Confederation of Indian Industry

IPR Issues with Respect to Pharmaceutical Sector

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The idea of the report was conceived by Mr Satish Reddy, Chairman, Dr. Reddy's Laboratories Ltd during the CII Mission to S Korea in April 2023, on the subjects of Innovation and IP. It draws inspiration from Mr Satish Reddy's thoughts that India needs to identify key imperatives, challenges, drivers and opportunities in the IP strategies for the Pharmaceutical Sector. We would like to thank Mr Reddy for his thought leadership.

We are also grateful to Dr B Dinesh Kumar, Head, IPM, Dr Reddy's Lab for sharing his insights and comments as well as compiling the comments from the Stakeholder and preparing the draft copy of the book.

This is the 1st edition of book, and it comes to its final published form after a series of internal reviews and discussions. CII would like to specifically acknowledge the contributions of its members - Dr Mangesh Pawar, Asst. Director, Global Intellectual Property, Wockhardt Ltd.; Dr Arshad Jami, Chief IP Counsel and Global IPR Head; Dr Sumathy K, Head- R&D, Bharat Biotech International Ltd; Dr. Dinesh Kumar Sarwal, Senior Director & Head-IPR (Radiopharma), Jubilant Pharmova Ltd; and Dr P K Minocha, Director, Meril Life sciences, who worked with Mr R Saha (Senior Advisor, CII) and Ms Nabanita Mukherjee, Director CII, for coming up of this book. We would like to thank Mr Saha and Ms Nabanita Mukherjee for advising and leading the work from CII side during the content development and publication of the book. Wide span of ideas, recommendations and suggestions covered by the book, reflect the quality of extensive deliberations held by the above stakeholders and the CII Team.

It is sincerely envisaged that the book will provide useful information to the Indian Pharmaceutical sector and contribute to the setting up of a robust IP regime in India.

Foreword

Dr Naushad Forbes
Past President CII,
Chairman, CII National Committee on Intellectual Property
and Co - Chairman, Forbes Marshall

Confederation of Indian Industry (CII) has constantly worked towards a robust, impactful, and conducive IP eco system in the country, especially for Indian industry. Through the collective experience of its members, CII addresses multiple dimensions of intellectual property rights necessary for policy advocacy, developing laws, developing human resources, awarding industries for their IPR systems, and preparing reports on topics of interest.

The pharmaceutical sector is undergoing substantial expansion, and it is projected that the Indian pharmaceutical industry will surpass US$ 372 billion by the year 2022, demonstrating a remarkable Compound Annual Growth Rate (CAGR) of 22.4%. The medical device market is poised to reach US$ 25 billion by 2025. This growth reflects India's commitment to becoming a pivotal force in global healthcare, with a focus on innovation, adaptability, and a dedication to quality in pharmaceutical manufacturing. These new areas will trigger new issues in the Intellectual Property management.

The CII National Committee on Intellectual Property has produced a detailed report on "IPR issues with respect to Pharmaceutical sector", with short and long-term recommendations.

Our objective is to address the key needs of the IP ecosystem in the Indian pharmaceutical sector.

We hope you find this report useful.

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A. Background

The COVID-19 pandemic had a substantial impact on global health. This pandemic highlighted the importance of healthcare infrastructure and the important role of pharmaceutical industries to fight with COVID-19 pandemic. The Indian healthcare sector, one of the fastest-growing sectors, is expected to cross US$ 372 billion by 2022. Indian pharmaceutical sector is expected to grow at a CAGR of 22.4% soon and the medical device market is expected to grow to US$ 25 billion by 2025. India is the second-largest contributor to the global biotech and pharmaceutical workforce. The Indian pharmaceutical industry generated a trade surplus of US$ 17.5 billion in FY21[1].

Though, there is no doubt that Indian Generic Manufactures shall grow in the future and serve not only India but across the world. However, there are some challenges, which are blocking the Indian Generic Manufactures' aspirations to reach its pinnacle where they can provide affordable and innovative medicines to the world. Some broad challenges are highlighted below:

1. Lack of specific timelines in IPR procedures
2. Slow-Moving IPR Litigation
3. No clarity on Stockpile
4. Cumbersome NBA approval requirements for inventions using biological resources obtained from India
5. Revision/ New Guidelines
6. Inadequate features on IP India Website for performing searches
7. Restricted scope of research exemption (Bolar provision) in certain countries- Ukraine, Russia and Brazil

1 Pharmaceuticals Industry Report (June 2022) published on (Assessed on 09 Sep 2022)

B. Identified issues by stakeholders

1. Lack of specific timelines in Intellectual Property Rights (IPR) procedures /disputes

a. TRIPS Agreement and Section 3(D)

IPR plays a pivotal role in safeguarding the interest of its creator. They are not only promoting innovation and creativity but also ensure ease of doing business. It is a need of an hour to grant the IPR in a speedy manner.

