



The importance of pre-grant patent oppositions in increasing access to medical products

In June 2022, the Economic Times reported that India's Economic Advisory Council (EAC)¹ to the Prime Minister recommends the period within which patent applications are open to challenge by the public be restricted to a mere six months from the date the patent claims are published.¹ The suggestion was made to stakeholder ministries and departments, including the Department for Promotion of Industry and Internal Trade (DPIIT), responsible for administering the Indian Patents Act and managing the Indian Patent Office (IPO).

Considering the vital record of patent oppositions in India and how they have helped ensure the affordability of medicines, the advice could end up undermining this important health safeguard that helps to preserve generic competition from India. In the context of lifesaving and essential medical products, our experience has shown that patent oppositions in India have successfully prevented undeserved patent monopolies, allowing timely generic production and supply to bring the price of medicines down for patients and health programmes both in India and across the world.

This FAQ provides details on the patent opposition mechanism and its role as a critical public health safeguard under the Indian Patents Act. It focuses on third-party opposition at the stage where a patent application is under examination by the IPO.

1. What is a pre-grant patent opposition?

Monopolies granted by patents on medical products keep prices high and block local manufacturers from supplying low-cost generic drugs. As India is a key supplier of affordable generic medicines, decisions made by the IPO can negatively impact generic competition and supply worldwide.

In 2005 Indian lawmakers from all political parties – supported by civil society globally – ensured that the IPO did not grant monopolies on old science or for compounds already in the public domain.ⁱⁱⁱⁱⁱⁱ The law is in place to stop pharmaceutical corporations from indulging in ‘evergreening’, a common abusive patenting practice aimed at filing and obtaining separate patent monopolies relating to different aspects of the same medicine to preserve the market monopoly of the patent holding companies.²

To bring ‘evergreening’ to the notice of the patent examiners, India's patent law allows any person to file a pre-grant opposition ‘anytime’ before the decision to grant or reject is made by the IPO. In a

¹ The EAC is an independent body constituted to give advice on economic and related issues to the Government of India; <https://eacpm.gov.in/>

² Filing numerous patent applications for the same medicine (evergreening) is a common practice in the pharmaceutical industry to try to delay the market entry of affordable generic medicines. Therefore, in addition to filing for a patent on a new therapeutic compound, pharmaceutical corporations routinely try to obtain patents on derivatives (salts, prodrugs, crystals, polymorphs); formulations (e.g. powders, tablets and capsules, injectables, syrups, dispersible tablets, etc.); dosage (route, regimen); combinations (e.g. a fixed-dose combination when different drugs are combined in the same pill); and new use of an existing drug to extend the period of their monopoly over price and supply. Also see: <https://msfaccess.org/evergreening-drugs-attack-access-medicines>

nutshell, a pre-grant patent opposition is a legal challenge to the validity of an unmerited patent application.

Section 25(1) of the Patents Act, 1970 allows *any person* to file an opposition to a patent application at *any time* before a decision to grant or reject a patent is made by the Patent Controller. The current mechanism allows any person to bring relevant information to the notice of the IPO, which can be further used to assess the patentability of a claimed invention as per the law. The pre-grant opposition is an aid to the IPO's examination process.

Since the IPO receives an average of 50,000 patent applications a year and the total number of patent examiners is under 900, examiners may miss critical information about the patent application under consideration.^{iv,v} This 'miss' becomes very important if the application in question pertains to essential drugs/pharmaceuticals in the health system. A recent study on India's pharmaceutical patent grants revealed that the IPO granted seven out of 10 patents in error between 2009 and 2016.^{vi}

A robust pre-grant opposition system provides an important layer of scrutiny that prevents the granting of evergreening patents through third parties' participation in the review process. Allowing any person to launch a pre-grant opposition also ensures sufficient public scrutiny and balance in the system.

Box 1: Impact of pre-grant opposition on prices of cancer medicine imatinib in India

In 2005, a cancer patient group, the Cancer Patient Aid Association (CPAA), filed the first pre-grant opposition before the IPO to a pending patent claim on imatinib mesylate, a lifesaving drug for treating chronic myeloid leukaemia.

Imatinib mesylate (Gleevec) is the salt form (mesylate) of an older medicine, imatinib. CPAA highlighted that the Swiss corporation Novartis's patent application on the selection of salt/ crystalline form (mesylate) of the active ingredient (imatinib) is a common practice within the pharmaceutical industry and should not be considered patentable. The IPO subsequently rejected the patent application.

