

Policy Brief on Patents and Pre-Grant Opposition in India

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Summary

An important component of the patent law in India is the provision for third parties to challenge patent applications through the pre-grant opposition (PGO) system. The PGO could prevent the grant of patents on applications that are not truly inventive or new; do not involve an inventive step; and that are minor modifications without significant enhanced efficacy, forms or derivatives of known compounds (secondary patents), etc. A large majority of patent applications for pharmaceutical products are for secondary patents, to extend the number of years of monopoly beyond the expiry of the original patent on the compound or molecule of the pharmaceutical product. Therefore, PGO provisions in the Patents Act in India is a public interest safeguard system that has the potential to pre-

vent non-deserving patent applications from getting patents. However, the PGO system is not popular and not used much, due to various reasons including scarce resources, and undue delay in the disposal of applications for patent opposition. Thus it displays the under-utilisation of one of the TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) flexibilities to ensure access to affordable medicines. The wrongful grant of patents on known pharmaceutical substances could result in monopoly and unaffordable prices. This policy brief suggests some measures to enhance the efficacy and utilisation of the PGO. India's experience also offers valuable lessons for other developing countries that are committed to public health and access to affordable medicines.

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Introduction

India, being a developing country, had to change its Patents Act in 2005 to introduce product patent protection for pharmaceutical inventions. India till then only had process patents for pharmaceutical products, which allowed the development of a huge generic pharmaceutical industry in the country, enabling access to medicines at affordable prices. While introducing product patents for pharmaceutical inventions, the Indian Patents Act incorporated provisions to generally restrict patent protection to new chemicals and not for new forms, incremental improvements, derivatives, etc. of known compounds. The law also retained most provisions for the PGO and introduced post-grant oppositions of patent. The opposition provisions are primarily a mechanism to prevent wrongful grant of patents.

This policy brief attempts to highlight the significance of PGOs, steps to be taken to file it, the current shortcomings and a few suggestions to improve the efficiency of the PGO system. The objective of this policy brief is to generate awareness about the system and to provide important recommendations in law and policy on the PGO within the patent law.

Pre-grant opposition mechanism

PGOs act as a check on preventing patents on applications that do not deserve patents under the law in India. They also serve as a supplement to the inquisitorial role of the patent office.

Provisions in the law

Patents are granted on inventions (Section 2j), that is, a new product or process involving an inventive step and that can be of industrial application. An inventive step (Section 2ja) is a technical advancement as compared to existing knowledge, with economic significance and that is not obvious to a person skilled in the art. A new invention (S.2l) is one that has not been anticipated by publication, or used

anywhere in the world or in the country, etc. Section 25(1) of the Patents Act lays down 11 grounds for opposition to patent applications that have been published but have not been granted a patent. The PGOs are filed at the Patent Controller's office under whose jurisdiction the patent applications are filed. An order from the Controller could be appealed against before the Intellectual Property Appellate Board. Orders of the Appellate Board are appealed against at the High Court and a further appeal from the High Court is before the Supreme Court.

The law allows any person to file an opposition prior to the grant of the patent on grounds laid down under Section 25 (1). Common grounds for opposition are lack of novelty, the subject matter having been published prior to the priority date in the application, is used or publicly known in India; and lack of inventive step. If the invention claimed is obvious and does not involve an inventive step, or is anticipated having regard to the knowledge available, or is not an invention or not patentable within the meaning of Section 3 of the Patents Act, it is a ground for opposing the patent application. The PGO could also state technical grounds such as the failure to provide information required to be submitted under Section 8 of the Act (regarding foreign applications), or that the application does not sufficiently and clearly describe the invention, or that the application was not made within 12 months from the filing in a country that is party to the Paris Convention for the Protection of Industrial Property, or it wrongly describes the source or geographical origin, etc. These provisions in the law act as a check on what is claimed as a novel or new invention but is actually not so under the law.

Importantly, Section 3 of the Patents Act describes '*inventions not patentable*' and disallows patents on the mere discovery of new forms of known substances that do not significantly enhance known efficacy. Section 3(d) renders claims of new forms, new properties, new use, etc. of known substances and processes as not patentable. The provision considers forms such as salts, esters, polymorphs, metabolites,

isomers, mixtures, derivatives, etc. of known substances as the same substance and renders them not patentable. Section 3(e) is also of much importance as it prevents patents on substances that are combined or mixed resulting in mere aggregation of their properties. Pharmaceutical patent applications need to undergo the test of Section 3 prior to obtaining a patent.