The TRIPS Agreement, which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on Intellectual Property. The areas of intellectual property that it covers are Copyright and related rights (i.e., the rights of performers, producers of sound recordings and broadcasting organizations); Trademarks including service marks; geographical indications including appellations of origin; industrial designs; patents, the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data.

India amended the Patents Act, 1970 three times from 1995 to comply with the norms of TRIPS:

- The Patents Amendment Act (1999) [w.e.f: 01-01-1995]
- The Patents Amendment Act (2002) [w.e.f: 20-05-2003]
- The Patents Amendment Act (2005) [w.e.f: 1-1-2005]

After the final amendment of the Patent Act in 2005, India began to allow pharmaceutical product patents per se. The Indian government also inserted Section 3(d) as one of the patent eligibility criteria in the Patent Act.

Importantly, Novartis Ag vs Union of India & Ors[2] noted the following about Section 3(d) spirit for pharmaceutical patents:

"103. We are clearly of the view that the importance of the amendment made in section 3(d), that is, the addition of the opening words in the substantive provision and the insertion of explanation to the substantive provision, cannot be under-estimated. ***It is seen above that, in course of the Parliamentary debates, the amendment in section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable.*** *We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant specially to deal with chemical substances, and more particularly pharmaceutical products.*

2 Novartis v. Union of India & Others (2013) SCC, Civil Appeal No. 2706-2716 of 2013

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."

Thus, it is recommended to maintain the same spirit of section 3(d) and not to amend its original scope.

b. Lack of specific timelines for disposing of the Patent Applications

According to the press release of the Ministry of Commerce & Industry dated 12 April 2022[3], filing of patents increased by more than 50% in the last 7 years and a nearly five-fold increase in the grant of patents 2021-22 as compared to 2014-15. Further, reduction in the time of patent examination from 72 months in Dec 2016 to 5-23 months at present, for different technological areas.

There is no doubt that the Indian Patent office is really improving in the speedy disposal of the patent application. However, there is a scope for improvement in the same.

There is no mandatory timeline for the controller to refer the application after the request of examination is filed. Specifically, according to Indian Patent Rules, 24 (2) (i)[4], the Controller shall refer to the first patent application in the order in which the request for examination is filed. Thus, the grant of patent application will be dependent on the backlogs of pending examinations. It is recommended to take the necessary steps for clearing the backlogs. If required, more quality examiners can be recruited for providing faster examinations on the same.

It is also recommended to create a detailed one-year training plan for the new patent examiners with industrial training of 1 month to provide a better overview and competency for analyzing the patent applications.

c. Disposal of the Patent applications

It has been observed that even if First Examination Report (FER) is provided in a timely manner and after submitting its response by the applicant, the subsequent process of a hearing has become very slow. The Patent rules 24 (C)(12)[5] provides strict timeline of three months from the last date to put the application in order for grant. However,

3 (Assessed on 10 Sep 2022)

4 (2) (i) Where the request for examination has been filed under sub-rule (1) and application has been published under section 11A, the Controller shall refer the application, specification and other documents related thereto to the examiner and such reference shall be made in the order in which the request is filed:

Provided that in case of a further application filed under section 16, the order of reference of such further application shall be the same as that of the first mentioned application:

Provided further that in case the first mentioned application has already been referred for examination, the further application shall have to be accompanied by a request for examination, and such further application shall be published within one month and be referred to the examiner within one month from the date of such publication.

(ii) The period within which the examiner shall make the report under sub-section (2) of section 12, shall ordinarily be one month but not exceeding three months from the date of reference of the application to him by the Controller;

(iii) the period within which the Controller shall dispose off the report of the examiner shall ordinarily be one month from the date of the receipt of the such report by the Controller.

5 (12) The Controller shall dispose of the application within a period of three months from the date of receipt of the last reply to the first statement of objections or within a period of three months from the last date to put the application in order for grant under section 21 of the Act, whichever is earlier:

Provided that this time limit shall not be applicable in case of pre-grant opposition.

it is rarely followed. **It is recommended to take the necessary steps for improving the disposal rate at this front.**

The controller's order can be appealed before a High Court. If the High Court remands back the case to the Patent Office controller, then the patent/ application go to the same controller for examining it afresh. **It is recommended that if the patent/ application is remanded back to the patent office then a different set of the patent examiners and the controller must be assigned for more transparency and fairness in the system. If required, the controller and examiner from different patent offices can be appointed.**

Thus, it is recommended to take the necessary steps for a speedy disposal of the patent applications and take necessary steps for more fairness and transparency in the system.

d. Lack of specific timelines for disposing of Pre-grant oppositions/post-grant oppositions

The Indian Patent Act allows to challenge the pending patent application and granted patent by filing an opposition before the patent office. There are two types of oppositions viz pre-grant oppositions and post-grant oppositions. A pre-grant opposition can be filed by any person before the grant of a patent and a post-grant opposition can be filed by any person interested after the grant but within one year from the publication of the grant. The main role of the pre-grant opposition is to help the patent examiner for considering all kinds of the prior arts before granting. It has been observed that there is no specific timeline for filing pre-grant opposition. Any person can file any time before the grant.

