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CHALLENGES TO INDIAN PHARMACEUTICAL AND AGROCHEMICAL INDUSTRY WITH RESPECT TO THE REPEALED PROVISION OF EXCLUSIVE MARKETING RIGHT UNDER PATENT LAW: A STUDY

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ABSTRACT

The word "Patent" indicates a legislation which provides an exclusive and monopoly rights to inventor to protect their product or process and provides the protection for an invention. The Indian patent legislation covers all patents except pharma and agrochemical industries whereas these are patentable in developed countries. The developed countries are exploiting the Indian market by launching their products because the Indian pharmaceutical industry is unprotected due lack of policy for protection. This process will harm the invention process due to lack of protective parameters. In this article the researcher is relying upon the secondary data including reports of International Conventions and Treaties, textbooks, and various judicial pronouncements and focus is being made on the knowledge of the repealed concept of Exclusive Marketing Right, its significance and hurdles faced by these industries after its removal from the Patent Act of 1970 with special reference to pharma and agrochemical products.

Keywords: Agrochemical, Invention, Infringement, Patent, Pharmaceutical, Product

I. INTRODUCTION

A *sui generis* right under ***The Patents (Amendment) Act, 1999***, was recently recognized as the ***Exclusive Marketing Rights or EMR***. A product patent application under agricultural chemical and pharmaceuticals will be kept in the *'mailbox'*

or 'black-box' until the grant of patent of the same. It gives the protection for agrochemical and pharmaceutical products even before the incorporation of the provision in the Patents Act.[1]

This 'mailbox' concept was inserted in the Patents Act as an intermediary understanding in the modes provided under the *Trade Related Aspects of Intellectual Property Rights* (TRIPS) Agreement. EMR is a right granted equal as Patent right in expectancy of a Patent. In view of the fact that its beginning, EMR has been approved to a number of foremost pharmaceutical companies, together with, Novartis India Ltd and Wockhardt India Ltd. for its life-saving drugs. (In these cases, infringement suits were brought against the competitors after the award of EMR).[2] After accepting the norms of Trade Related Aspects of Intellectual Property Rights (**TRIPS**) TRIPS Agreement, India had approved to perform/ convey the objects mentioned in the Agreement. Consequently, in the year of 1999, 2002 and in 2005 there were the amendments in the Patents Act.[3]

Patent is one of the most important IPR out of all others. It is a form of monopoly provided by the statute for a definite duration to an inventor or an owner of an invention or his assignee. Invention and only invention is the chief object as well subject of the patent and nothing less than that. The word invention is explained as something new and useful produced out of one's own intellectual labour and capital. On granting the patent on such new invention and new creation, that becomes the only and exclusive property of the inventor like any other form of property. It can be said that the basic objective of the award of patent is to give the inventor a status of the owner over the patented invention in the form of exclusive right to secure monetary benefits out of his invention. Such protection primarily encourages the inventors to explore their new and creative thinking and ideas for further invention with assurance of protection of law and governmental machinery. They will get an assurance about its protection and can be able to reap out the monetary benefits arising out of it.

However some necessary criteria are there which need to be satisfied and fulfilled by any invention for qualifying its registration. Those conditions are that the invention[4] must be "new invention"[5], useful[6], non-

[1] K. C. Kankanala, A. K. Narasani, and V. Radhakrishnan, *Indian patent law and practice*. New Delhi: Oxford University Press, 2012.

[2] R. L. Okediji and M. A. Bagley, *Patent law in global perspective*. New York: Oxford University Press, 2014.

[3] Stack A, *Domestic patent law: Autarkic analysis*, International Patent Law (2011).

[4] Indian Patent Act 1970 , (Act 39 of 1970), s. 2(1)(j)

[5] Indian Patent Act 1970 , (Act 39 of 1970), s. 2(1)(l)

[6] Bishwanath Prashad Radhey Shyam v. Hindustan Metal Industries(1979) 2, SCC 517

obvious[7], having inventive step[8], capable of industrial application[9], having technological improvements to even earlier stock of knowledge[10]or gained economic significance[11] etc. It is worthwhile to say that any one criterion is not enough always in all cases of patent application and the invention sought for registration should qualify even all the criteria or to fulfil most of them. Apart from that, the legislation on patent also specifically mentioned certain types of inventions which are not patentable[12] under Indian legislation as it is against or not in line with the public order or morality or the invention which is dangerous or harmful to mankind, plant, animal or even an environment[13].