Pharmaceutical companies try to obtain a monopoly on medicines which would give them 20 years of exclusivity and also file applications to extend their monopoly beyond the first granted patent period by filing patent applications for forms or combinations of the compound. The data (as depicted below) shows that there are many applications for pharmaceutical products claiming novelty or inventive step even though it is commonly known that there is truly very little innovation and only a very small percentage of pharmaceutical products are new inventive compounds.

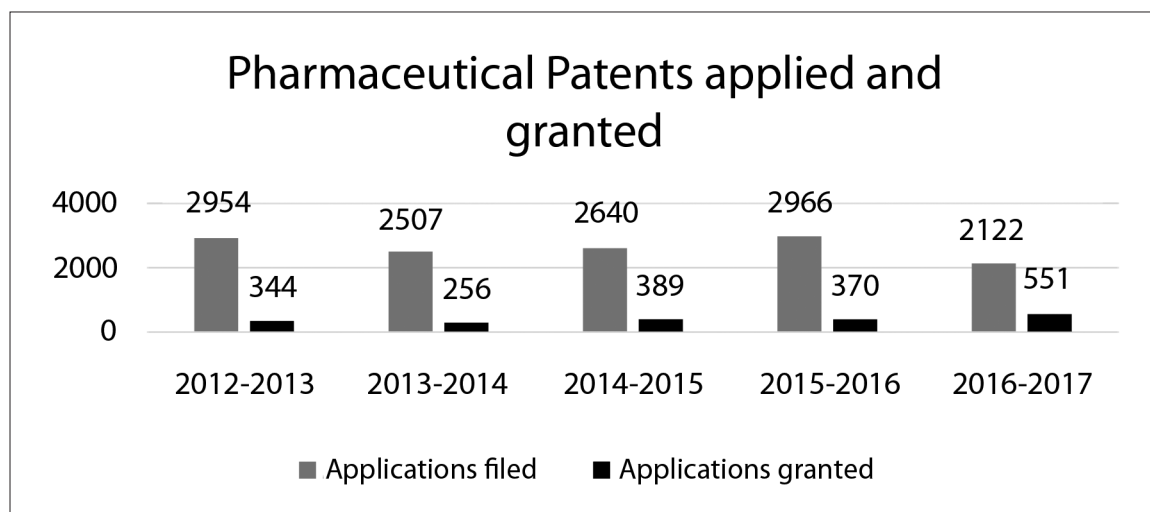
Most of the applications for patents are of known substances that do not deserve a patent under the Indian law. Unfortunately, pharmaceutical companies, despite knowing the provisions of the Indian law that do not allow patents on new forms of known substances, file patent applications to extend the period of their exclusive market rights.

Patents are meant to be granted for truly novel inventions to promote innovation. As seen in Figure 1 below, there has been a steady increase in the number of patents granted for pharmaceutical applications, from about 10-12% to 25% of applications filed in the period 2012 to 2017. Many applications are pending in the various patent offices, some have been abandoned, and some withdrawn. However, the fact is that more than 72% of patents granted for pharmaceutical products are secondary patents, not for novel products but for increments, derivatives, combinations or minor modifications of known medicines or substances that are not patentable in India.¹ This reveals a weak system of screening of the patent applications resulting in a diminished value of true innovation and reduced access to affordable medicines.

The PGOs potentially serve as a mechanism of scrutiny of the patent applications, improve the analysis of the patent office of patent applications, and bring prior art to the attention of the patent examiner that may not have been identified earlier, leading to rejection, withdrawal or abandonment of patent applications that are not truly inventive. The

1 Ali, Feroz and others, 'Pharmaceutical Patents Grant In India: How our safeguards against evergreening have failed, and why the system must be reformed'; April 2018. Available at <http://accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf>

Figure 1



Source: Data obtained from annual report 2016-17 of the office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications

due diligence by the Patent Controller and the PGOs can prevent such unlawful patents from being granted.

Impact of use of pre-grant oppositions

The interesting part of the law with regard to PGOs is that 'any person' can file a PGO. This offers an opportunity for public interest groups, patient groups and other civil society organisations (CSOs) to intervene to prevent the grant of wrongful patents. Using the PGO, many CSOs have successfully opposed patent applications, including on first and second line HIV/AIDS medicines and cancer medicines.