An article[6] (Rathod, S.K. (2022)) published in Access to Medicines and Vaccines (2022), provided the data related pre-grant oppositions in India between 2007-2020. According to the data, the annual pre-grant opposition disposal rate has not kept pace with the trend of increased patent application filings, or the number of examiners inducted, nor it has matched the pace of increase in new opposition filings.

The following Fig 1 provides the pre-grant opposition data:

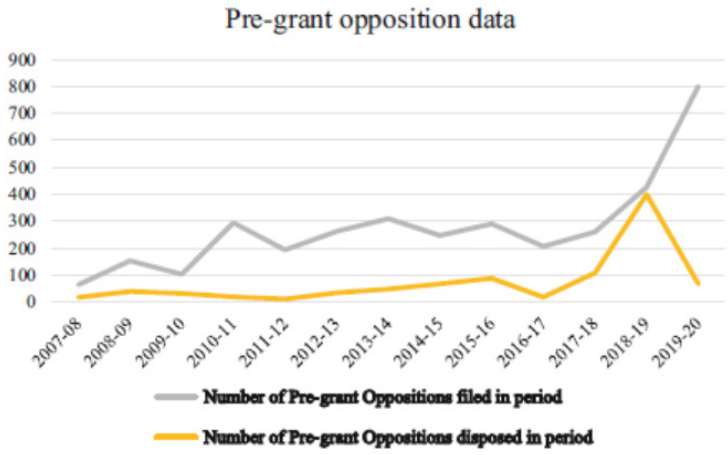

Fig. 1 Pre-grant opposition data 2007–2020

6 Rathod, S.K. (2022). Patent Oppositions in India. In: Correa, C.M., Hilty, R.M. (eds) Access to Medicines and Vaccines. Springer, Cham.

Section 25(1) of the patent act allows any person to file pre-grant opposition at any time. There is a problem with “any time” before the grant as some opponents file opposition at any time even after the competition of controller’s examination hearing or controller has reserved the judgement. For example, 1920/DELNP/2015, two pre-grant oppositions were filed in 2019 but till now there is no decision on the oppositions, though the patent application term of 20 years expired in May 2022”).

Thus, it is recommended to create a specific timeline for filing the pre-grant opposition(s) to make the system more predictable. For example:

A. A specific time-period of 6 months from the date of issuance of first examination report (FER) can be put as cut-off date for filing any pre-grant opposition(s), so that the controller will get views from opponent(s).

B. The controller must notify the applicant within 1 months from the filing of pre-grant opposition(s).

C. The applicant must file response within 1 month from the receiving date of controller notification.

D. The controller can fix a hearing within 2 months from applicant’s response.

E. The controller can proceed for grant or reject the patent application, ordinarily within 2 months from the competition of above proceeding.

F. Hence, it is recommended to dispose of any pre-grant opposition within one year time frame.

Rathod, S.K. (2022) also provided the data related post-grant oppositions in India between 2007-2020. According to the data, the annual post-grant opposition disposal rate (Disposal rate is a rate by which post-grant opposition will be disposed of by the patent office in a year.) has also not kept pace with the filing. It has been observed that the filing of post-grant oppositions is increasing, but they are kept idle without disposal. Instead of no link between patent filing and oppositions, there has to be a faster disposal rate. For example, a post grant opposition was filed in 2011 for IN244233, but till date it has not been disposed of. Thus, it is recommended to create a specific timeline for disposing of the post-grant oppositions say 6 Months-1 year from the filing of post-grant opposition.

In view of the above, it is recommended to create a ‘specific timeline’ for filing the pre-grant oppositions and its disposal timeline to make the system robust and predictable. Further, it is recommended to create a ‘specific timeline’ for disposing of the post grant opposition.

2. Slow-Moving IPR Litigation

a. Intellectual Property Appellate Board (IPAB) Abolishment

On 15 Sep 2003, Intellectual Property Appellate Board (IPAB) constituted to bring the best set of expertise in the IP regime through technical members. Though, IPAB was created with huge expectation, but it was non-functional on account of lack of technical manners for about 1130 days[7]. This led to pendency and delay of matters. The President promulgated the Tribunals Reforms (Rationalization and Conditions of Service) Ordinance, 2021 to dissolves various tribunals, including the IPAB, and transfers their functions to judicial bodies. The major reasons include that the board has not led to quicker delivery of justice and has failed at optimistic reduction of burden. As per the order in Mylan vs UOI (2019)[8], there are following cases were pending with IPAB.

