

PATENT PROSECUTION HIGHWAY: AN OVERVIEW AND A CRITICAL STUDY OF INDO-JAPAN PPH AGREEMENT

SOURAV KUMAR* AND JYOTSHNA YASHASWI**

ABSTRACT

This article has been written with a focus on India's Patent Prosecution Highway agreement with Japan, which happens to be India's first-ever PPH program. A PPH Program is a work-sharing agreement, where two patent offices share their work while examining the same patent claim filed in two jurisdictions resulting in expedited and efficient patent prosecution. This agreement has been analysed specifically while examining the needs and importance of PPH in general. A PPH program is claimed to pose a threat of harmonisation of patent regimes and thereby dilute the strict patentability threshold of countries such as India. There are various other concerns that surround the program, the impacts of which are yet to be known. India is one of the biggest markets globally and one of the first developing nations to sign such an agreement. The India-Japan PPH program will be the first among many such programs to follow. An analysis of the India-Japan agreement has been undertaken to predict its outcome on the Indian patent regime and the economy. The Patent Rules 2003 has been amended in a way to accommodate all such future programs. Therefore, it has been suggested that a comprehensive policy be prepared that may guide such future programs to prevent harmonisation and dilution of the patentability threshold. Lastly, the biggest concern arising out of this program was that pharmaceutical companies may use this arrangement to garner exclusivity, thereby threatening the availability of cheap medicines in India. Drawing upon this argument a case has been made to exclude the pharmaceutical sector from future PPH arrangements.

*Sourav Kumar, 3rd Year student at The National Law School of India University, Bangalore. The author can be reached at souravk@nls.ac.in.

**Jyotshna Yashaswi, 3rd Year student at Chanakya National Law University, Patna. The author can be reached at jyotshnayashaswi@gmail.com.

I. INTRODUCTION

Globalisation has resulted in making the world more and more interconnected, and commerce is the most significant element of such interconnected development. Commerce is driven by constantly improving technology through research & development. To get ahead of its competitors, enterprises put a lot of effort and investment into research & development. New developments are protected by patent rights, to ensure that the developer can enjoy the benefits of their effort and investment. However, the patent rights are granted by the patent office of that particular country or the region and have a territorial limit. This is known as the principle of territoriality.

In a globalised world, all the big enterprises and MNCs seek to make commercial use of its research and development in several jurisdictions. However, as patent right is a territorial right, it is not enough to get a patent only in one country. The developer needs to obtain such patent rights in all those countries where it aims to make commercial use and protect its rights. The process of obtaining a patent is time and resource consuming. Going through this tedious process several times is difficult for the applicant and it is wastage of effort of the patent office. In such a scenario, the Patent Prosecution Highway [“**PPH**”] has proved to be of great help.

In this paper, the authors study the evolution of the PPH framework and the reasons that propelled the rise of this work-sharing arrangement. Since India has signed its first pilot PPH agreement with Japan, an analysis of the agreement and its impact on the Indian patent regime shall be undertaken. The authors shall also argue that PPH agreements are a better option than global harmonisation treaties such as TRIPS, especially for developing economies like India as it may result in boosting the manufacturing sector without diluting Indian patent laws. However, the authors shall conclude by making a case for exclusion of the pharmaceutical sector from such future PPH agreements. It is to be noted that India has signed its first PPH agreement, whose impact cannot be predicted and hence, the trends and results from the USA and Japan have been used to analyse its impact on the Indian patent regime.

II. PATENT PROSECUTION HIGHWAY: NEED AND IMPORTANCE

The process of filing a patent application before a patent office indicating the claims and its examination by a patent examiner is called patent prosecution. The role of a patent examiner can be seen as a gatekeeper who rejects the scope of the claims made by the applicant repeatedly so that the applicant concedes the claims, which are already in existence.¹ The work of a patent examiner involves research on relevant databases for prior arts, which is a highly tedious and

¹ John M. Carson *et al.*, *A Practical Guide to the Patent Prosecution Highway*, 188 *MANAGING INTELL. PROP.* 24 (2009).

time-consuming task. In case, an applicant makes an application before two offices, the patent examiner of both the offices will have to do the same work resulting in duplication of work. In such a case, if there is a mechanism of work and information sharing between the two offices, then the repetition and duplication of work can be avoided.

