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Patent Oppositions

Opposition proceedings before (pre-grant oppositions) and/or after (post-grant oppositions) the grant of a patent are provided for in patent laws of many countries. Patent Oppositions are aimed at assisting the Patent Office with all available information on a product or process on which a patent is sought. Ultimately, it is the responsibility of the Office to ensure that patents are granted only to genuine inventions; but with tens of thousands of applications to examine, the role of oppositions is particularly important in bringing frivolous applications to light.

Importance of Patent Oppositions

Patent oppositions, particularly in developing countries can be of great assistance to patent offices (that are typically underfunded, under-resourced and overburdened with foreign patent applications) with necessary information and evidence regarding the patentability of a product or process. This is particularly true in a field as crucial as health. According to UNDP, UNAIDS and WHO, "providing for public-health sensitive patent examination guidelines as well as pre- or post-grant opposition procedures can help to prevent the patenting of products and processes that lack innovation." In other words, patent oppositions help ensure that only high quality patents are granted. For developing countries that are adopting stricter standards of patentability as compared to developed countries, the role of oppositions is all the more important.

Patent oppositions typically involve one party opposing the grant of a patent on one or more grounds including failure to meet patentability criteria and the patent applicant presenting arguments in response rebutting the opposition. Sometimes a hearing may be held. In many countries, oppositions take place at the patent office; in some countries however oppositions can only be introduced before a competent court. Some countries do not allow for oppositions but only third party observations which is a more passive approach where information is only sent to the patent office.

Patent oppositions can be pre-grant (before the grant of the patent) or post-grant (after the grant of the patent). Developed countries that oppose public-health safeguards in patent law argue for only one form of opposition – usually post-grant stating that the patent procedure is too cumbersome when multiple avenues for opposition are permitted. From the public health perspective, it is critical that both pre- and post-grant opposition proceedings are provided for in law; the former is particularly important because of the difficulty of opposing or revoking a patent once it is granted. Even if a patent is challenged after it is granted, it usually remains in force during the period of the challenge, impeding access to the medicine for those who need it.



TABLE 1 Examples of pre-grant oppositions to patent applications in India: HIV

Medicine	Patent applicant	Opponent (public interest groups that have opposed the patent application)	Status of the patent application
Abacavir	GSK	Indian Network for People Living with HIV/AIDS	Patent application withdrawn
Amprenavir	GSK	Uttar Pradesh Network of Positive People and Indian Network for People living with HIV/AIDS	Patent application abandoned
Atazanavir	Novartis	Karnataka Network for People Living with HIV and AIDS and Indian Network for People living with HIV/AIDS	Patent application abandoned
Imatinib mesylate	Novartis	Cancer Patients Aid Association	Patent application rejected
Lamivudine/ zidovudine	GSK	Manipur Network of People Living with HIV/AIDS, Indian Network for People Living with HIV/AIDS	Patent application withdrawn
Lopinavir	Abbott Laboratories	Delhi Network of Positive People, Network of Maharashtra by People Living with HIV and AIDS and Indian Network for People Living with HIV/AIDS	Patent application rejected
Lopinavir/ritonavir (soft gel)	Abbott Laboratories	Delhi Network of Positive People and Indian Network for People Living with HIV/AIDS	Patent application abandoned
lopinavir/ritonavir (tablet)	Abbott Laboratories	Initiative for Medicines, Access & Knowledge	Patent application rejected
Ritonavir	Abbott Laboratories	Delhi Network of Positive People and Indian Network for People Living with HIV/AIDS	Patent application abandoned
Tenofovir disoproxil (TD)	Gilead Sciences	Delhi Network of Positive People and Indian Network for People Living with HIV/AIDS; Brazilian Interdisciplinary AIDS Association (ABIA) and Sahara (Centre for Residential Care and Rehabilitation)	Patent application rejected
Tenofovir disoproxil Fumarate	Gilead Sciences	Delhi Network of Positive People and Indian Network for People living with HIV/AIDS	Patent application rejected
Raltegravir Potassium Salt	Merck	Delhi Network of Positive People	Pending

TABLE 2 Examples of pre-grant oppositions to patent applications in India: Hepatitis C

Medicine	Patent applicant	Opponent (public interest groups that have opposed the patent application)	Status of the patent application
Pegylated Interferon alpha 2a	Roche	Sankalp Rehabilitation Trust	Patent revoked
Sofosbuvir	Gilead	Initiative for Medicines, Access and Knowledge (I-MAK)	Pending
Sofosbuvir	Gilead	Delhi Network of Positive People, Initiative for Medicines, Access and Knowledge (I-MAK)	Pending
Sofosbuvir	Gilead	Asia Pacific Network of People living with HIV and AIDS, Sankalp Rehabilitation Trust, Hepatitis Coalition Nagaland	Pending

Patent Oppositions on Medicines

Over the past two decades, public health groups in India, China, Argentina, Brazil, Vietnam and Thailand have successfully used patent opposition systems to challenge patents applications on key medicines. In Brazil, for instance, public health groups were successful in having a patent application by Gilead Science' on tenofovir disoproxil fumarate rejected (see Keith Alcorn, 2008). In India successful patent oppositions by networks of people living with HIV have resulted in first and second line ARVs being largely off-patent in the country. Such oppositions are now being filed in several more countries This includes developed countries; in the European Union, patent oppositions have been filed by public interest groups on the sofosbuvir patent. The involvement of patients groups and public interest groups in filing oppositions has taken on greater importance in light of generic companies (who traditionally oppose patents) entering into restrictive licenses with patent applicants and withdrawing their oppositions.