Details of Pending Cases

S. No.	Subject of Cases	No. of Cases Pending as on 23/05/2019
1.	Trademark	2626
2.	Patent	617
3.	Geographical Indication	01
4.	Copyright	691

After abolishment of IPAB, all pending cases would be listed before the High Courts. The number of pending cases are huge, and these cases again would burden the overloaded High Courts.

Thus, it is recommended to create a "Patent Appellate Board" within patent office as original jurisdiction for appeal matters (as defined under Section 117A of the patent act). The Patent Appellate Board can be chaired by the two controllers. An appeal system is always beneficial to justice delivery and many countries have in place such a system. For example, Europe has "Board of Appeal[9]" where an appeal can be filed against decisions of the departments of first instance of the European Patent Office (EPO).

After abolishment of IPAB, now High Court is the original jurisdiction to file the revocation petition under section 64 of the Patent Act. The proceeding before High Court is costly and slow due to lot of procedural issues. Thus, it is also recommended to allow revocation petition before the patent Office, like New Zealand[10] to dispose of the matter speedily and inexpensively. It is felt that an appeal system is always beneficial to the justice delivery and many countries have such a system in place. An alternative system may think of and put in place even if it requires an amendment to the law.

7 The Case for Shutting Down the Intellectual Property Appellate Board (IPAB) | SpicyIP

8 Mylan Laboratories Limited vs Union Of India & Ors on 8 July, 2019 (indiankanoon.org)

9 https://www.epo.org/law-practice/case-law-appeals.html

10 NZ patent Act 2013, Section 112 Revocation of patent

"(1) The Commissioner or the court may, on an application under this section, revoke a patent on any of the grounds set out in section 114.

(2) An application under this section may be made by any person.

(3) An application to the Commissioner under this section must be made in the prescribed manner (if any).

b. Requirement felt for creation of IPD" division in each High Courts

PR litigation has significantly evolved in the last decade. Among the various high courts in India, the Delhi High Court has maximum no of IPR litigations[11]. In Feb 2022, the Delhi High Court created the Intellectual Property Division ("IPD") in the Delhi High Court to deal with matters relating to Intellectual Property Rights ("IPR"). IPD is created to provide for procedures and mechanisms for simpler, effective and efficient adjudication of such patent litigations before the Delhi High Court. In May 2022[12], the Department Related Parliamentary Standing Committee on Commerce has recommended the Central Government to take measures to set up Intellectual Property Division (IPD) in various High Courts, in line with the establishment of IPD in the Delhi High Court, following the dissolution of the Intellectual Property Appellate Board (IPAB). Indeed, the creation of IPD Delhi is a progressive movement for providing exclusive benches to deal with IPR litigation. However, it is need of an hour to create a "IPD" division in each High Courts for the same.

The one of important aspects of IPR litigation is a time bound conclusion of disputes. It has been observed that the disposal of IPR disputes is significantly delayed. Lately, for the patent infringement cases between 2005-2015[13], there were only 5 litigations out of 143 litigation where judgments were delivered by the High Courts after the conclusion of trial. These figures are scary. There is a famous legal maxim- "Justice delayed is Justice denied".

The speedy disposal of IPR litigation is utmost important for the Indian generic/biosimilar manufacturer as it will enable them to take predictable decisions. For example, in Apixaban product, Bristol Mayer Squibb (BMS) filed a patent infringement suit against Emcure Pharmaceutical, and the Single Bench granted an injunction[14] on 12 Dec 2019. Emcure appealed the decision[15] in Dec 2019, but there is no decision on merit till the expiry of the suit patents viz. 17 Sep 2022. And finally, the generic player withdrew their appeals on 06 Oct 2022[16]. These delayed adjudications make Indian generic manufacturer helpless. To overcome this issue the cases can be prioritized based on remaining drug patent life, where the drug patent is close to expiry can be considered as top priority. Recently, High Court of Delhi Rules Governing Patent Suits, 2022, realized the importance of summary adjudication in cases where the remaining term of the patent is 5 years or less[17].

In last decade, there are several patent litigations in India for pharmaceutical products. However, there is no clear jurisprudence available on Markush claims, interpretation of product by process claims in infringement cases, selection inventions and the like. In 2013 Novartis v. Union of India & Others[18] provided guidance on section 3(d). Though,

11 https://spicyip.com/2017/06/143-patent-infringement-lawsuits-between-2005-and-2015-only-5-judgments.html

12 http://www.pharmabiz.com/NewsDetails.aspx?aid=150902&sid=1

13 https://spicyip.com/2017/06/143-patent-infringement-lawsuits-between-2005-and-2015-only-5-judgments.html

14 CS (COMM)-684/2019

15 FAO(OS) (COMM) 377/2019

16 Status of FAO(OS) (COMM) 377/2019 and other appeals checked on the Delhi High Court website () on 19 Oct 2022.

17 See Rule 16 of High Court Of Delhi Rules Governing Patent Suits, 2022 (233727.pdf (egazette.nic.in))

18 Civil Appeal No. 2706-2716 of 2013

almost nine years have been passed from the Novartis, and section 3(d) applicability is still not crystal clear for different types of pharmaceutical inventions.