PPH is a mechanism to share work generated by one office with the other. It aims to accelerate the process of prosecution by sharing of information among different patent offices. Under a PPH framework, an application for patent approved by Office of Earlier Examination [“**OEE**”] is eligible for an expedited examination in another Office of Later Examination [“**OLE**”], if requested by the applicant.

It is well known that different jurisdictions have different standards of patentability, and therefore one patent office cannot rely on the decision of other patent offices with full credit and faith. Therefore, PPH mechanism is not complete reliance on the work of other office but it is a mechanism where OLE can use the search result of OEE as a jumping-off point for its patentability search and thus reduce the duplication of work by the examiners.²

With increasing globalisation, the number of patent applications filed across the globe is also significantly increasing. Predictably, the number of applications for the same claim being filed before multiple patent offices is also increasing. At the beginning of the previous decade, the number of patent applications filed globally was 89.6 million, which rose to 122.9 million patent applications at the end of the decade.³ In such a scenario, it can be concluded that the patent office faces a huge backlog of applications. This situation is also problematic from the perspective of applicants as in today’s globalised world the technology keeps changing day by day and an applicant may face severe losses during the pendency of the patent application. Therefore, a need for expedited examination of the patent applications was being felt. PPH is a result of this need for expedited examination to help the patent offices as well as the applicants.

The first-ever PPH program was started in 2006 between the United States Patent Office [“**USPTO**”] and the Japan Patent Office [“**JPO**”] on a pilot basis.⁴ The purpose of the pilot project was stated to expedite the examination process of a patent application before the OLE, if

²*Id.*

³Japan Patent Office, *Introduction to Patent Prosecution Highway*, WORLD INTELLECTUAL PROPERTY ORGANIZATION (last visited Dec. 31, 2020), https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_ryd_13/wipo_ip_ryd_1-3_www_258896.pdf.

⁴ Christopher A. Potts, *The Patent Prosecution Highway: A Global Superhighway to Changing Validity Standards*, WORLD INTELLECTUAL PROPERTY ORGANISATION (May 23, 2011), https://www.wipo.int/edocs/mdocs/mdocs-en/wipo_ipr_ge_11/wipo_ipr_ge_11_topic15.pdf.

certain corresponding claims were allowed by the OEE, by using the search and examination result produced by the Office of First Filing [“**OFF**”].⁵ The efforts put in by the OFF are thus not repeated and redundancy is reduced to result in expedited examinations.

There were certain major takeaways from the pilot project, which proved to be very beneficial to applicants in getting applications approved and for the patent offices in clearing the application backlog. In the USA, of all the applications filed through the PPH route, 94% of the applications were approved, while the allowance rate for non-PPH applications was less than half of that. In the non-PPH route, an average of 3.2 to 3.4 substantive actions was required to dispose of an application. However, for PPH applications it took an average of only 1.7 substantive actions in disposing of an application⁶, mostly resulting in allowing the claim. The PPH route doubled the chances of a claim being accepted and reduced the number of substantive action by half. Substantive action or office action is a refusal of the application by the trademark office on certain grounds, allowing the applicants to respond to the objections. The time taken for a claim to be allowed in a PPH route application was 2-3 months instead of an average of 27 months.⁷ The benefits of a PPH mechanism were quite visible and therefore several bilateral, as well as multilateral PPH agreements have been signed. Global PPH and IP5 are the most important examples of such a multilateral PPH mechanism signed by major patent offices of the world.

III. WORKING MECHANISM OF PPH

PPH is a work-sharing agreement and such work-sharing agreements are a result of the pursuit of patent offices to reduce the backlog. Backlogs in patent offices are a result of an ever-increasing number of applications and reduced budgetary allotment.⁸ Globally, since the 1990s the numbers of patent applications have increased at a rate of 20-30% per annum. In 2003, in the US, the average total pendency was of 26.7 months, which increased to 34.6 months in 2009.⁹ These trends during that time were not limited to the USA but were reflected globally and thus, pressurised the patent offices to take actions to ameliorate this condition. As a result, inter alia, USA and Japan formalised the first-ever PPH pilot program in 2006.