The TRIPS Agreement offers patent protection for invention of any product or process in all ground of technology to meet the India's international requirement but it is necessary that the invention must be new, a step which could be counted in the term of 'inventive' must be there and its industrial application is possible. India had carried out to arrange in a line its patent laws with TRIPS Agreement by 1 January 2005.[14] Developing countries like India were granted a ten-year period to line up their patent laws so as to provide patent protection for food or drugs. In response, India had agreed to offer some special consideration during this transition period, the most important of these being the grant of EMR for products patented in other countries, awaiting contemplation of the applications for product patent in the Patent Office in India. Previously just process patents were granted for drugs and medicines by the Indian Patent Office. This authorized Indian pharmaceutical companies to produce drug products patented somewhere else by using a different process. EMR was established to restrain such unauthorised duplication of patented drugs.[15]

For the period of the **Uruguay Round** of the WTO negotiations, the developed countries introduced EMR as move to get into the unprotected medicine and food markets of the developing countries. It appears a lot possible that the idea of EMR developed from a US federal legislation, the **Hatch-Waxman Act 1984**.

[7] Graham v. John Deere Co. 383, US 1(1966) p. 1142.
[8] Indian Patent Act 1970, (Act of 1970), s. 2(1)(ja), F Hoffman-la Roche Ltd and Ors v. Cipla Ltd, 2008(37).
[9] Indian Patent Act 1970, (Act 39 of 1970), s. 2(1)(ac)
[10] Ram Narain Kher v. Ambassador Industries New Delhi & Anthers AIR 1976,(Delhi, India).
[11] Bajaj Auto Ltd. V. TVS Motor Co. Ltd, 2008 (36) PTC 417,(Mad, India)) at p. 440.
[12] F Hoffman-la Roche Ltd and Ors v. Cipla Ltd, AIR 2008(37).
[13] Indian Patent Act 1970, (Act 39 of 1970), s. 3.
[14] Germany enacts a biotechnology patent law; AVI Bio Pharm receives stem cell Antisense technology patent and allowance; Third amendment to Indian patent law takes effect; U.S., Israel in dispute over patent law on drugs. Biotechnology Law Report. 2005, *24*(2), 185-186.
[15] Kuanpoth J, *Patent rules and procedures: Indian law,* Patent Rights in Pharmaceuticals in Developing Countries, . (2010).

The Act endow for five years with exclusivity to the innovator - a time duration which is much similar to the duration of EMR.[16]

The award of EMR would give protection like patent, which the foreign companies would not have benefitted from, set the loose form of patent protection offered by the developing countries. A deep examination of measures prior the introduction of EMR in India would disclose that India was loaded by the developed countries into compliant with the suggestion of granting EMR.[17]

The matter of EMR was taking into the front by the United States facing the Panel of the WTO's Dispute Settlement Body. The European Community (EC) afterwards intrude in as a third party, however had selected not as a co-complainant of the United States. The major concern in **United States v India** was whether India had recognized a method that satisfactorily potted novelty and main concern was related to patent applications including pharmaceutical and agro- chemical inventions settled in the Indian Patents Act matter categorized as "food, medicine or drug" were not allowed to patent protection.

[16] Mirza, Z, *Pharmaceuticals and health: Impacts and strategies*. Development, (1999), *42*(4), 92-97.

[17] Sreenivasulu NS and Raju CB, *Biotechnology and patent law: Patenting living beings*. Manupatra, (2008).

The provisions related to the difference of opinion were of the two Article of **TRIPS Agreement** (Articles 70(8)(a) and 70(9))**.**

India differ that TRIPS didn't require legitimate assurance that the patent applications and the licenses dependent on them won't be dismissed or nullified later on. India likewise dealing with the motivation behind the EMR arrangement under Art. 70(9) was to empower creating nations to postpone authoritative changes.[18]

Then again the United States, was dealing with that under Art 70(8), down to earth undertaking of the executives for post box applications must be given. The United States additionally contended that the impulse to give EMR in Art 70(9) got viable upon section into power of the WTO Agreement in 1 January 1995, and not in 2005, as India contended. The WTO Panel presumed that India didn't conform to its commitments under craftsmanship 70(8)(a) of the TRIPS Agreement, and disregarded its commitment to give EMR during the transitional period under workmanship 70(9). The WTO Appellate Body maintained the board's decisions. [19]

II. PROVISIONS UNDER INDIAN LAW IN REGARD OF EMR

The Grant of EMR

[18] Rao, M. B., Rao, M. B., & Guru, M. (2010). *Patent law in India*. Kluwer Law International B.V.