The slow-moving IPR litigation are acting as roadblocks in the success journey of Indian generic/biosimilar manufacturer. It is urged to create specific IPD in all the high courts with time bound timelines for speedy disposal of cases.

3. No clarity on Stockpile

The patent monopoly is granted for a limited period. After the expiry of the patent, the patented invention can be exploited commercially. Generally, pharmaceutical product preparation is a several steps process and requires several months for commercially manufacturing the product. If any generic company wants to launch the product on the first day after the expiry of the patent, then it must require some activities performed during the term of patent. Stockpile is an "early working exception" to patent rights--in other words, that allows a third party to use a patented invention during the term of patent protection, as long as the use is for obtaining regulatory approval of an equivalent product to be sold once the patent expires. Section 107A(a) of the patent act is silent about stockpiling of drugs. The stockpiling of drugs in anticipation of patent expiration was not considered as valid practices under the WTO ruling involving the Canadian Bolar provision that allowed a stockpiling exception six months prior to the expiry of the patent. It is recommended to allow stockpiling of patented products 6 months prior to patent expiry. If required, the generic companies can inform the Innovator before doing so to safeguard their interest. There is an interesting case[19] related to drug Pazopanib, where court agreed to hear the matter on stockpile. As a result of this, there will be a delay in launching the product even patent expires as the Indian industry require some time (in months) for commercially manufacturing the product. Further, foreign non-patented countries companies can import the product into India for the day-1 launch, wherein Indian industries will be in the process of manufacturing the product and miss the Day-1 launch.

Department Related Parliamentary Standing Committee on Commerce Eighty Eighth Report on Patents And Trademarks Systems in India, presented in the Rajya Sabha on the 24th October 2008.[20] The 'introduction part' of the above report mentioned the following for the scope of Bolar provision:

"Bolar Provision: Those interested in manufacturing generic version of a patented product on expiry of the patent can make necessary preparations for production even during the validity of the patent (Section 107). This provision facilitates availability of generic version of the patented product at competitive prices immediately on expiry of the patent."

In view of the above, the intent of the legislature, while adopting 107A, maybe not stop for the day-1 launch after the expiry of the patent. If the stockpile would not be allowed, then the generic entry of the product would be delayed for several months.

Thus, it is recommended to provide clarity on stockpile provisions.

19 CS(COMM)-370/2021, order dated 18 May 2022

20 http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Commerce/88th%20Report.htm

4. Cumbersome NBA approval requirements for inventions using biological resources obtained from India

The invention related to any research or information on a biological resource obtained from India requires the permission from National Biodiversity Authority (NBA). The purpose of India's Biodiversity Act 2002 (BD Act) is to conserve the rich biodiversity of the country.

NBA is responsible for access and benefit sharing, approval for access to and transfer of biological resources, results or technology of scientific research to foreign citizens, companies or non-resident Indians and several other matters related to conservation of India's biodiversity. The BD Act insists upon appropriate benefit sharing under mutually agreed terms related to access and transfer of biological resources or knowledge occurring in or obtained from India for various purposes.

The relevant provisions under the Indian Patent Rules, and the BD Act are:

Provision	Purpose
Section 10(4)(d)(ii) Of Indian Patents Act, 1970	Suitable amendments were made in the Indian Patent Act in 2005 for mandatory disclosure of the source and geographical origin of the biological material in an application for patent when the said material is used in an invention.
A declaration in Form 1 of the Indian Patents Rules, 2003.	While applying for a patent in India, the patent applicant needs to give the declaration that if the invention as disclosed in the specification uses the biological material from India, then the necessary permission from the competent authority shall be submitted before the grant of patent.
Section 6 of BD Act	Section 6[21] of the BD Act came into force on 1st July 2004, and prescribes that obtaining IPRs from the utilization of biological resources in India is subject to the approval of the National Biodiversity Authority (NBA).[22].
Form III[23] under BD Act	The Form III is for applying for Intellectual Property Rights for inventions based on any research or information on a biological resource obtained from India.

Form III compliance is required for commercial exploitation of the biological resource(s) or parts thereof, originating from India. However not all R&D projects get translated into commercial products, and hence signing such a form on access and benefit sharing, right upfront when a patent is filed from R&D activities should be reviewed further.

NBA mandates royalty payments on commercial products developed from any biological resource originating from India including microorganisms and viruses. There is another

21 No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of National Biodiversity Authority before making such application; provided that, if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned; provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof."

