Section 3 of The Patents Act 1970, Vs. Article 27.1 of The Trips Agreement

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Abstract

Is section 3(d) compatible with the TRIPS agreement? Did India fully comply with its obligations under the TRIPS agreement particularly? The obligation under article 27 of the agreement has been significant controversy among the foreign pharmaceutical companies, leading to an important 3(d), litigation between the Swiss pharmaceutical company, no worries, and Union of India. This paper argues, unambiguously that section 3(d) does not violate the mandate of article 27 of the TRIPS. This paper will examine this, limited question by reference to, important TRIPS flexibility, allowing India to shape its patent regime, particularly section 3(d). This paper will discuss in brief the relevant, Madras high Court judgment of nowhere this on section 3(d) as a compatible aspect. This paper, lastly argues that section 3(d) is fully compliant, with article 27 of the TRIPS, and any further challenge, if any 2 section 3(d) before WTO, would not hold, water.

Keywords : Section 3(d), TRIPS, Article 27

Introduction

Indian patent regime, has undergone various significant changes with 3 major amendments in the patents act 1970, in 1999, 2001 and 2005 to make it fully compliant with the WTO's, World Trade Organization, TRIPS agreement. By the 2005, patent amendment, India fulfilled its obligation under the TRIPS agreement, by introducing product patents. No, Indian patent law was fully compliant with the TRIPS agreement. By the way of 2005 patent amendment, section, 3(d) of the patents act 1970, also came to be significantly amended. This amended section, 3(d) of the patents act, became a major talking point for foreign pharmaceutical companies. No, as per the amended section, 3(d) new form of the known substance could not be put in table, unless it showed a significant enhancement in efficacy over the known efficacy of the previous product.

Section 3(d) has been at the center of controversy. The objective and intention of section 3(d), raising concerns that this section, "3(d) was designed in such a way as to stymie their patents right. They have expressed their fear that section 3(d) would not allow them to get their inventions patented in India, which now called for a tougher patentability standards. They also expressed their opinion. Section, 3(d) did not comply with article 27 of the TRIPS agreement" (Jabade, 2012).

This paper argues that section 3(d) is fully compliant with article 27 of the TRIPS Agreement. This paper will discuss an exam in the Madras high Court judgment in Novartis Ag Vs Union of India, to answer the compatibility aspect. This paper will also discuss TRIPS flexibility, which allowed India to enact, its patent law particularly section 3(d) in consonance with its national public health concerns.

This paper concludes that section 3(d) is fully compatible with article 27 of the TRIPS agreement and if any future challenges posed to it in WTO, it will stand up to scrutiny. This paper will refer to Madras High Court judgment only that in brief. The people will not discuss the NOVARTIS judgment of the supreme Court as this issue of section 3(d) is compliance was not touched by it.

What is "Section 3(d)"?

"Section 3(d)" was amended by the 2005 patents amendment in the principal act of the patents act 1970. The 2005 patents amendment was the third and the last amendment, carried out by India in order to fully comply with the TRIPS agreement. "Section 3(d)" is hereby being reproduced for examination as under:

"Section 3(d)" "what are not inventions?"

The unimportant disclosure of the new category of the already known substances which does not conclude into the improvement of the known level of adequacy for the substance or the straight and obvious revelation of new characteristics or a unknown use of the well known substances or of the ignorable exploitation a known practice, mechanization or contraption excluding that if such realized procedure results in the another item or make use of less than one new reactant.

Explanation

"With the end goal of this condition, salts, easters, ethers, polymorphs, metabolities, unadulterated structure, molecule estimate, isomers, blends of isomers, edifices, mixes and different subordinates of realized substance will be viewed as a similar substance, except if they vary essentially in properties concerning adequacy."

What is Article 27 of the Trips Agreement?

The Article 27 of the "TRIPS agreement" offers the guidelines related to the patentable subject matter as stated here under:

I. Subject to the provisions of paragraphs 2 and 3 patents shall be available for any innovations, regardless of whether items are forms, all fields of innovation, gave that they are new, contribution, imaginative advance and are equipped for modern application. Subject to section 4 of article 65, passage 8 of article 70, section 3 of this article, licenses will be accessible and patent rights charming without segregation with regards to the spot of development, the field of innovation and whether items are imported or privately delivered.