The rejection of the patent claim by the IPO was upheld by the Madras High Court and the Supreme Court of India. The pre-grant opposition by CPAA on the cancer drug aimed to protect the existing price reduction from over INR 1,400,000 (US\$32,000) per patient per year from Novartis to less than INR 90,000 (\$2000) per patient per year from generic manufacturers. The decision helped advance access to generic imatinib for Indian cancer patients by many years, as the grant of the frivolous application would otherwise have resulted in a monopoly until 2017.

However, in the United States – where patents are granted easily on obvious forms of known medicines – the patent monopoly on the drug lasted nearly 30 years. The price of patented imatinib (Gleevec) rose to \$92,000 per patient per year during that period.^{vii}

2. What is the suggestion by the EAC and its basis regarding pre-grant oppositions? Is it justified?

It was reported in the media that the EAC has suggested a limited six-month timeline for filing pre-grant oppositions from the date of publication of the patent. This move, if confirmed, will severely cut short the timeframe in the current arrangement, where an opposition may be filed ‘any time before the grant’.

The EAC has made this recommendation to address delays in patent examination. However, restricting the timeframe for pre-grant opposition will not impact pendency unless systemic issues around examination are also addressed.

As per data released by the IPO, while around 50,000 patent applications are examined annually, nearly 400 pre-grant oppositions (across all categories) are filed each year.^{viii} Thus, less than 1% of all patent applications actually face a pre-grant proceeding. The delay in disposing of patent applications should not be attributed to the small number of pre-grant oppositions. In any case, fixing a term for filing pre-grant oppositions will not address the issue of delay in adjudication, as patent examination will continue with or without any opposition.

To further justify the timeline on pre-grant oppositions, the EAC compares the number of granted patents in India to that of the United States (US) and China. Such a comparison is unjustified considering the large quantity of patent applications filed and granted does not correspond to quality of granted patents in the US and China.^{ix,x,x} In fact, in recent years, the Chinese government has been addressing the issues of quality of patents, including those related to the excessive number of patents.^{xii}

Experts globally acknowledge that, at the time of introducing the WTO-mandated product patent system in 2005, Indian lawmakers made a conscious decision not to replicate the US IP system designed for profiteering by their pharmaceutical corporations.^{xiii} Instead, parliamentarians looked at balancing patent monopolies with the health needs of Indians and people in low- and middle-income countries (LMICs) who need access to affordable generic medicines.

In the United States, high medicine prices have been a significant issue attributed to pharmaceutical corporations abusing the patent system.^{xiv} Oncologists in the US highlighted the unaffordability of \$100,000 prices for cancer drugs like imatinib under monopoly.^{xv} A study published in 2018 found that 74% of drug patents between 2005 and 2015 in the US were granted on existing drugs, not new medications.^{ix} As recently as July 2021, the US Patent and Trademark Office (USPTO) noted that the patent system is misused to delay generic competition of medicines, and committed to increasing public participation in the patent system.^{xvi}

China grants more than 500,000 patents in a year, but the quality of those patents remains a crucial issue.^{xvii}

In China, the affordable generic formulations of a number of essential HIV and hepatitis C drugs cannot be supplied domestically even though the country has a robust generic industry to produce both active pharmaceutical ingredients (API) and finished products, and exports raw materials for producing

generics to other countries, including India. This is mostly due to patent monopolies held by major pharmaceutical companies in the country over these medicines.

The Chinese government is now tackling patent quality issues amidst a large number of patent filings, so merely looking at the number of patents granted as the indicator of innovation is misleading.^{xviii} During the COVID pandemic, China National Intellectual Property Administration (CNIPA), the national patent office, issued a policy note to tackle excessive patent filing practices and control patent quality.^{xii} In addition to cutting down subsidies for patent applications at all levels, in its recent patent survey report (2020) the CNIPA signalled its intent to increase patent fees. This initiative will filter a large number of potentially poor patent applications and improve patent quality, considering that patent fees are relatively low in China compared to other jurisdictions.^{xix}

There is growing evidence that policymakers should not equate the grant of patents to increased innovation and investment.^{xx} An increasing number of studies have shown that despite increased levels of patent protection over the last 20 years, the innovation rate has been falling, with an increase in the number of ‘me-too drugs’ of little or no therapeutic gain.^{xxi,xxii}

This undermines the claim of the pharmaceutical industry that more patent protection would result in more medical innovation. On the other hand, globally, a lack of balance in the patent system, including granting evergreening patents to extend monopolies, has impeded the timely availability and accessibility of essential medicines.^{xxiii}

Instead of racing to grant more patents at the cost of quality and at the risk of stifling genuine innovation, patent offices should contribute to access to more affordable medicines by rejecting evergreening patent applications for known medicines. The current mechanism of pre-grant opposition under India’s patents law is an important tool to use in this context.