22 https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf

23 http://nbaindia.org/uploaded/pdf/guidelines/Guidelines_for_filling-up_of_Form-III.pdf

govt. agency which of late has mandated royalty payments for any help rendered in product development by the private manufacturer, which could be as trivial as performing a pre-clinical assay or assays during clinical development. Any duplication of royalty payments to Govt. of India through more than one agency should be done away with.

When a PCT application is filed, and if the patent is granted outside India prior to NBA approval, objections are raised by NBA on grant of ex-India patents. The NBA should consider filing date of application, and if possible, NBA approval should be deemed as granted if the delay is more than 60 days from the date of filing the application.

NBA approval is becoming challenging as this is a cumbersome and lengthy process. Making it a mandatory prerequisite to the grant of a patent contributes to delays in securing a patent successfully. This has become a pain point for every biotechnology company.

Thus, in view of the above it is recommended to take substantial steps in modifying NBA approval process and in particularly the declarations in Form III.

5. Revision/ New Guidelines

The website[24] of Intellectual Property Rights provides various guidelines on patents, trademark, and geographical indications. On perusal of the patent's guidelines, it is found that there are very old examination guidelines of patent application available for pharmaceuticals[25] (2014) and biological inventions[26] (2013). It is need of an hour to provide the latest guidelines for pharmaceutical and biological inventions to understand the position of the patent office on the patentability criteria.

The updated guideline can provide the guidance- "whether Lead compound analysis is required for product patent in India or not"? Or What is the scope of derivatives in section 3(d)? Only one change will be considered for derivatives under section 3(d)? Whether known substance should have known efficacy under section 3(d) or structural similarity for the same indication would be considered? We have observed that the patent applicant is using these decisions for arguing patentability of the invention. For example, in IN4412/DELNP/2007[27], Novartis was rebutting the pre-grant oppositions by citing the above Erlotinib decision and got the granted patent. Thus, there is a need to understand the view of the patent office in these decisions for analyzing inventive step.

The inventions related to radiopharmaceuticals are often objected under secrecy directions, and their review process takes longer time. This delay in the review period, the impacts on international collaborations.

Thus, it is recommended to create a guideline on radiopharmaceuticals to clear the doubts of the applicant.

Section 8 of the Indian Patents Act, relates to 'Information and undertaking regarding foreign applications' and consists of two mandatory requirements:

24 https://ipindia.gov.in/index.htm

25 https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

26 https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf

27 Controller decision- 14 Dec 2022

Sec.8(1). submission of information pertaining to corresponding country outsideations along with an undertaking that up to the date of grant of patent in India, Controller would be informed in writing, from time to time, detailed particulars in respect of any application filed in a country outside India by way of Form 3 on voluntary basis, within six months from the filing date of the application or within six month from the date of filing the application in the foreign country and Sec. 8 (2). submission of documents pertaining to processing of application in other Foreign Patent offices and especially in relation to aspects relating to patentability of the invention on request of the Controller within six month from such request of the Controller.

Failure to disclose this information makes the grounds for:

a. Pre-grant opposition under Section 25(1) (h) of the Act,

b. Post grant opposition under Section 25(2) (h) of the Act, or

c. Revocation under Section 64(1) (m) of the Act.

To the best of our knowledge there are no guidance available from the patent office on fulfilling the requirement under Section 8. Some patent applicants are giving a lot of information and some applicants are taking exception due to lack of specific guideline. There are some case laws around the same, but it recommended to create a specific guideline for compliance of Section 8.

It is also recommended to take in account of any new case laws provided in last five years for creating/ revising the guidelines.

6. Inadequate features on IP India Website for performing searches[28]

The IP India website provides information about the status of patents, trademarks, design, and Geographical Indication. There is no doubt that the IP India website improved a lot in the last decade. However, there are a lot of development still pending like:

a. *Incompetent Prior Art Search Facility:* A Prior Art search related to patents is important for the evaluation of any purported innovation. The prior art search is easy on US and EP websites. However, we have observed that the search results on inPASS[29] are not complete or their capabilities are limited in term of search criteria. It is recommended to improve the website and make it user-friendly. We should develop a portal in the lines of USPTO or EPO.

b. *Unavailability of granted patents/applications on public databases like Espacenet [30]or google patents*[31]: On performing searches on public databases like Espacenet or google patents, we get patent family details for most of the countries. However, it has been identified that most of the family details does not includes Indian equivalent(s). Thus, it is recommended to take necessary steps for the availability of Indian equivalents on public databases.