In the traditional approach, all the offices examine the application in isolation and vacuum of information, apart from what is furnished by the applicants. The work done by other offices in

⁵ Alicia Pitts & Joshua Kim, *The Patent Prosecution Highway: Is Life in the Fast Lane Worth the Cost*, 1(2) HASTINGS SCI. & TECH. L.J. 127, 129 (2009).

⁶John M. Carson, *supra* note 1, at 26.

⁷Pitts, *supra* note 5, at 130.

⁸Potts, *supra* note 4, at 3.

⁹*Id.*

examining the patentability of the same invention is not formally recognised and this aspect of traditional patent examination has been changed by a PPH arrangement.

Under PPH arrangement, a member office will use the search and examination results of the priority application filed before the other agreeing office to expedite the review of the same application. Whether OLE will utilise only search results or both search and an examination result of the OEE depends on the specific agreement between the two offices. This factor has a significant implication on the outcomes of patent examination. If the OLE relies on the examination result and there is a substantive difference in the patentability criteria, standard, and law of the two offices, then there is a concern that the jurisdiction with higher patentability threshold and standard will suffer dilution in its standards.

Under this arrangement, if an applicant gets at least one claim approved by the OEE, then a request for expedited examination can be made before the OLE for the corresponding claim. OLE will then utilise the search and examination result produced by OEE to examine the claim in an expedited manner by avoiding duplication of work.

Post the USPTO-JPO pilot program, various offices have initiated several other PPH programs. PCT PPH, Global PPH, IP5 PPH are some significant multilateral PPH arrangements apart from numerous bilateral PPH arrangements. Although different PPH arrangements have different specific requirements, there are certain general principles and requirements in most of the PPH arrangements, such as valid filing of the application of priority before OEE, approval of at least one of the claims by the OFF, and the non-commencement of the substantive examination at the OLE.¹⁰

IV. PPH: A TRADE-OFF AND NOT A SHORTCUT

It is sometimes perceived that a PPH route application guarantees success in the OLE and thus, PPH is criticised for diluting the patent law and standard of the jurisdiction of the office of second filing. However, this notion is misconceived, as PPH does not guarantee the success of the application.

If we look at the data from the pilot project between USPTO and JPO, it is known that 6% of the applications were rejected. A PPH is a trade-off undertaken by the applicant,¹¹ where the applicant gives up a chance on carefully re-drafting the claim and the larger scope of the claim, as the office of the first examination has already denied it. In exchange for this, the applicant gets an earlier and expedited examination of application resulting in early disposal and decreased cost.

¹⁰ Potts, *supra* note 4, at 5.

¹¹ Carson, *supra* note 1, at 27.

Given the nature of trade-off involved in a PPH mechanism, it is of more relevance to certain big companies that indulge in fast-changing technologies.

As PPH is a trade-off for the applicant and not all gain, the applicant should look to derive the most benefit out of it. This can be done by identifying certain directions of the PPH, which favours the applicant. In the case of the USPTO-EPO highway, the preferred direction is US1-EU2. Here, the USPTO is preferred as the OFF, while EPO, which is by default the office of second filing is approached through the PPH application.¹²

The direction of a preferable route can be identified by deciding the OFF based on two factors - first, the amount of time generally taken to complete the prosecution and second, the tendency of the office to limit the scope of the claim. An office, which takes lesser time to decide on the claim should be allowed and has a lesser backlog, should be preferred as the OFF. This will result in patent getting approved in the least possible cumulative time in both offices. In respect to the second factor, the office, which has lower and liberal standards to allow a claim should be preferred. This will mean that the applicant will approach the office of second filing with the maximum scope of the claim. A carefully selected PPH route can immensely help an applicant in the process.