A well-known case in recent times, that caught national and international attention, was the *Gleevec* case. In this case, a PGO was filed by the Cancer Patients Aid Association and some generic pharmaceutical companies, against the patent application filed by Novartis AG for the beta-crystalline (β -crystalline) form of *imatinib mesylate* used for the treatment of chronic myeloid leukaemia. The Patent Controller dismissed the application filed by Novartis taking into account the PGOs filed under Section 25(1), prior art documents cited in the oppositions and Section 3(d) as the application claimed a new form of a known substance. The case was appealed and went right up to the Supreme Court, where the appeal filed by Novartis was rejected and the court upheld the rejection of the grant of patents. The Supreme Court interpreted the term efficacy as stated in section 3(d) to mean 'therapeutic efficacy' that needs to be based on research data. Importantly, the medicine containing the β -crystalline form of *imatinib mesylate* was made affordable to cancer patients who could not afford the Rs.1,20,000/- per month price of *Gleevec* (sold by Novartis), and could then buy the generic medicine at prices lower than one-tenth (1/10) the price of Novartis.

Similarly, PGOs have been filed for a medicine used for the treatment of HIV, cancer, tuberculosis, diabetes, etc. The impact of such oppositions has shown that:

- (a) The Patent Controller does a far better scrutiny when a PGO is filed;
- (b) Applications for patents that clearly do not deserve a patent due to lack of novelty or inventive step are not granted a patent easily if a PGO is filed;
- (c) There is prevention of a monopoly if the PGO is successful;
- (d) The generic industry can produce or continue to produce the medicine(s) as the patent is not granted;
- (e) There is competition in the market and the prices of the medicines remain competitive and not monopolistic; and
- (f) There is a huge public health impact.

In fact evidence shows that the impact of PGOs is the emergence of domestic firms as market leaders in the case of many important molecules for treatment of cancer, HIV, etc., where patent applications have been rejected or withdrawn as a result of the PGO.² From a public health perspective, the PGO of patent applications is an important tool within the Indian law that should be enhanced and encouraged.

Filing of PGOs

It is of utmost importance to first understand the claims made in the complete specification of the patent application, after which the prior art documents can be researched and obtained. The PGO must be based on the grounds under section 25(1) of the Patents Act to challenge the patent applications filed.

Common claims in pharmaceutical patent applications

A patent application may claim a new compound or molecule or, as a large majority of the pharmaceutical applications claim, combinations, mixtures of compounds. Most patent applications have claims for salts, prodrugs, isomers, polymorphs, esters, ethers, formula-

2 Abrol, D and Ors. 'Pharmaceutical Product Patents and TRIPS implementation', Working paper 191, Institute of Studies in Industrial Development, New Delhi, March 2016. Available at <http://www.isid.org.in/pdf/WP191.pdf>

tions or derivatives of known compounds/substances. Some of the claims also relate to use of the compounds, whereas some relate to the formulation, dosages and methods of treatment. Some patent applications are for such secondary patents, only to extend the market monopoly period beyond the 20 years of the first patent, with overlapping or consecutive patents.

The Indian law prohibits patents for derivatives and forms of known substances, combinations, dosages and use of the compounds in a particular treatment, etc. Therefore, what is required is strict scrutiny at the time of filing of the application itself, so that claims that are not patentable are deleted from the patent application. What is commonly seen is a large number of claims in the patent application at the time of filing, but the claims are reduced or amended after the first examination report (FER) is sent by the Patent Controller, and is sometimes substantially reduced, combined or amended if a PGO is filed. However, the

patent office often does not do a thorough scrutiny after the claims are amended pursuant to the FER, thereby granting patents wrongfully.

Process for filing PGOs

The first step is to identify the patent application for pharmaceutical products which would involve screening the patent database and retrieving the necessary documents. Extensive research based on *chemical and pharmaceutical compounds databases* needs to be undertaken to procure prior art data. This search would help identify whether the patent application is worthy of opposition. Once the lack of patentability has been identified, the application can be opposed based on the grounds laid down under Section 25(1) of the Patents Act.