[19] Liu K. *Innovation, economic development, and intellectual property in India and China*. Springer Nature, 2016.

Compared to the large number of mailbox applications made to the Patent Office, the number of EMR applications have been far and few. Two instances of the grant of EMR, ie, to Novartis India Ltd.[20] for Glivec (imatinib mesylate) and Wockhardt India Ltd. for its Nadoxin (nadifloxacin), have led to contentious proceedings both before the Controller of Patents as well as the high courts. The EMR granted to Glivec, being the first grant from the Patent Office, is discussed below in detail:

In November 2003, the Controller of Patents allowed EMR to Novartis, for its licensed enemy of malignancy medicate, Glivec utilized in the cure of Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumours (GIST). The medication containing Imatinib Mesylate didn't appreciate patent insurance in India, however it was licensed in different nations. In any case, under Chapter IVA of the Patents Act, Novartis had the option to get EMR for Imatinib Mesylate which permitted Novartis to solely sell or disperse the medication. This move influenced numerous Indian pharmaceutical organizations who had been fabricating a similar medication under various exchange names.[21]

Procedure for the Grant

The procedure of granting the EMR is quite unique. Though the EMR grants a patent-like protection to the holder, it does not follow a patent-like procedure in its grant. The grant of EMR results in a privileged right to sell or dispense the drug covered by the grant. There is no provision for anyone to oppose the grant of EMR at, before or after, its grant. Whereas the Patents Act has rigorous procedures for opposing a grant of a patent. It is submitted that the procedure for the grant of EMR is against the principles of natural justice, and can result in arbitrary exercise of the power in granting the EMR. In short, EMR can be used as an instrument to get quick monopoly right to sell or distribute a drug without any opposition over the grant.[22]

III. EMR BEFORE THE PATENTS (AMENDMENT) ACT, 2005

The Patents Act, as it was before the Patents (Amendment) Act, 2005, contained the conditions for the grant of EMR. The preconditions stipulated under that section were:

- The applicant should have made an entitlement for a patent;
- On or before 1 January 1995, in convention country an application should have been made for the same invention;

[20] Novartis AG v. Union of India & Ors.(Civil Appeal 2706-2716/2013) and Wockhardt Ltd. v. Hetro Drugs Ltd.(O.S.A.232/2005).

[21] Kankanala K, Narasani A, & Radhakrishnan V, *Indian patent law and practice*. OUP India, (2012).

[22] Mathur, V, *Intellectual property rights and their significance in biomedical research*, International Journal of Biomedical Research, 2012, *3*(2).

- The date of making a claim in India, approval should have been granted to sell or dispense the invention in that country; and
- The concerned authority in India should grant the approval to sell or distribute the invention;
- EMR is granted for five years after satisfying all the conditions.
- The award of EMR guarantees a patent-like assurance to be reached out to the item even before the patent application is prepared.

IV. EMR AFTER THE PATENTS (AMENDMENT) ACT, 2005

The Patents (Amendment) Act, 2005 omitted Chapter IVA of the principal Act dealing with EMR and provided for certain transitional provisions. The said amendment introduced certain provisions to protect the interest of the generic manufacturers who have been manufacturing certain drugs patented elsewhere. Section 11A (7) deals with certain privilege and rights granted to the patentee during the period from the date of the publication for patent till the date of grant. It deems like a grant of patent immediately on the date of its publication.[23]

As the above provision pertains to applications made under s 5(2) of the Patents Act, a question naturally arises as to whether certain manufacturers of a product covered by EMR could avail the benefit of this provision. It is pertinent to note that s 78 of the Patents (Amendment) Act, 2005 states that EMR granted prior to First day of January will be effective upon the same term and conditions.[24] Moreover, the proviso requires that such enterprises must continue the manufacturing of the products which are the subject of the patent. As the EMR holder would have restrained most of the Indian manufacturers from manufacturing the product covered by the EMR, the benefit of the provision will not be opened to enterprises that have discontinued the manufacture of the concerned product.[25]

Effect of Section 11A (7)

EMR clearly stands outside the scope of s. 11A (7). This is evident from the first proviso to s. 11A (7) which prohibits the applicant to file any suit for infringement before the grant of patent. On the other hand, s. 24E of the Patents Act, as it was before the Patents (Amendments) Act, 2005 expressly provided the power to institute infringement proceedings as it equated suits relating to infringement of EMR to patent infringement suits. Moreover, it is clear that the above provision will take effect only after a patent

[23] Majumdar AB. *An economic analysis of Indian patent law,* SSRN Electronic Journal, (2013).