Given the nature of the procedure, it can be said that beneficiaries of PPH arrangement tend to be predominantly larger companies engaged in fast-moving technologies. According to the data provided by USPTO, the most number of PPH applications were filed for the Computers and Electronics sector, followed by Biotechnology and Chemical Engineering.¹³

V. CONCERNS EMERGING FROM PPH

A concern inherent to the patents allowed through PPH is that such patents have weakened validity. It is often claimed that work-sharing arrangements, especially a PPH may result in a situation where the OLE, by relying on the search and examination result of the OEE often lose control over the examination process.¹⁴ This loss of control over the required standard and criteria by the OLE may result in producing a highly compromised patent regime. The bigger concern is that, since PPH is a bi-directional mechanism, both the offices cede the control over the examination to each other. This may lead to the harmonisation of patent laws, which is far from the ideal situation.

¹²*Id.* at 24.

¹³*Id.* at 25.

¹⁴Potts, *supra* note 4 at 6.

A PPH arrangement may also lead to constitutional challenges to the validity of such programs. The reliance of the OLE on the search and examination result of the OEE may result in the patent examination process of the OLE becoming bifurcated. This may in effect result in two separate patent regimes- first, for the patents granted through PPH with lower standards and requirement and second, for the patents granted through the non-PPH route with higher requirements and standards. This situation will be created by the backing of the law. Thus, a challenge may arise against such a mechanism for being discriminatory.

Most of the modern constitutions invariably enunciate the principle of equality and provide equal protection of law to people. The Equal Protection Clause of the American Constitution, which reads, “[no state shall] deny to any person within its jurisdiction the equal protection of the laws.”¹⁵ Similarly, the fundamental right to equality of the Indian Constitution reads, “the State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.”¹⁶ Most of the Constitutions in the world provide similar protection to the citizens.

Such a challenge has not arisen in the US till now, but with changing jurisprudence the possibility of such a challenge cannot be denied. However, after the IPO-JPO pilot patent program, such a challenge is more likely to arise in India. The reason for this is that historically the US constitutional jurisprudence has accorded a higher pedestal to liberty than equality,¹⁷ but the Indian Supreme Court has accorded higher respect to equality.¹⁸ Therefore, the pilot PPH program in India may need to pass a very strong Constitutional test.

The concerns emanating from a PPH arrangement discussed above are based on the sole premise that while examining an application in an expedited manner, the office of second filing cedes its control over the examination process to the office of first filing. This is possible only when, the OLE completely relies on the examination result of OEE without any scrutiny on its own. As of now, no major patent office has issued such guidelines. However, as discussed in the previous parts, a lot of applications filed through PPH route are rejected as well, which indicates that the actual practice of examination corresponds with this argument.

This premise seems to be misguided as when the OLE examines an application under PPH, it uses OFF’s examination and searches result merely for reference for the reduced scope of the

¹⁵U.S. CONST, amend. XIV, § 1.

¹⁶INDIA CONST. art. 14.

¹⁷ Herman Belz, *Liberty and Equality for Whom? How to Think Inclusively about the Constitution and the Bill of Rights*, 25(3) THE HISTORY TEACHER 263, 266 (1992).

¹⁸ Uday S. Mehta, *Constitutionalism*, THE OXFORD COMPANION TO POLITICS IN INDIA 15 (Niraja Gopal Jayal & Pratap Bhanu Mehta eds., 2010).

claim. Therefore, a PPH arrangement between two offices results in the harmonisation of the procedure and not the substantive law. However, this does not mean that there is no possibility of harmonisation of substantive law by reduced validity standards. The argument is based on the will and skills of the examiner at OLE, and will not stand correct if the examiner decides to completely rely on the examination and search result of the OEE. Thus, it is suggested that binding guidelines must be provided by any office entering a PPH arrangement to pre-empt complete reliance by any examiner on the search and examination result of OEE.

Further, a legal challenge that has arisen in many countries out of PPH is of reduced validity presumption. This was also one of the questions before the US Supreme Court in *Microsoft Corp. v. i4i Ltd. Partnership*.¹⁹ The concept of presumption of validity of patents means that in case a patent is challenged, the court shall presume it to be valid once it is granted by the patent office. The onus to prove the invalidity of the patent is on the person claiming so. US Patent regime provides for such presumption in favour of validity. Consequently, US courts require 'clear and convincing' standard of evidence to invalidate a patent. This standard flows from the presumption that the patent office has done its job properly.²⁰ A patent granted through a PPH route might appear to not fit well within this presumption. In *Microsoft Corp. v. i4i Ltd. Partnership*, Microsoft argued to change this 'clear and convincing' to 'preponderance of probabilities' standard. However, the US Supreme Court rejected this argument and upheld the 'clear and convincing' standard for invalidating a patent.