3. Why is MSF concerned regarding the EAC recommendation?

Over the years, civil society organisations have consistently put efforts in opposing various evergreening patent applications at the IPO, resulting in their rejection.³ This has encouraged early competition and affordable access to generic medicines for millions of people in India and across the world.

As a medical humanitarian organisation, Médecins Sans Frontières (MSF) has worked closely with patient groups on challenging unmerited patent applications on key lifesaving medicines in India. MSF has supported pre-grant oppositions on HIV, drug-resistant tuberculosis (DR-TB), hepatitis C medicines and pneumococcal vaccines (PCV) in India.^{xxiv,xxv,xxvi}

The pre-grant opposition mechanism is an essential safeguard in Indian patent law. Any attempt to dilute the window period to file pre-grant oppositions will have significant public health repercussions in India and beyond.

³ <https://www.patentoppositions.org/>

Box 2: Pre-grant opposition to J&J's evergreening patent application on new DR-TB drug bedaquiline to prevent unmerited monopolies

Bedaquiline, a drug for treating drug-resistant tuberculosis (DR-TB), has a granted Indian patent which expires in July 2023. The patent holder Janssen Pharmaceuticals (Johnson & Johnson) filed an evergreening patent application for the fumarate salt of bedaquiline that would potentially extend the term of protection until December 2027 – an unwarranted monopoly of four and a half years.⁴ A civil society group filed a pre-grant opposition against this bedaquiline fumarate salt patent application in March 2013. The IPO did not move to adjudicate this opposition for at least six years thereafter.

In Feb 2019, two TB survivors filed a detailed and scathing pre-grant opposition against this patent application.^{xxvii} This new opposition not only asserted that this was an evergreening patent application, it also explicitly highlighted that the claims were not 'new' and sections were a copy-paste of material by the patent applicant from an earlier patent filing relating to an HIV drug, rilpivirine, which the IPO had already rejected. This copy-paste confirmed that bedaquiline fumarate was not a novel invention but merely a result of tried and tested laboratory techniques well known to the applicant and others for years. Had the six-month restriction been in place, it would have been impossible to bring this information to the patent office.

Box 3: Pfizer filed new evergreening patent applications despite pending challenge on PCV-13 patent

Pneumococcal conjugate vaccine (PCV) is recommended in children to prevent and reduce pneumonia-related deaths and decrease antibiotic use in infants and children by significantly reducing common childhood infections and potentially lowering antimicrobial resistance (AMR). The IPO has incorrectly granted a patent to Wyeth (Pfizer) for its PCV-13 product, which has been challenged and a decision has been pending both before the Delhi High Court and the IPO since 2017. The patent grant is a setback for vaccine producers, who will now have to develop non-infringing versions of pneumococcal vaccines, which have led to delays in the market launch for a more affordable PCV made in India.^{xxviii}

Despite pending challenges on Wyeth's PCV-13 main patent, Wyeth has filed several other evergreening patent applications on PCV, which are aimed at broadening the scope of protection⁵ and covering multi-dose formulations.⁶ These evergreening applications could impact the development of higher valent PCV products and multi-dose vials providing long-term stability.

Considering the secrecy around patent applications by pharmaceutical corporations, MSF was able to file pre-grant oppositions only five years after Wyeth filed these evergreening applications. A timeframe limitation on filing pre-grant opposition would not have allowed MSF to oppose these secondary patent applications, which would have affected the manufacture of higher valent PCV, including PCV-14 by Indian manufacturers.