[24] Mathur V. & Musyuni, P, *Plant variety protection legislation: Overview of an Indian and African perspective*, International Journal of Drug Regulatory Affairs, 2018 *2*(1), 12-17.

[25] Bijle MN, *Patent law in dentistry: An overview,* Indian Journal of Dental Research. 2011. *22*(4), 574.

is granted. As the grant of EMR precedes the grant of a patent, the above provision will not be attracted.[26]

Problems in Transition

Certain issues have arisen with regard to the maintainability of a suit for infringement of EMR after the EMR is terminated. In the infringement suit filed before the Madras High Court by Novartis, one of the defendants had moved an application for rejection of the plaint in the light of the Controller's order rejecting the patent application for Glivec. The defendant has also filed an application for vacating the interim injunction granted in favour of Novartis in 2004 based on EMR. In defence, the plaintiffs raised a novel plea that the suit will survive even after the rejection of patent application for the purpose of damages suffered during which period a validly granted EMR existed.[27]

It is pertinent to note that in confirming the interim injunction granted in favour of Novartis, the Madras High Court had in fact granted a prayer which was beyond the scope of s. 24B. Section 24B restricts the EMR so granted on two accounts. First, EMR confers a right only to sell or to distribute the protected product. It does not confer any right and any consequent restraint over its manufacture and export. Secondly, the application of EMR will be limited to India as clearly stated in the above section. It would be beyond the scope of the section to restrain exports to countries where the drug does not enjoy any form of protection.[28] It may be argued that since sale or distribution is prohibited in India, manufacture of the drug should also be precluded, as it is a prelude to the sale. Such a contention will have to be studied in the light of the Patents (Amendment) Act 2005 which has introduced a new exceptional provision for the export of products (Pharmaceutical) which are patented. On an application taken by one of the defendants, the court clarified and restricted its order to selling or distributing in India.[29]

V. REPERCUSSIONS ON INDIA: PROVISIONS OF INDIAN PATENT LAW AND ITS INCOMPATIBILITY WITH TRIPS

The Indian patent law is discovered to be conflicting with the Outings on the accompanying territories all things considered. The patent law of India, in the pre-WTO period, presented 7 years as the term of patent if there should arise an occurrence of food or drug item and 14 years

[26] Kankanala KC, *Genetic patent law and strategy*, Manupatra, 2007

[27] Martin HD, *Patent rights worldwide, patent applications: Prosecution, oppositions, priority rights*, *Polymers, Patents, Profits*. 2007, 87-128.

[28] Warrier, V. S,*Understanding patent law*, 2015

[29] Parulekar, A, *Indian patents law: Legal and business implications*, 2006.

in the event that in some other item. Notwithstanding, this was changed to 20 years regardless of the kind of item in compatibility of the Outings arrangement. Licenses will be allowed independent of the reality whether the medications were delivered locally or imported from another nation.

Indian Patent law allows just cycle licenses if there should arise an occurrence of food or medication or medication for example food item or medication or medication couldn't be protected. Just the cycles fabricating them could be protected. These items could be fabricated by different cycles. To follow the arrangements of the Excursions understanding, India had 10 years to change its patent laws (5years for being a creating nation and 5yrs for being a nation not conceding an item patent, completely as per article 65.3 and 65.4 of the arrangement).

VI. EFFECT ON INDIAN PHARMACEUTICAL INDUSTRY (IPI)

Process patent assisted with thriving IPI into an elite generics industry. In the homegrown market, the portion of Indian organizations has consistently expanded from around 20 percent in 1970 to 70 percent now. Ranbaxy Research centres is the market chief as far as incomes followed by Dr Reddys Labs and afterward Cipla. Glaxo is one of only a handful few multinationals to figure among the best ten pharma organizations in India. India and Japan are the main two nations where drug organizations of USA and Europe don't overwhelm. Nonetheless, since the usage of the product patent system, the small-scale companies have been hard hit. Piece of the pie of the best 20 organizations has expanded while the greater part of the small-scale drug units have shut down over the most recent 2 years.