However, there won't be any such impact on the Indian law as there is no presumption of validity of a patent in India as decided by the Supreme Court in *Biswanath Prasad Radhey Shyam vs. Hindustan Metal Industries*²¹ and also codified in the Patents Act.²² Therefore, this pilot program will not impact Indian law on this aspect.

VI. INDIA- JAPAN PPH: THE INTRICACIES

¹⁹Microsoft Corp. v. i4i Ltd. Partnership, 564 U.S. 91 (2011).

²⁰Rajiv Kr. Chaudhri, *Presumption of validity of a (an Indian) Patent*, SPICY IP (June 25, 2011), <https://spicyip.com/2011/06/presumption-of-validity-of-an-indian.html>.

²¹Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries, AIR 1982 SC 1444 (India).

²² Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 13(4) (India).

The Indian Patent Office signed its first Patent Prosecution Highway program with Japan Patent Office in 2019 on a pilot basis.²³ This program may prove to be a boost to 'Make in India', emerging start-ups, and MSMEs of India. Japanese entities will also benefit from the scheme.

Given the new emerging geo-economic order of the world in light of the COVID-19, this PPH may help India in becoming a major manufacturing hub. The Japanese government has asked its companies to move out of China, and thus companies such as Sony are looking for alternate countries.²⁴ India is one of the preferred countries with adequate and cheap manpower, and the PPH will further reduce the entry barrier by expedited patent examination.

There are certain claims that this PPH will prove to be disastrous for the Indian patent regime. It is claimed that it will lead to dilution of the strict patentability criteria provided by the Indian Patent Act. It is feared that it would result in harmonisation of India's patent law with those of Japan's.²⁵ This notion is misconceived as PPH is just a route for expedited examination and not a route for guaranteed approval. As it has been discussed previously, applications coming through the PPH route can be rejected also. The office of second filing merely relies on the search and examination result of the earlier office and it examines the scope of claim allowed again. Therefore, the claim that it would dilute the patentability criteria is misguided.

The critics of this PPH are particularly concerned with the dilution of criteria for drug and medicine patenting as foreign drug companies' ploys for patenting medicine in India has constantly been rejected by the Indian patent criteria.²⁶ Once again, this scepticism is misguided, as, under the current arrangement, IPO will not be receiving PPH application for drug patents. The procedure guidelines released by IPO states that "*IPO will receive Patent applications only in the technical fields of Electrical, Electronics, Computer Science, Information Technology, Physics, Civil, Mechanical, Textiles, Automobiles, and Metallurgy.*"²⁷ Therefore, the fear and criticism of the pilot program are completely misguided. However, a strategic selection of the PPH route as discussed previously

²³ Office of Controller General of Patents Designs and Trademarks (DIPP), *Notice: Patent Prosecution Highway*, DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE (Dec.04, 2019), available at: <http://www.ipindia.nic.in/newsdetail.htm? 593>.

²⁴Nandini Oza, *Gujarat looks to make hay as Japan plans to move businesses out of China*, THE WEEK (Apr. 16, 2020),<https://www.theweek.in/news/biz-tech/2020/04/16/gujarat-looks-to-make-hay-as-japan-plans-to-move-businesses-out-of-china.html>.

²⁵LathaJishnu, *Patent Prosecution Highway: The fast track to disaster*, DOWN TO EARTH (Feb.17, 2019),<https://www.downtoearth.org.in/blog/economy/patent-prosecution-highway-the-fast-track-to-disaster-63088>.

²⁶ *Id.*

²⁷INDIAN PATENT OFFICE, PROCEDURE GUIDELINES FOR PATENT PROSECUTION HIGHWAY, at 8 (2019).

may result in Japan-India being the preferable route as Japanese patent criteria are liberal in comparison to India.