A request could be made under Rule 55 (1) of the Patent Rules, for a hearing of the case. The PGO should be filed along with Form 7A and Form 26 (authorisation – where applicable).

Figure 2

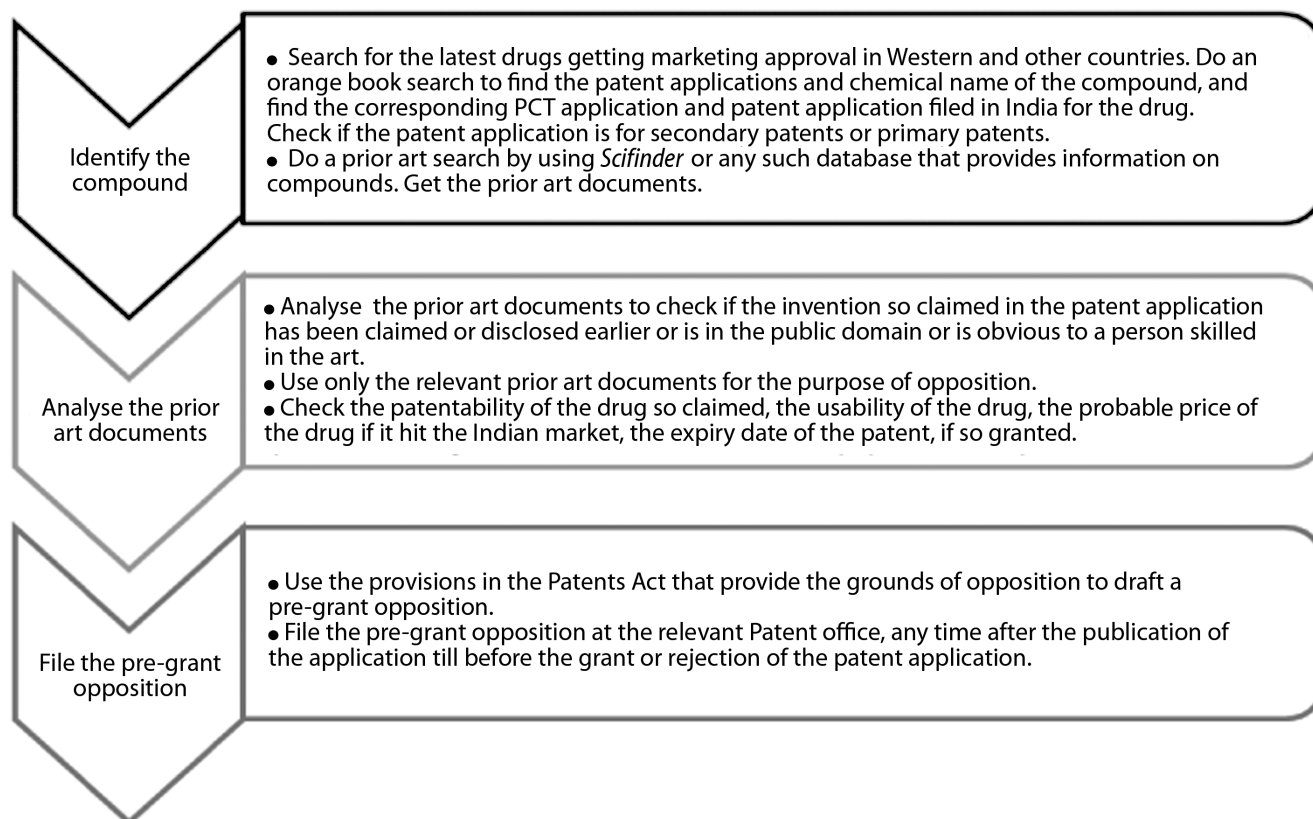


Table 1

Year	% pre-grant opposition of the patent applications published	Year	% pre-grant opposition of the patent applications published
2011-12	0.70	2014-15	0.92
2012-13	1.01	2015-16	0.70
2013-14	0.98	2016-17	0.24

Source: Annual report 2016-17 of the office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications

Deficiencies of PGOs

Even though the PGO offers an opportunity to speed up generic competition and to strengthen scrutiny against the granting of wrongful patents, there is an underutilisation of this public interest safeguard. As shown in Table 1 only a small percentage of the published patent applications are opposed. It is not used as much as it potentially could, with less than 1% of patent applications being opposed at the pre-grant stage.