Effect on Public Health in India

Several individuals kicking the bucket as a result of absence of wellbeing offices, neediness and significant expense of medications. India doesn't have an exceptionally energetic clinical protection area which will pad the consistently increasing expenses of medications and treatment. In a nation where one-fourth of the populace can't get essential luxuries of life, and where the condition of general wellbeing is bleak as shown over, the main conceivable answer for accessibility of modest medications in mass is measure patent.

A larger part of the populace doesn't approach the fundamental prescriptions (the majority of which are off patent) either in the legislature or private medical services frameworks since they are not inside their ability to reach. Item patent has prompted soaring of the costs of medications which cannot be managed by a greater part of populace. Let us take a couple of outlines

1. Indian Organization for Substance Innovation created AZT, the Guides hostile to retroviral drug, through a substitute cycle without imitating the patent-holder, Borrough-Wellcomea™ measure. The innovation was given to CIPLA. It was likewise offered to a Brazilian maker. The expense of the critical medication through this course was down to not exactly 33% of its cost, and hence turned out to be more reasonable.

2. Gleevac, the counter blood malignancy drug created by Novartis costs around $2750 every month. Nonetheless, its conventional rendition made by Indian organizations costs around one-10th of the value, consequently making it more reasonable.

Thusly, an administrative framework zeroed in just on measure licenses assisted with building up the establishment of a solid and exceptionally serious homegrown drug industry which in the hold of an unbending value control structure changed into a world provider of mass medications and prescriptions at reasonable costs to the everyday person in India and the creating scene.

The new patent regime generated lively debate upon implementation. Following its repeal Chapter IV A was almost forgotten; but interest in this provision has since been revived by the recent Supreme Court decision in Glaxo Smith Kline LC and others v Controller of Patents and Designs and others[30]. This case clarifies the effect of the repeal of the EMR provisions on the litigation of pending and decided applications for the grant of EMR.

Based on the judgments given in M/s Hoosain Kasam Dada (India) Ltd v The State of Madhya Pradesh and Ors[31] and M/s Gurcharan Singh Baldev Singh v Yashwant Singh and Ors[32] these facts, the Supreme Court held that the High Court ruling disregarding the application of Section 78 of the amendment act to proceedings which had been concluded before the appointed day appeared to be correct. Since Chapter IVA was merely repealed, the situation was to be dealt with under the provisions of Section 6 of the General Clauses Act, which specifically states that repeal affects no right, privilege, obligation or liability acquired, accrued or incurred under any enactment so repealed. The provisions of Section 78 were conditional and did not apply to cases where the application for EMR had already been rejected. Thus, the order of the Division Bench could not be sustained. The appeal was allowed with no order as to costs.

[30]. Civil Appeal No.5588 of 2008
[31] (AIR 1953 SC 221).
[32] (1992 (1) SCC 428).

VII. CONCLUSION

The procedure of progression started in 1991 has created arrangements that are centred around pulling in capital from abroad and making India a worldwide modern base. The resultant inflows of remote direct speculation and innovation moves have made a condition for dynamic development and expanded intensity of Indian industry. India is gradually moving into worldwide markets and contending with global quality models and costs. In spite of the fact that R&D is a significant factor to guarantee a serious edge in the global field, the fate of the Indian pharmaceutical industry relies on protection of patent.

The stipulation is that the item more likely than not been enlisted for a patent and has gotten showcasing rights in any of the WTO part nations. In this manner, it is an indirect access technique for allowing syndication rights. Moreover, there is additionally a hazy area here. In the event that advertising rights are conceded for just five years, what will be its situation over the five-year time frame, until the nation being referred to really has corrected its patent laws? Transnational organizations (TNCs) control 90% of every single enlisted patent on the planet. Truth be told, given such restraining infrastructure control over licenses and the EMR provision, India, or so far as that is concerned any creating nation, doesn't have any change period. This is valid on account of secured innovation, and in the event that one deciphers that from the patent/item starting nation point. This is the haziest piece of the TRIPs Agreement, concerning the pharmaceutical and furthermore the agrochemicals divisions. Given such a murky situation, it is hard to anticipate the fate of the Indian pharmaceutical industry under the « new » system of protected innovation rights and its relationship with worldwide exchange. Worldwide organizations don't have any enthusiasm for creating tropical medications. Given its customary therapeutic plant base, India can take a main situation in creating, delivering and sending out those medications. The medication approach of the legislature must be a professional dynamic one – to exploit the TRIPS system.