services must be universal, guaranteed for all on an equitable basis. Accessibility has four overlapping dimensions: Non-discrimination, Physical accessibility, Economical accessibility (affordability) and Accessibility of information; *Acceptability* - All health facilities, goods and services must respect medical ethics. They must respect dignity, provide culturally appropriate care, be responsive to needs based on gender, age, culture, language, and different ways of life and abilities; and *Quality*: - Health facilities, goods and services must be scientifically and medically appropriate and of good quality.

As per section 83 of the Indian Patent Act, patents should not impede protection of public health but the patent should act as instrument to promote public interest especially in sectors of vital importance. However, in reality, the existing patent practices are prejudicial to the public health especially in the developing and least developing countries.

## 6. Pharmaceutical Patents and Public Health Issues

Pharmaceutical patents are designed to stimulate investment in new lines of R & D. However, there is no exaggeration in stating that the product patent regime in pharmaceutical products, directly or indirectly, creates private monopolies encouraging ever-greening of patents, resulting in patent abuse affecting the human rights of millions of patients in low income countries, facilitating giant multinational pharmaceutical companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high. For example, coincidently, in the parliamentary debates on the amendment of the patent law in 2005 to comply with the TRIPS requirements by shifting from the regime of process patents to product patents in pharmaceuticals *etc*., there has been reference to the 'Novartis' and the medicine 'Gleevec/Glivec' and how Novartis has excessively high priced the drug after the grant of EMR.

India has played a very significant role in the pre-TRIPS regime as the producer and supplier of drugs to different parts of the world where impoverished humanity was critically in need of drugs at cheap and affordable prices. India has been the leader in the global supply of affordable antiretroviral drugs and other essential medicines prior to the conclusion of TRIPs Agreement. It was supplying 50 per cent of the cheapest drugs in the world to places like Papua New Guinea, Laos, Kenya, Africa, *etc*. India has also taken leadership in promoting access to and supplying affordable essential generic HIV medicines to those most in need in developing countries. As the countries worst hit by AIDS do not have sufficient manufacturing capacity in the pharmaceutical sector, they rely upon imports from major generic drugs producing countries such as India for HIV treatment of the millions of their patients.

However, the TRIPS Agreement required crucial legislative changes mandating product patent which had aroused grave concerns about its impact on public health. It also had raised

[21] UN General Comment on the Right to Health in 2000.

concern on the impact of TRIPS' drugs patent regime on the local production and supply of generic antiretroviral agents. 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. When India had a product patent regime, we had to depend upon imports for the 85 per cent of our medicinal requirements. This situation was reversed when we shifted to process patent regime, *i.e*., 85 per cent of India's medicinal requirement was met by our own products. From 1970 after the patent system in India barred the grant of product 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 under developed countries. After studying the situation in and experience of other countries and recommending India to introduce process patent system, Justice Ayyangar said thus:[22]

> I have considered the matter with the utmost care and have reached the conclusion that the chemical and pharmaceutical industry of this country would be advanced and the tempo of research in that field would be promoted if the German system of permitting only process claims were adopted.

During the process patent regime, India has benefited from the low cost generic industry to dominate 30 per cent of the low cost drugs in the world. India was a large supplier of generic antiretroviral drugs to several countries such as Ghana, Lesotho, Malawi, Namibia, Bangladesh, Cambodia, China, Indonesia, Korea, Laos, Thailand, Papua New Guinea, Vietnam *etc*.

On 01.01.2005, to comply with the TRIPS requirements India had to shift again from the process patent regime to product patent regime in medicines, agricultural and chemical substances. However, to prevent the abuse of product patent several changes were introduced in the 2005 amendment including pre- grant oppositions,[23] amendments in section 3 widening the scope of non-patentable inventions and redrafting of section 3(d). Amendment in section 3(d) was the most crucial amendment directly preventing ever-greening of pharma patents and checking attempts for repetitive patents.