28 https://ipindia.gov.in/

29 https://ipindiaservices.gov.in/publicsearch

30 https://worldwide.espacenet.com/

31 https://patents.google.com/

c. *Limitation in downloading Prosecution History on inPASS:* Once the patent applicant files the patent application, then it is published and the communication between the patent applicant and the patent office started. The inPASS provides communication between the patent applicant and the patent office (commonly referred to as prosecution history) on the website. However, downloading the prosecution history in 'a single-click' is not possible, which is possible for US and EP. Due to the unavailability of this feature, the public has to download each communication one by one, which takes substantial time.

Thus, it is recommended to give 'the single-click' feature for downloading the prosecution history in chronological order.

Non-Publication of granted Patents: In most countries, the patent office's publishes both patent applications, and granted patents separately. However, inPASS publishes only granted patent number but not a single granted patent document for the reference and perusal. The interested person must find the last amended claims on inPASS as the granted claims or have to request from the patent office. The current practice is creating confusion in the mind on the scope of any granted claims unless it is cross-checked from the patent office.

Thus, it is recommended to publish the granted patent with claims for clarity.

7. Restricted scope of research exemption (Bolar provision) in certain countries- Ukraine, Russia, and Brazil

A granted patent creates negative rights by which the patentee can stop others from making, using, selling, importing, offering to sale the patented invention. While granting of a patent provided the monopoly to the patentee, there are certain exceptions to it. The one of the exceptions allows to use the patented invention for development and submission of information to a drug approval authority. This is called Bolar exemption. The exemption was so named after the landmark US case Roche Products v Bolar Pharmaceuticals, wherein it was held that Bolar's use of the patented compound for government mandated testing was an infringement of the patent. However, soon after this judgment, the US Congress overturned the decision by enacting a law permitting the use of patented inventions in research to seek Food and Drug Administration approval.

The Bolar exemption in India is broader in terms of scope of coverage and provides greater liberal provision(s) when compared to its counterparts. When viewed from the perspective of the definition of S.107A of the Act ,'.....development and submission of information required under any law for the time being in force in India or in a country other than India....'; since the clinical trials and marketing approvals/ marketing authorization application would come under information required under the Indian Drug regulations viz. Drugs and Cosmetics Act, 1940 and Rules, 1945, it would be safe to interpret that generic manufacturers can use this pathway for clinical development (conduct of clinical trials) and filing of marketing authorization applications for their generic products of Invented Drugs / Patent Protected Drugs.[32]

In accordance with Article 30 of TRIPS agreement, many countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval. However, in some countries it has been observed that bolar provision scope is not clear.

32 https://www.mondaq.com/india/patent/691036/bolar-exemption-in-india

Brazil: In Brazil, the patent act does provide the right to keep generic manufacturer ready before actual expiry of the patent, but due to regulatory guidance's, the generic players are facing patent infringement suits. In Brazil, the patent act, article 43, Item VII[33] of Industrial Property Law N° 9279/96 allows generic manufacturer to take the approval of the product during the term of the patent. But, due to regulatory guidance's under Article 12 (8) (item II) of Law 6360/1976[34] , the generic players are facing patent infringement suits. Under Article 12 (8) (item II), the generic players must market the approved product for at least the time corresponding to the final two thirds of the validity period of the registration. If the generic players do not launch the product in the final two thirds, then the registration shall not be re-validated.

Russia: Russian law does not expressly provide for the Bolar provision. However, there are some general provisions which are close to the idea of a Bolar exemption. According to Art. 1359 (2) of the Russian Civil Code[35] of the Russian Federation, carrying out scientific studies on a patented product or method, is not deemed a patent infringement. However, under Article 32(8)[36] and Article 34(13(3))[37] of Federal Law of Circulation of medicines, API or medicinal product shall be cancelled if the product is not on sale after three years from the registration. Thus, if any generic players take the approval prior to three years from the expiry of the patent can face patent infringement suits.

Ukraine: In Ukraine, bolar provision is implemented by the Law of Ukraine "On Elimination of Artificial Bureaucratic Barriers and Corruption Factors in the Sphere of Healthcare" ("Law"), which entered into force on 5 July 2020. The Law introduced Bolar related amendments to the Law "On Protection of Rights for Inventions and Utility Models" ("Patents Law"). Specifically, article 31 (5) of the Law of Ukraine dated December 15, 1993, No. 3687-XII[38] deals with Bolar provision. The Law does not refer to the type of application/marketing authorization. Thus, theoretically import of a patented product and its use in the studies conducted for the purpose of preparing and submitting regulatory information for marketing authorization

33 Article 43, Item VII - to acts practiced by unauthorized third parties related to the invention protected by a patent, for the sole purpose of producing test results, information and data in order to obtain the commercialization registration in Brazil or abroad for the exploitation and commercialization of the product that is the subject matter of the patent, after expiration of the terms set forth in article 40. (Item included by Law n° 10.196, of 2.14.2001)

34 L6360 (planalto.gov.br)

Art. 12, § 8 item II

Art. 12 - None of the products dealt with in this Law, including those imported, may be industrialized, exposed for sale or delivered for consumption before being registered with the Ministry of Health.