VII. RULES AND PROCEDURES FOR IPO-JPO & IMPACT ON INDIAN LAW

The pilot PPH arrangement signed with Japan consists of both Normal PPH as well as PPH MOTTAINAI.²⁸ PPH MOTTAINAI is a specialised Japanese PPH program started in 2011, which aims to reduce the wastage of time and resource.²⁹ Under the Normal PPH scheme, the OFF, has to provide the outcomes of its examination, before any of the offices approve a PPH request. Such a necessity bars the other offices from efficiently utilising the search and examination conducted in other offices. This is a situation of “MOTTAINAI” or “waste”, which is aimed to be reduced by PPH MOTTAINAI.

In India, the patent regime is controlled and regulated by the Patent Rules 2003. The Patent Rules, 2003 was amended in 2016 to include a provision for expedited examination. However, the option of expedited examination was available only on two grounds- firstly, if the applicant has indicated India as the competent International Searching Authority or as an International Preliminary Examining Authority in the corresponding international application³⁰ and secondly, if the application is by a start-up.³¹ However, the rules were suitably amended in September 2019. The Patent (Amendment) Rule 2019, inter alia stated new rules where applicants are eligible for the expedited examination provided that they are eligible under an arrangement between IPO and the patent offices of other countries or regions.³² The amendment was brought about to accommodate expedited examination under the Indo-Japan PPH. It can be said with conviction that the PPH has not brought about any substantial change in the Patent Rules but merely procedural change. Therefore, there will be no harmonisation of substantial law, which is feared by many but only of procedural aspects. The changed rules also indicate that India might be entering into more PPHs in the future.

Both offices started accepting PPH requests from 5th December 2019. The number of PPH requests in both the offices has been capped at 100 cases per year.³³ This seems to be a well thought out strategy. It needs to be considered that as we are witnessing reduced time for PPH

²⁸*Id.* at 3.

²⁹MOTTAINAI is a Japanese term meaning “a sense of regret concerning waste when the intrinsic value of an object or resource is not properly utilized”.

³⁰The Patent Rules, 2003, Gazette of India, pt. II sec. 3 (Sept. 20, 2002), rule 24C (1)(a).

³¹*Id.* at rule 24C (1)(b).

³²Astha, *Availing India Japan Patent Prosecution Highway for Faster Patent Prosecution*, MONDAQ (Jan. 29, 2020), <https://www.mondq.com/india/patent/888154/availing-india-japan-patent-prosecution-highway-for-faster-patent-prosecution>.

³³Indian Patent Office, *supra* note 27 at 4.

cases, the average pendency time for non-PPH cases is ever increasing.³⁴ This is because the PPH cases are consuming a significant time resulting in neglect of the non-PPH application.³⁵ An upper cap of 100 cases per year will ensure that the non-PPH cases are not neglected.

The results of the first set of PPH applications before the IPO may come soon in near future. The application process started on 5th December 2019 and the review of all 100 applications was completed in less than 3 months. IPO, through a notice dated 25th February 2020 informed that the review of applications has been completed and 56 applicants were allowed to file a request for expedited examination on Form 18A. Applications for rest 44 spots were called again.³⁶ The researcher attempted to find out the details of applicants to understand the nature of companies making use of the pilot program. However, IPO has not published any such detail.

VIII. PATH AHEAD FOR INDIA

India-Japan pilot program of PPH will surely be the first among many such programs that will follow. As argued earlier, there are various advantages of such PPH programs for the manufacturing sector and the Indian economy. However, there may be certain disadvantages that may follow if these PPH Programs are not well thought and crafted.

The biggest advantage of a bilateral PPH over a global treaty such as TRIPS is that two countries can prepare a tailor-made PPH framework that suits their needs and aspiration. The needs and aspirations from a patent law are very different for developing jurisdictions like India and developed nation, as clarified by the Supreme Court in *Novartis v. Union of India*.³⁷ Keeping in mind these aspirations, India needs to prepare a well-crafted policy that guides the future PPH agreements that India undertakes.

This policy must seek to prevent the dilution of local patent law. This may be done by expediting the patent granting process through PPH and by making suitable changes only to the procedural part of the patent law and not the substantive part. Special focus should be paid to design the policy in a way to boost domestic manufacturing without lowering the pre-existing threshold. On the same note, we argue that the pharmaceutical sector must be kept out of future PPH agreements. This is because the nature and implications of the pharmaceutical sector are much different from other sector and thus needs special protection.