## 7. Section 3 (d) – Non patentable inventions and the *Novartis* case

**8.**

Section 3 of the Indian Patent Act deals with non-patentable inventions. A close look at the Indian Patent Act, as it stands today clarifies that "invention" and "patentability" are two distinctly separate concepts. This is a vital distinction which is at the heart of the Indian Patent Act. The duality of the two concepts is best understood from the concepts of 'non patentable inventions'. For grant of a statutory patent in India, like any other jurisdiction, the subject matter must satisfy the twin tests of "invention" and "patentability". The test of 'invention' is satisfied if it fulfil the three pre-requisites of patentability - novelty, inventive step and industrial utility as discussed above. Something may be an "invention" as the term is generally understood and yet it may not qualify as an "invention" for the purposes of the Act.

[22] Justice Ayyangar observed that the provisions of the Patent law have to be designed, with special reference to the economic conditions of the country, the state of its scientific and technological advancement, its future needs and other relevant factors, and so as to minimize, if not to eliminate, the abuses to which a system of patent monopoly is capable of being put. See, N. Rajagopala Ayyangar Committees' Report – 1957.

[23] S. 25 (1).

Further, something may even qualify as an "invention" as defined under the Act and yet may be denied patent for other large considerations/public interest as may be stipulated in the Act.

The most controversial section among the non-patentable clauses is the section 3 (d). The section 3 (d) after 2005 amendment reads thus: "The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant." The *Explanation* to section 3 (d) sates thus: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy." It is important to take a note of section 3 (d) of the erstwhile Patent Act before 2005 amendment which read as: "The mere discovery of any new property or *mere* new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

As evidenced, there is, in the amended provision, an addition of the opening words in the substantive provision and the insertion of explanation to the substantive provision. It adds the words "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or" at the beginning of the provision; and deletes the word "mere" before "new use"; and also adds an explanation at the end of the clause.

## 9. *Novartis A. G.* v. *Union of India: The Facts*

Jürg Zimmermann invented a number of derivatives of N-phenyl-2- pyrimidineamine, one of which is CGP 57148 in free base form (later given the International Non-proprietary Name '*Imatinib'* by the World Health Organisation). These derivatives, including Imatinib2, are capable of inhibiting certain protein kinases, especially protein kinase C and PDGF (platelet-derived growth factor)-receptor tyrosine kinase and thus have valuable anti-tumour properties and can be used in the preparation of pharmaceutical compositions for the treatment of warm-blooded animals, for example, as anti-tumoral drugs and as drugs against atherosclerosis. The N-phenyl-2-pyrimidine-amine derivatives, including Imatinib, were granted patent on 28.05. 1996 (US Patent No. 5,521- the Zimmermann Patent). The Zimmermann compounds (i.e., derivatives of N-phenyl-2-pyrimidine-amine) were also granted a European patent ( Patent No. EP-A-0 564 409).

An application was filed subsequently in India (Application No.1602/MAS/1998) for grant of patent for Imatinib Mesylate in beta crystalline form at the Chennai Patent Office on 17.07. 1998 in which it was 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. It further claimed that the aforesaid properties makes the invented product "new" and superior as it "stores better and is easier to process;" has "better processability of the methanesulfonic acid addition salt of a compound of formula I", and has a "further advantage for processing and storing". In short, Novartis filed an application before the Chennai patent office related to a drug name GLIVEC which was slightly a different version of its 1993 patent for Anti Leukaemia drug.