Implementation: How to file a patent opposition

STEP 1. Check your national or regional patent law

Although many countries provide for opposition systems in their patent laws there are considerable differences in these laws when it comes to the type of oppositions system, who can file, the time period etc. **Some countries don't allow oppositions at all. So before deciding to commit resources to patent oppositions on medicines, it is important to check you national or regional patent law to understand the exact scope for oppositions. In particular, the following questions are important to answer:**

What sort of patent oppositions can be filed?

You will have to examine your law to understand whether it allows for pre- or post-grant patent oppositions or both. **If neither are provided for then see if third party observations or some form of review or revocation is permitted. If there is no provision for oppositions, you could consider campaigning for patent law reform to include such a procedure.**

Who can file a patent opposition?

If your law allows for patent oppositions you then have to see who is allowed to file such oppositions. For instance in India "any person" can file a pre-grant opposition; as a result even international NGOs have filed pre-grant patent oppositions in India. However, only an "interested person" can file a post-grant opposition. This provision is typically understood to mean researchers or commercial competitors. However, in India and Thailand, patients groups have successfully argued that they are also interested persons when it comes to filing oppositions. If your law limits standing to "interested persons" you may also have to argue and establish your right as a public interest or patient group to file an opposition.

When can a patent opposition be filed and how much will it cost?

If you can file patent oppositions under your law, you now have to check how much time you have. Some laws allow pre-grant oppositions to be filed any time before the grant of a patent. But far too many laws in developing countries provide an extremely short and unrealistic time line of 90 days from publication of the patent application for the filing of an opposition. Some countries also require opponents to pay a prescribed fee which you will need to factor into the cost of undertaking an opposition.

STEP 2. Identify the patent applications and/or the patents covering a medicine

Now that you know you can file a patent opposition, you need to undertake the tricky process of identifying the patent application or granted patent that you want to oppose.

If you are filing a pre-grant opposition, you will need to identify the patent application on the medicine you are concerned with. In Factsheet No [] you will find the process of doing a patent search. Using the steps detailed in that factsheet you may be able to identify the patent applications on the medicine of your concern and possibly the national patent application as well. In addition, a search of the database of the Patent Cooperation Treaty (PCT) administered by the World Intellectual Property Organisation (WIPO) for 144 member states may also be useful. The PCT allows patent applicants to file their patents simultaneously in multiple national and regional patent offices (Factsheet No []). This is known as the national phase and this information can be accessed at www.wipo.int/pctdb. If you are filing a post-grant opposition, use Factsheet No [] to do a patent search to identify the patent you want to oppose.

You can also seek this information from your patent office or from activists and lawyers also working on patent oppositions.

In your patent application and patent search, you are likely to come across multiple applications and patents. Among these, you need to identify the patent application or patent that is actually in the way of generic access i.e. which is the blocking patent? Some patents may cover the process to manufacture the medicines, a therapeutic indication or a method of administration (depending on what the national law allows, [see factsheet n°X](#)), but not cover the active ingredient *per se* and would not prevent the production or importation of generic versions of the medicines. Discussions with generic producers can help in the process of identifying the blocking patent or patent application.

FIND OUT MORE (SOURCES AND RESOURCES)

→ [<https://www.patentoppositions.org>]

STEP 3. Researching, drafting and filing the Opposition

If you have identified the patent or patent application you wish to oppose, you now have to back to your national or regional law to identify the grounds on which you can oppose. In some countries oppositions can only be based on the patentability criteria ie you must find and present the scientific and expert evidence to show that the medicine is either not new or not inventive or not capable of industrial application. Other countries allow more grounds for challenge. For instance in India, the failure of the patent applicant to reveal information about foreign applications related to the patent application can be a ground for opposition. The time frame for the entire process varies by country; for instance once your opposition is filed, you may have to participate in a hearing before the patent office and if your opposition is successful, in all likelihood the patent applicant will file an appeal.

Although this sounds like a daunting task, as patent oppositions are increasingly used by public interest groups considerable public interest oriented scientific expertise, research assistance and expert evidence has become available. In some countries public interest groups work with universities to analyse patent applications and provide the research for oppositions. This patent opposition database [<https://www.patentoppositions.org>] also makes available copies of oppositions on key medicines already filed in other countries along with relevant documents that can assist you in drafting your own opposition. A local law firm, lawyer or legal aid group may be required for you to file the opposition and argue it before the patent office; check if this is a necessary requirement under your patent law.