⁴ Indian Patent Application Number 1220/MUMNP/2009, titled "Fumarate Salt of (Alpha S, Beta R)-6- Bromo-alpha-[2-(dimethylamino) Ethyl]-2-methoxy-alpha-1-naphthalenyl-betaphenyl-3-quinolineethanol"

⁵ Indian Patent Application Numbers 2182/DELNP/2015 and 2183/DELNP/2015 both titled "Multivalent Pneumococcal Polysaccharide-protein Conjugate Composition"

⁶ Indian Application Number 10072/DELNP/2012 titled "Streptococcus Pneumoniae Vaccine Formulations"

4. Why is the six-month timeline insufficient for filing patent oppositions?

The information in patent applications does not permit the public to identify the claimed medical product rapidly. The process is time-consuming as multiple patent claims could be pending on the same medicine, vaccine or technology. Although patent information is in public documents maintained by the IPO on its website, it is not a simple matter to search for patents on a drug, diagnostic, vaccine or technology. With titles that are deliberately vague and meaningless, patent applicants seem to conceal the known International Non-proprietary Name (INN), which are attributed by the WHO as unique names that identify particular pharmaceutical substances or active pharmaceutical ingredients. For example, GSK's patent application for an obvious formulation of lamivudine in India (479/CAL/1998) was entitled 'Pharmaceutical Compositions', while its application for a salt form of abacavir (872/CAL/98) was entitled 'A Novel Salt'.

To address this issue of transparency in patent searches, India in global forums such as the World Intellectual Property Office (WIPO) has advocated for the disclosure of INN in patent applications. But the reform itself, though proposed in 2014, was never implemented.^{xxix}

Further, once an application on a particular product is finally identified, a rigorous analysis is required to ascertain the application's novelty and potential impact on competition, which is time consuming.

The Indian Patents Act allows the public to provide relevant information to the IPO when it becomes available, without any time limitation, cutting social costs generated due to poor-quality patents.

Not mandating patent applicants to give INN details in patent applications puts an undue burden on opponents to identify patent claims on lifesaving medical products and then challenge them within this short timeframe.

Box 4: Concealment of INN in patent applications

Patent applicants seem to deliberately conceal the known INN by providing vague and meaningless titles. For example, an application by Janssen Pharmaceuticals in India (6315/DELNP/2006), covering a combination of the new TB drug bedaquiline with other TB drugs, is entitled "A Combination of a Compound Of Formula (IA) Or (IB) and One or More Other Antimycobacterial Agents". The name of the drug is not contained in the abstract or even in the full specifications. More importantly, the applicant is under no obligation to reveal to the examiner that they have already obtained an Indian patent on the compound bedaquiline (IN236811) and are now seeking another patent on its combination with other TB drugs.

5. Is the proposal to restrict the timeframe for pre-grant opposition new?

Evergreening monopolies on medical products is a lucrative game for pharmaceutical corporations, allowing them to charge high prices for years beyond the expiry of the main patent of a pharmaceutical product.

In the 2000s, there was strong pressure from pharmaceutical corporations to severely dilute the robust pre-grant opposition mechanism whilst the Indian Patents Act was being amended due to the TRIPS Agreement requirement to introduce pharmaceutical product patents.^{xxx} However, this attempt failed after severe criticism from the media, civil society, domestic industry and political opposition.ⁱⁱ

However, even after the law was settled in 2005, the Organisation of Pharmaceutical Producers of India (OPPI) – Big Pharma's association in India – has attempted to undermine this safeguard in the patent law for years and has recently renewed efforts.^{xxxi}

6. What should be the focus of improving the efficiency of the patent office?

The efficiency of the IPO can be effectively addressed by improving the functioning of the patent office. Far from being the problem, pre-grant oppositions are part of the solution as they can help address the problem of low-quality patents by providing relevant and focused information to the IPO for aiding the examination process. Moreover, fixing a timeline for filing pre-grant opposition is a legislative mandate and requires a more comprehensive public consultation. It is beyond the executive's prerogative and cannot be introduced through the Patent Rules.

The attempt to dilute the timeline on pre-grant opposition diverts from addressing the real problem facing the patent system in India. The following recommendations will ease the burden of the IPO and increase transparency:

1. The IPO should mandate patent applicants to disclose INN in patent applications to identify the multiple patents on the same drug and vaccine. Disclosure of INN by the applicant to the IPO would serve as an essential tool to further improve transparency and accessibility of patent information, and also assist in effective management of patent applications across different patent offices.
2. The IPO should dispose of a patent application in accordance with the timelines already prescribed under the Patent Act and Rules.
3. Initiatives to filter a large number of potentially poor patent applications and improve patent quality should be prioritised. Studies have shown that the application of the anti-evergreening provisions—sections 3(d), 3(e) and 3(i)—is poor by examiners and controllers. The examination cadre of the IPO and its patent examination guidelines need to be trained and strengthened respectively to weed out unmerited patents by strictly applying the patentability criteria.

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