Before the application for patent was taken up for consideration, the appellant made an application (Application No. EMR/01/2002) on 27.03.2002, for grant of exclusive marketing rights (EMR)[24] under erstwhile section 24A of the Patent Act and on 10.11. 2003 EMR was granted. The patent application was taken out of the "mailbox" for consideration only after amendments were made in the Patents Act, with effect from January 1, 2005. By that time the application had attracted five pre-grant oppositions in terms of section 25(1) of the Act. On 15.12.2005 the Assistant Controller of Patents and Designs rejected the application for grant of patent under section 3(d) holding *inter alia* that (i) the invention claimed by the appellant was anticipated by prior publication, i.e., the Zimmermann patent and (ii) the invention claimed by the appellant was obvious to a person skilled in the art in view of the disclosure provided in the Zimmermann patent specifications. Against the orders a writ was filed in the Madras High Court. Novartis prayed the Court to declare section 3(d) of Patent (Amendment) Act 2005 non compliant with the TRIPS Agreement and violative of Article 14 of the Constitution. The argument on Article 14 of the Constitution of India was based on arbitrary discretionary power vested in the Patent Controller in determination of enhanced efficacy. The high court of Madras upheld the constitutional validity of section 3 (d) by holding that 'efficacy' means 'therapeutic efficacy'. While dismissing the writ petitions assailing section 3(d) of the Act, the High Court observed thus: "When the Appellant was holding the right as EMR on GLEEVEC it used to charge Rs.1,20,000/- per month for a required dose of the drug from a cancer patient, not disputed by the Appellant, which in our view is too unaffordable to the poor cancer patients in India. Thus, we also observe that a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well. Considering all the circumstances of the appeals before us, we observe that the Appellant' 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 on such grant as stated above, which also is being attracted by the provisions of section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which could create public disorder." The Court said that the Amendment was intended to preventing

[24] TRIPS required that WTO member countries not having provision in their laws for granting product patents in respect of drugs and agrochemical, must introduce during the transition period, Exclusive Marketing Rights (EMR) for such products, if the following criteria are satisfied: (i) A patent application covering the new drug or agrochemical should have been filed in any of the WTO member countries after 01.01. 1995; (ii) A patent on the product should have been obtained in any of the member countries (which provides for product patents in drugs and agrochemical) after 01.01.1995; (iii) Marketing approvals for the product should have been obtained in any of the member countries;(iv) A patent application covering the product should have been filed after 01.01.1995 in the country where the EMR is sought; and (v) The applicant should apply seeking an EMR by making use of the prescribed form and paying requisite fee. EMR was valid only up to a maximum period of 5 years or until the time the product patent laws came into effect. EMR provided exclusive marketing rights to sell or distribute the article or substance covered in a patent application. The purpose of EMRs was to ensure that the innovator can market free copies of his product. In India the EMR was made applicable *w. e. f.* 01.01. 1995. A new Chapter IVA has been added by The Patents (Amendment) Act, 1999 with retrospective effect from 01.01. 1995 to provide for the EMR. EMR's are intended to be a transitory device, until process patent jurisdictions migrate to a full product patent regime. An EMR application lies only if the corresponding patent application is already in the mailbox. Also see Sangeeta Vohra, "Understanding Exclusive Marketing Rights as a Specie of Patents" available at *http://www.algindia.com/publication/article1200.pdf*, visited on 01.12. 2013. When India entered in the full fledged product patent regime on 01.01.2005 as per art. 65 of TRIPS agreement exclusive marketing rights have been abolished by omitting chapter IVA from the Patents Act. The EMRs granted before 01.01.2005 continued to enjoy the same terms and conditions on which it was granted.

ever-greening; to provide easy access to the denizens of this country for life saving drugs; and to discharge their constitutional obligation of providing health care to its citizens.

On the same matter, Intellectual Property Appellate Board (IPAB), held that the patentability of the subject product was hit by section 3(d) of the Act.[25] The order of the IPAB clearly stated that "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. 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 substances."

The IPAB's order was challenged in the Supreme Court in a petition under article 136 of the Constitution. The court at length examined the section 2(1)(j) defining invention as "a new product or process involving an inventive step and capable of industrial application" and section 2(1)(ja) defining inventive step as "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," and held that Imatinib Mesylate did not qualify the test of 'invention' as laid down in the aforesaid provisions.

The Supreme Court of India on appeal disapproved the contention that section 3(d) is a provision *ex majore cautela* and is an exception to clauses (j) and (ja) of section 2(1) of the Act. According to the court, 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 the patent term on spurious grounds. By giving a purposive interpretation of sub sections (j) and (ja) of section 2(1) with section 3(d) the court held that the Act sets different standards for qualifying as "inventions" things belonging to different classes, and for medicines and drugs and other chemical substances, the Act sets the invention threshold further higher, by virtue of the amendments made in section 3(d) in the year 2005.