³⁴U.S. PTO, 2010-2015 STRATEGIC PLAN, 10 (2010).

³⁵Potts, *supra* note 4 at 6.

³⁶Office of Controller General of Patents Designs and Trademarks (DIPP), *Notice: Patent Prosecution Highway*, DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE (Feb. 25, 2020), <http://www.ipindia.nic.in/newsdetail.htm?662/Notice+Patent+Prosecution+Highway>.

³⁷*Novartis v. Union of India*, (2013) 6 SCC 1.

A. SPECIAL PROTECTION TO PHARMACEUTICAL SECTOR:

Pharmaceutical companies have always been attempting to secure exclusivity in the market. They have been engaging in practices such as rent-seeking, patent ever greening, patent layering, etc.³⁸ These acts have often resulted in a severe impact on the poor segment as they are denied access to affordable medicine.³⁹ Patent laws, especially for the Pharmaceutical sector have attempted to balance between the corporate incentives for innovation and the needs of the poor of a healthy life and access to medicines. This never-ending dichotomy has had varying impacts on various countries depending upon their economic status, and therefore we have divergent regimes of patent law across the world.⁴⁰

During the latter half of the twentieth century, the well-established industries from developed countries adopted a maximalist rights culture⁴¹ resulting in the explosion of patents in the Pharmaceutical sector.⁴² However, developing nations such as India were more focused on ensuring access to medicine resulting in the development of cheap generic drug industries.⁴³ Therefore, developing nations have always attempted to counter the effect of patent ever greening and patent layering.

The main reason for treating the pharmaceutical sector as a special case and keeping it out of any PPH arrangement for the near future is that there is a basic difference between medicine and other products. For other products, the need of it is a choice of the consumer, which depends upon the economic wellbeing of the concerned consumers. However, in the case of medicine, it is not a choice but a necessity or compulsion, which may be faced by the rich and poor equally. If this sector is protected in favour of pharmaceutical companies, it will result in the death of millions of impoverished populations of India. Therefore, a developing and welfare state like India should and must aspire to develop a patent regime that ensures access to cheap medicine

³⁸Saby Ghoshray, *3(d) View of India's Patent Law: Social Justice Aspiration Meets Property Rights in Novartis v. Union of India*, 13 J. MARSHALL REV. INTELL. PROP. L. 719, 721-722 (2013).

³⁹Greg Martin, Corinna Sorenson & Thomas Faunce, *Balancing intellectual monopoly privileges and the need for essential medicines*, GLOBALIZATION AND HEALTH (June 12, 2007), <https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-3-4>.

⁴⁰Ghoshray, *supra* note 38, at 722.

⁴¹*Id.* at 723.

⁴²In the USA, the number of Patent granted in 1980 was 66,170 which has reached more than 3,91,000 in 2019. *See* Patent Technology Monitoring Team, *U.S. Patent Statistics Chart Calendar Years 1963 – 2019*, U.S. PATENT AND TRADEMARK OFFICE (last visited Dec. 31, 2020), https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm; a similar trend has been witnessed in the Europe.

⁴³Martin Khor, *Generics under Threat: Can India Still Supply Cheap Medicines for the World*, 259 THIRD WORLD RESURGENCE 4, 4-5 (2012).

affordable by all. This obligation of the state can be traced back to the Constitutional and International obligations.

Although the Indian Constitution does not provide for the right to health expressly, it provides for the right to life as a fundamental right.⁴⁴ The right to life is not just a negative but, a positive obligation on the state to ensure healthy life to all citizens. The Supreme Court of India has read the right to health inherent to the right to life in *Bandhua Mukti Morcha v. Union of India*.⁴⁵ The Supreme Court in *State of Punjab v. Mohinder Singh*⁴⁶ reaffirmed this position and stated that the government has the obligation to provide healthcare services to citizens. Keeping this in mind, the amendment to section 3(d) of the Patents Act, 1970 was introduced. This amendment mandated an increased threshold for pharmaceutical patents to be granted by subjecting such products to the test of increased efficacy.⁴⁷ The validity of this provision was challenged and was upheld by the Supreme Court.⁴⁸ This judgment made the aspirations of the Indian state for maintaining the availability of cheap drugs abundantly clear. Apart from the Constitution, various international treaties cast similar obligations.⁴⁹

The above discussion makes it clear that there is a need to treat the pharmaceutical sector with caution while preparing future PPH framework with other nations. Since billions of people across the world are dependent on India as ‘only’ source of cheap lifesaving drugs⁵⁰ it is necessary to maintain the status quo in the sector. Therefore, we submit that the pharmaceutical sector must be kept out of all future PPH agreements or any such arrangement, which may have the potential to dilute the patent regime.