Some of the reasons for the small number of PGOs being filed are the scarcity of resources, the high costs of litigation (when appeals to the courts are made), voluntary licences entered into by generic pharmaceutical companies with multinational pharmaceutical companies, etc.

Table 2

Year	Number of PGOs	Number of Disposals
2012-13	262	34
2013-14	309	48
2014-15	247	67
2015-16	290	88
2016-17	206	18
Total	1,314	255

Source: Compiled from Annual Report of the Office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications.

An important issue is the undue delay in the disposal of the PGO applications. Table 2 shows that only a handful of PGO applications are disposed of every year. As shown in the table out of 1,314 patent oppositions received during the five years starting from 2012-13 only 255 were disposed of. According to the Patent Rules a PGO could be considered only after receiving the patent applicant's request for examination. The Patent Rules provide 48 months, either from the date of priority or the date of patent application, whichever is earlier, to the patent applicant to file a request for examination. Similarly, a patent applicant may file divisional applications³ to keep the original application alive. As a result, the applicant can delay the disposal of the PGOs by not filing the request for examination. Further, there is no prescription of time period in the Patents Act or Rules for the disposal of a PGO application after receiving the request for examination from the patent applicant. Therefore, PGO applications remain pending for years. A speedy mechanism needs to be put in place, as it seriously undermines the effectiveness of the PGO system.

³ A divisional patent application contains matter from a previously filed patent application (parent application); it may retain the parent application's filing date, and will generally claim the same priority date. It is used in cases where the parent application lacks unity of invention, where such parent application describes more than one invention and the applicant is required to split them into one or more divisional applications.

Often the applicant delays the consideration of the application along with the PGO application by continuously amending the patent claims using the loopholes in the Patents Act and Rules. Patent applicants often do not state the international non-proprietary names (INN) of the pharmaceutical products in the patent application. This lack of disclosure of INN makes it a longer process and is also difficult for persons not specialised in the field to identify the important and most relevant patent applications for which PGOs could be filed. Similarly, the lack of access to scientific databases, which are very expensive, and not freely available, prevents the effective use of PGOs by individual persons, civil society, patients groups, etc.

There is also a lack of trained human resources to file the PGO. The lack of expertise results in overdependence on a limited number of professionals for filing the PGO, especially in the case of CSOs. There is an urgent need to enhance the capacity in utilising the PGO systems through trainings and workshops.

Conclusion

PGOs should be encouraged. What is required is a good scientific scrutiny of the patent applications along with an understanding of the patentability criteria in India, so as to prevent wrongful patents from being granted. Improved awareness and understanding of the PGO process is necessary to reinforce the judicious approvals of patents. More organisations should be encouraged to develop knowledgeable teams to identify patent applications lacking creditability, and to file PGOs.

Recommendations

- Make necessary amendments to either the Patents Act or Rules or both to provide a clear timeline for the disposal of PGO applications. This would avoid the undue delay in the disposal of the PGO applications and enhances the efficiency of the system. If a PGO is filed it should be considered on a priority basis.
- Make necessary amendments to either the

Patents Act or Rules or both to prevent patent applicants from indulging in delaying tactics by amending the claims in pharmaceutical patent applications as and when they like, and restrict such amendments to only one or two amendments.

- Make necessary amendments to the Patent Rules to dispose of the patent application on receipt of a representation for pre-grant opposition, without a request for examination.
- Pre-grant oppositions can be enhanced by improving the quality of information by making provisions for submission of the relevant data, including the International Nonproprietary Name, use of the new molecule or compound for the treatment of specified diseases, etc. in the published patent applications and the summaries.
- Develop an open access database that would enhance the search for relevant documents and is easily accessible to all those interested in filing PGOs.
- Provide training on the PGO system by developing a course on pre-grant oppositions as a component of intellectual property law and practise as part of the National Intellectual Property Rights Policy.
- Introduce courses to train scientists specialising in pharmaceuticals on patents and pre-grant oppositions.
- Introduce incentives to generic companies to make use of pre-grant opposition.
- Re-look at the provisions of the Patents Act and make amendments that would allow the full use of flexibilities in the Trade-related Aspects of Intellectual Property Rights Agreement administered by the World Trade Organisation, and for the enhancement of public health and make medicines affordable and accessible.

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