The Supreme Court held that both the Zimmemmman patent and the new claimed substance - are basically one and the same. Regarding the issue of 'efficacy' the court observed that the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. In the case of a medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy'. The court was of the view that the 'therapeutic efficacy' of a medicine must be judged strictly and narrowly. On the issues of 'enhancement of the known efficacy' and the explanation that requires the derivative to 'differ significantly in properties with regard to efficacy', the court said that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, is its therapeutic efficacy. The mere change of form with properties inherent to that form would not qualify as 'enhancement of efficacy' of a known substance. This explains what is not to be considered as therapeutic efficacy.

[25] Though agreeing with the Assistant Controller that no product patent for the subject patent could be allowed in favour of the appellant, the IPAB held that the appellant could not be denied the process patent for preparation of Imatinib Mesylate in beta crystal form.

## 10. Moral of the Case

The *Novartis* case thus gives a clear indication that India would no longer permit ever greening of patents risking public health and at the cost of poor patients in the country. The judgment gives a strong message to the world that India will give pharmaceutical companies extended market monopoly only of a medicine is genuinely innovative and involves substantive innovation. The decision pre-empts pharma companies to seek ever-greening of patents in India by extending patent on known drugs and the consequent delay on the availability of affordable generic versions. It would certainly facilitate early entry of generic medicines into the market for other medicines too. The impact would be felt not only in India but also across the developing world that depend on Indian generic versions. *Novartis* is a precedent for other countries as well in determining the patentability of 'minor improvements.' No legal system should permit the artful drafting of claims by giant pharma companies to decide the scope of patent law. The judgement itself says: "We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skilful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent.

## 11. Conclusion and suggestions

It is estimated that more than 8,000 people around the world die every day owing to non- accessibility to treatment and only about one in ten people in urgent need of HIV antiretroviral treatment in 'low and middle income' countries has access to existing medicines. Patents are needed to encourage innovations. The patent system provides necessary incentives for investment in research and encourages inventors to engage in new lines of R & D, thus it stimulating further creativity. At the same time, there should be vital areas like public health, which should be the paramount consideration and countries must use TRIPS flexibility to exclude/revoke patents to protect public health.

The Novartis court was not against patent law. The Novartis judgement is not contradiction to the patent laws. The court considered only public interest and public health while deciding the case. The right to health is a cause of concern in many parts of the world. One-third population of the world does not have access to basic medicines and among this one-third, majority of population lives in African and Asian continent. Since price is one of the major factors in accessibility, this decision was of great significance as it allowed many poor countries to access the patented drug at affordable prices.[26]

The need of the hour is to create balance between the *patents and the patients* - A balance between the patent laws and public health considerations, so that the drugs are affordable by the common people. Availability and affordability of drugs must be considered as two sides of the same coin. Check and balances in the Patent system including TTRIPS flexibilities, exclusion from patentability, compulsory licensing etc. must be boldly evoked by countries to address public health issues. Article 27.2 of The TRIPS Agreement itself provides that "members may exclude from patentability inventions, the prevention within

[26] http://www.lawctopus.com/academike/evergreening-an-abuse-of-the-patent-system/.

their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law".

The countries must penalise ever-greening practices by making necessary amendments in their patent laws. For instance, Australian patent law provides safeguards against ever-greening by imposing penalties under sections 26C and 26D of Australian Patent Act, 1990. The Act also has a mechanism for damages to be paid to the government if ever-greening practices are proved. Similarly, Article 18.9.4 of the Republic of Korea-United States Free Trade Agreement (KORUSFTA) has been specifically drafted to permit the establishment of pharmaceutical patent "anti-ever-greening" oversight agency.[27]

Ever-greening of patents is against the scheme and spirit of patents and it is highly unethical. Patents should not result in non-availability and non-affordability of medicines. Developing and least developing world must take *Novartis* as a case study to understand how the TRIPS flexibilities can be used against unethical ever greening of patents.

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[27] http://www.foxmandal.com/wp-content/uploads/2015/06/Malpractices-in-the-Patent-system-final-June-15-21.pdf