IX. CONCLUSION AND SUGGESTIONS

Ever-increasing workload and backlog of applications, have forced various patent offices to look for alternative methods of fast-track disposal of patent applications. The USPTO was a pioneer in the pursuit and looked for various work-sharing arrangements. As a result, the PPH pilot program was started, which proved to be immensely successful in reducing backlogs and expediting the process, and was later emulated by various patent offices in the world. PPH

⁴⁴INDIA CONST. art. 21.

⁴⁵*Bandhua Mukti Morcha v. Union of India*, AIR 1984 SC 802 (India).

⁴⁶*State of Punjab v. Mohinder Singh*, (1997) 2 SCC 83 (India).

⁴⁷Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 3(d) (India).

⁴⁸ *Novartis v. Union of India*, (2013) 6 SCC 1 (India).

⁴⁹G.A. Res. 217 (III) A, Universal Declaration on Human Rights (Dec. 10, 1948) art.25; International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.

⁵⁰Randeep Ramesh, *Cheap Aids Drugs Under Threat*, THE GUARDIAN (Mar. 23, 2005), <https://www.theguardian.com/world/2005/mar/23/india.aids1>.

arrangement mainly aims at reducing the redundancy and duplication of work done by the patent examiners and thereby providing expedited examination to the applicants.

As opposed to common perception, a PPH is not a sure-shot guarantee to the success of a patent application, but instead, it is a trade-off undertaken by the applicant. Therefore, an applicant must aim at optimising the application process to get the application approved with the maximum scope of the claim and within the least cumulative time. This is done by selecting the preferred OFF strategically. The office that poses the lowest bar to patentability and has lesser backlog shall be selected as OFF. The indirect positive global impact of this strategy is that spreading out of examination workload results in efficient usage of global resources.

However, there are certain concerns regarding the PPH framework. The biggest concern is that in a PPH arrangement, the OLE cedes its control over the examination process to the OEE. This might lead to a bifurcated patent regime in a country. However, these concerns are based on a misguided premise that OLE will blindly follow the examination result of the OEE. It is to be kept in mind that a PPH is a work-sharing program and not a result-sharing program. However, to pre-empt any such situations, it is suggested that Patent Offices mandate the examiners to follow the local substantive law in the examination. Also, a mechanism should be developed by both the offices to review the working of each other.

Harmonisation of patent law is sought to be achieved by international agreements such as TRIPS. While harmonisation has its benefits, it poses various challenges to the developing nations. The rich and poor nations have been opposed to each other on this front. PPH might be a mechanism that can lead to indirect and gradual harmonisation while providing developing nations with an adequate amount of safeguards. In order to avoid harmonisation the patent office should issue binding guidelines for examiners and review the working of the two patent offices by each other. The biggest advantage of a PPH over any global agreement is that two or three nations can easily negotiate the agreement in a way to maximise their respective interests, which is not possible in a multilateral treaty.

India's recently entered PPH program will certainly help in boosting the Make in India program, especially in a post-COVID economic order when Japanese companies are moving out of China. However, currently, the number of PPH applications is capped at 100 per annum, it is expected that the number will go up in the coming years. India should also seek to enter PPH with other countries after considering the result of the pilot PPH with Japan.

India, being one of the biggest markets in the world, needs to tread carefully in the future while entering into PPH agreements. The aspirations and needs of patent law in India are significantly

different from that of developed nations. Therefore, a concrete and comprehensive policy needs to be formed to guide the future PPH frameworks, which provide an adequate safety net to the local companies and not let it dilute the patenting thresholds envisaged by the Patents Act.