II. Members, may reject from patentability creations, the counteractive action inside their domain of the business misuse of which is important to ensure Order open or profound quality, including to secure human, creature or vegetation or wellbeing, or to evade genuine partiality to nature, gave that such avoidance isn't made only on the grounds that the abuse is precluded by their law.

III. Members may likewise prohibit from patentability

   a. Diagnostic. Remedial plants and careful strategies for the treatment of people or creatures;

   b. Plants and creatures other than microorganisms, and basically organic procedures for the generation of plants or creatures other than non-natural and microbiological forms. Be that as it may, individuals will accommodate the security of plant assortments either by licenses or by a compelling Sui generis framework, or by any mix thereof. The arrangements of this sub passage will be inspected 4 years after the date of section into power of the WTO, agreement.

Flexibilities under Trips Agreement

The WTO's TRIPS agreement contains and provides for certain flexibilities which can be resorted to by the developing and the least developed countries in the enactment of their domestic intellectual property laws with regard to pharmaceutical products. Following are the important TRIPS articles which provide for flexibilities to the member countries while enacting their domestic IPR (Intellectual Property Rights) legislation:

Article 8 (Principles)

1. Members may, in defining or changing the laws and guidelines, embrace estimates important to secure general wellbeing and sustenance, and to advance the open enthusiasm for divisions of imperative significance to their financial and mechanical improvement, furnished that such measures are reliable with the arrangements of this understanding.
2. Appropriate measures, furnished that are steady with the arrangements of this agreement, might be expected to keep the maltreatment of protected innovation rights by right holders or the retreat to rehearses which absurdly limit exchange or unfavorably influence the worldwide exchange of innovation.

Articles 30, exceptions to rights Conferred

Individuals may give constrained special cases to the selective rights presented by a patent, gave that such exemptions don't preposterously strife with the ordinary misuse of the patent and don't nonsensically bias the real interests of the patent-proprietor, assessing the real enthusiasm of the outsiders.

Article 31 (other use without authorization of the right holder)

Where the law of part takes into account other utilization of the topic of a patent without the approval of right holder, including use by the legislature or outsiders approved by the administration, the accompanying arrangements will be regarded:

A. Authorization of such utilize will be considered on its individual benefits;

B. Such use may possibly be allowed if before such use, the proposed client has attempted endeavors to get approval from the correct holder, on sensible business terms, and conditions that such endeavors have not been fruitful inside a sensible time of the time. This prerequisite might be deferred by a part on account of national crisis or different conditions of extraordinary earnestness, or on account of open noncommercial use. In circumstance of national crisis or different conditions of outrageous earnestness, the right-holder will, by the by, be informed when sensibly practicable. On account of open non-business use, where the legislature or temporary worker, without making a patent hunt, knows, or has self evident grounds to realize that a legitimate patent is or will be utilized by or for the administration, the correct holder will be educated expeditiously;

C. The extent of the degree and length of such utilize will be restricted to the reason for which it was approved, and on account of semiconductor innovation, will be for open noncommercial use or to cure a training, decided after legal or authoritative procedure to be hostile to aggressive;D. Such utilize will be nonexclusive.

E. Such utilize will be known, assignable, aside from with that piece of the endeavor or altruism which appreciates such use;

F. Any such utilize will be approved overwhelmingly for the supply of the local market, of the part, approving such use;

G. Authorization for such utilize will be obligated, subject to satisfactory security of the genuine enthusiasm of the individual so approved, to be ended if and when the conditions which prompted it, stop to exist and are probably not going to repeat. The skillful expert will have specialist to survey, upon spurred demand, the proceeded with presence of these conditions;

H. The right holders will be paid sufficient compensation in the conditions of each case, considering the monetary estimation of the approval;

I. The lawful legitimacy of any choice identifying with the approval of such use will be liable to legal survey or other autonomous audit by an unmistakable higher specialist in that part;

J. Any choice identifying with the-compensation gave in regard of such restriction gave in regard of such use will be liable to legal survey or other autonomous audit by an unmistakable higher expert in that part;

K. Members are not obliged to apply the conditions put forward in sub sections b and f, where such use is allowed to cure a training

decided after legal or authoritative procedure to be hostile to aggressive. The need to address hostile to focused practices might be considered in deciding the measure of compensation in such cases. Capable experts will have the specialist to deny end of approval, if and when the conditions which lead to such approvals are probably going to repeat.