§ 8 the - shall not be revalidated registration:

I - of the product not classified as a medicine that has not been manufactured in the period of validity of the expired registration;(Included by Law No. 13,411 of 2017)

II - the medicine that has not been marketed for at least the time corresponding to the final two thirds of the validity period of the expired registration

35 Actions Not Deemed an Infringement of the Exclusive Right to an Invention, Utility Model or Industrial Design: "the carrying out of scientific research of a product or method in which the invention or utility model is used or of scientific research of an article in which the industrial design is used or the carrying out of an experiment in respect of such product, method or article".

36 Article 32 (8) of the Law stipulates that a registered medicinal product may be excluded from the State Register if the product is absent on the market for three or more years.

37 Article 34 (13(3)) of the Law stipulates that a pharmaceutical substance (API) may be excluded from the State Register if this substance, produced for sale, is absent on the Russian market for three or more years.

38 "On Protection of Rights to Inventions and Utility Models" (the "Patent Law" – as amended in 2020):

"Importation of goods, manufactured using an invention (utility model), into the customs territory of Ukraine for the purposes of research and/or use of invention (utility model) in research conducted to prepare and submit information for marketing authorization of a medicinal product, is not considered violation of patent rights".

of another original medicinal product fall under the domestic version of the Bolar provision. At the same time, the complete lack of any judicial practice leaves a significant room for possible future interpretations[39].

It is apparent from the above that at least in the above countries, the scope of bolar exemption is not clear. The Indian generic manufacturer tries to file the medicinal product dossier in most of the geographies together to avoid approval data generation at different intervals. However, due to the above blocks, they have to wait for filing the dossier, unless they will face notice letters and infringement suits.

39 https://cms.law/en/int/expert-guides/cms-expert-guide-on-bolar-provisions/ukraine

C. Long Term and Short Term Recommendations to be consider by

The Indian Patent Office

Short term

- Strict timeline should be followed for disposing pre-grant oppositions and post-grant oppositions.
- Latest/new guidelines for pharmaceutical, biological inventions, radiopharmaceuticals to understand the current position of the patent office on the patentability criteria's considering recent courts jurisprudence.
- Amplify features on IP India Website (like searches and download of prosecution history). Publication of the granted patent.

Long term

- "Patent Appellate Board" (like EP) within patent office must be created as original jurisdiction for appeal matters (Section 117A of the patent act).
- Revocation petition should be allowed to file before the Patent Office (like New Zealand and China) in addition to the courts.
- Expediate National Biodiversity Authority (NBA) approval process to secure the grant of patent in speedily manner.
- Qualified Patent examiner must be recruited for providing faster examinations (provision of pharmaceutical industrial experience must be explored).

The Indian Courts

- **Short term:** Minimum roaster change in IPD division.
- **Long term:** Strict timeline should be followed for disposing of revocation petition, infringement suits and declaration of non-infringement.

The Central and State Government

- **Short term:** IPD division (like Delhi) must be created in other High Courts for hearing IPR disputes with specialized IP judges.
- **Long term**
  - Stockpile should be allowed to launch on Day-1 of the patent expiry.
  - Suggestion for Compatible Bolar Provisions in Ukraine, Russia and Brazil.

Confederation of Indian Industry

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering Industry, Government and civil society, through advisory and consultative processes.

CII is a non-government, not-for-profit, industry-led and industry-managed organization, with around 9,000 members from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 300,000 enterprises from 286 national and regional sectoral industry bodies.

For more than 125 years, CII has been engaged in shaping India's development journey and works proactively on transforming Indian Industry's engagement in national development. CII charts change by working closely with Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness and business opportunities for industry through a range of specialized services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

Extending its agenda beyond business, CII assists industry to identify and execute corporate citizenship programmes. Partnerships with civil society organizations carry forward corporate initiatives for integrated and inclusive development across diverse domains including affirmative action, livelihoods, diversity management, skill development, empowerment of women, and sustainable development, to name a few.

As India strategizes for the next 25 years to India@100, Indian industry must scale the competitiveness ladder to drive growth. It must also internalize the tenets of sustainability and climate action and accelerate its globalisation journey for leadership in a changing world. The role played by Indian industry will be central to the country's progress and success as a nation. CII, with the Theme for 2023-24 as **'Towards a Competitive and Sustainable India@100: Growth, Inclusiveness, Globalisation, Building Trust'** has prioritized 6 action themes that will catalyze the journey of the country towards the vision of India@100.

With 65 offices, including 10 Centres of Excellence, in India, and 8 overseas offices in Australia, Egypt, Germany, Indonesia, Singapore, UAE, UK, and USA, as well as institutional partnerships with 350 counterpart organizations in 133 countries, CII serves as a reference point for Indian industry and the international business community.

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