L. Where such use is approved to allow the abuse of a patent ("the second patent") which can't be misused without encroaching another patent, ("the main patent"), the accompanying extra conditions will apply;

   i. The creation guaranteed in the second patent will include an imperative specialized development of extensive monetary essentialness in connection to the innovation asserted in the primary patent;

   ii. The proprietor of the primary patent will be qualified for a cross permit on sensible terms to utilize the development asserted in the second example; and

   iii. The utilize approved in regard of the primary patent will be known, assignable acknowledge with the task of the second patent;

Therefore, the TRIPS agreement provides for these inbuilt flexibility framework to be used by member Nations, in the enactment of their domestic laws to suit their national and public health care concerns.

Doha Declaration on Trips and Public Health

Doha declaration on TRIPS and public health was adopted on 14th Nov 2001 by the WTO member countries. This Doha declaration address the concerns of public health and access to affordable medicines raised by developing countries to address the prevention of disease like HIV, tuberculosis and malaria. Paragraph 4 of the Doha declaration is quiet significant for our examination. Paragraph 4 of Doha declaration is reproduced their under "TRIPS agreement does not and should prevent members from taking measures to protect public health. Accordingly, while reiterating our commitments to the TRIPS agreement, we affirm that the agreement can and should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and in particular, to promote access to medicines for all" (nopr.niscair.res.in).

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in agreement, which provide flexibilities for this purpose. Therefore, Doha declaration also provides enough elbowroom for members to enact their domestic laws in their national public health and access to medicines concerns.

Novartis AG Vs Union of India

A patent application was filed by Novartis in 1995 for its imatinibmeylate, a beta crystalline form of imatinib in free base. Known as Gleevec this patent application was kept in mailbox. Gleevec was used for the treatment of chronic myeloid leukemia. The said patent application was rejected by the Patent office on the ground that it did not fulfill the enhanced efficacy requirement of "Section 3(d)". Following are the two issues take up for consideration by the Madras high court:

   i. Whether Indian courts had jurisdiction to adjudicate upon the issue that "Section 3 (d)" was in compliance with article 27 of the TRIPS agreement and whether Indian courts could grant a declaratory relief in this respect.

   ii. Whether "Section 3(d)" was violative of article 14 of the Constitution of India. While deciding issue number 1 the madras high court categorically held that courts in India didn't have jurisdiction to adjudicate upon an issue which pertain into compliance compatibility of municipal law with that of an international treaty or law. The madras high court held that since the nature of international law is contractual in nature and since it incorporate certain inbuilt dispute settlement provisions; therefore; the dispute with regard to compatibility of a national law with that of an international treaty should be dealt by the dispute settlement body of the WTO .The Madras High Court referred to article 64 of the TRIPS agreement which clearly provides for a mechanism of dispute settlement by its dispute settlement body and therefore ruled that if Novartis was aggrieved by the rejection of its patent application on the

ground of "Section 3(d)"'s noncompliance with article 27 of the TRIPS agreement then it should approach the dispute settlement body of the WTO which was the appropriate forum for adjudication of this issue.

The Madras High Court also held that "Indian courts could not in such a situation grant a declaratory relief in favour of the Novartis as Novartis if granted a declaratory relief could not compel Indian Parliament to amend and enact a law in its favor. The Madras High Court further held that there were flexibilities is contained under the TRIPS agreement which could be applied and resorted to by the member countries to address their National Public Health concerns and SS2 affordable medicines."

The Madras High Court finally held that "Section 3(d)" of the patents Act 1970 was not violative of article 14 of the Constitution of India.

Therefore, the Madras High Court judgement is crystal clear as it categorically held that in case of conflict between a Municipal Law and international law the Municipal Law will prevail and secondly the court held that Novartis should take the issue of violation of international law to the dispute settlement body of the WTO which is the appropriate forum to decide the issue of violation of international law.

Section 3(D) Confirms to Article 27 of the Trips Agreement

Novartis had challenged rejection of its application for patent before the Madras High Court on the ground that "Section 3(d)" was not in compliance with article 27 of the TRIPS agreement. As we have earlier reproduced both "Section 3(d)" and article 27 of the TRIPS agreement. Article 27 of the TRIPS agreement cast out the exceptions to the patents which we can record them at the flexibility provisions namely Novelty and intensive step paragraph to of article 27 specifically provides for exclusions from patentability those inventions to be resorted to by member Nations within their geographical scope the avoidance of the commercial over accessible use of which is essential to defend the order public or morality incorporating the protection of human being or botanical plat life or medial health and well being or to avoid noticeable prejudice to the environment nearby that such exclusion is not made nearly because the exploitation or the access and unlawful use is strictly prohibited by the law.

"Section 3(d)" was amended by India by way of its last 2005 patent Amendment Act The purpose undoubtedly was to ensure protection of Public Health concerns and to ensure access to affordable medicines. The main objective of amendment to "Section 3(d)" was to put a check on the practice of ever greening of patents by the multinational Pharma Companies on mere modifications of their existing patents. The purpose of "Section 3(d)" was to keep the free Wallace modifications of existing patent at bay thereby promoting and encouraging the real invention based on the criteria of enhanced efficacy aspect incorporated in "Section 3(d)". Therefore, India amended "Section 3(d)" using to the hilt the inbuilt flexibility provisions provided as exceptions to patentability not only under article 27 but also under article 30, 31 of the TRIPS agreement and under Doha declaration. India was fully justified in amending "Section 3(d)" in the interests of its National Public Health and access to affordable medicines.

The multinational companies have always had an attitude of exploiting their patent rights to continue for eternity on frivolous modifications minting money at the cost of the expensive patented drugs which public at large find difficult to afford as these patented medicines are made available to them at exorbitant prices. Many Scholars argued that "Section 3(d)" is a bold legislative move that has become successful in preventing the practice of ever greening of patents and this bold move has paved the way for other member Nations to follow suit

Conclusion

"Section 3(d)" is a unique act of Indian Parliament which has effectively put a check on the practice of ever greening of existing patents and paved the way for their inventions by promoting the heart care research and development activities in the field of pharmaceuticals. This section discourages the frivolous inventions on minor modifications to be patentable unless these inventions pass and qualify the rigor of enhanced efficacy criteria. India has effectively used all the available flexibility in designing in enacting this unique provision of higher patentability standard under "Section 3(d)"

"Section 3(d)" is not a departure from

International practices to regulate the patenting of derivatives and new users. The argument of Novartis to the effect that "Section 3(d)" was not compatible with article 27 of the TRIPS agreement does not hold water. If Novartis challenges action 3(d) compliance before the WTO, then India may successfully withstand the challenge India has resorted to the inbuilt flexibilities.

Specifically, under paragraph 1 and 2 of the article 27 of the TRIPS agreement. Article 27 of the TRIPS mandates that "patents shall be available for any inventions, whether products or processes, in all fields of Technology, provided that they are new, involve and inventive step and are capable of industrial application." Therefore, the text of article 27 contents inbuilt criteria giving a leeway to the member Nations to incorporate: these criteria, namely, Novelty, inventive step etc. in their national laws India to has adopted these criteria of Novelty and inventive step apart from "Section 3(d)" "enhanced efficacy criteria in the patents Act 1970 it can which is an extension of Novelty and inventive step. It can be summed up that Novartis will fail if it challenges "Section 3(d)" in the WTO. Now MNCs will have to get into real research and development active by investing their efforts to produce original invention which could pass the test of patentability Under India's 3(d) test.

References

Jabade (2012). "Patents: A Background", Perspectives in Nanotechnology.

Web References

Niscair – Online Periodical Repository - nopr.niscair.res.in