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The patenting process

Patents are territorial rights granted by local patent offices (at national level in most cases, or at regional offices when countries have signed a regional agreement: European Patent Office (EPO), African Organization of Intellectual Property (OAPI), African Regional Intellectual Property Organization (ARIPO), Eurasian Patent Organization (EAPO), etc.) Although each country follows its own patenting process, there are common steps and national or regional processes are coherent with a generalized procedure for granting a patent that is presented in this factsheet.

The general procedure

The filing

Applying for a patent is a legal process governed by strict timescales, deadlines and fees. The applicant chooses a filing route, i.e. national, regional or international. The initial filing of the application is considered the “priority filing”. The Paris Convention for the Protection of Industrial Property (Art. 4) established a “priority period” of one year from this “priority date” during which further filings can be made in different countries where the invention will still be considered new. The priority date is considered the “effective date of filing” for the examination of novelty and inventive step or non-obviousness, regardless of when the patent application is filed in other countries over the course of the year following the priority date. As an example, the priority date for the basic molecule for tenofovir was July 26, 1996. This is the date when the patent was filed in the United States of America by Gilead Sciences: the first time ever this patent application was filed. The application was then filed at the European Patent Office on July 25, 1997. For the patent examiner at the European Patent Office, as well as elsewhere, the effective filing date for the application was July 26, 1996 and so while examining novelty and inventive step or non-obviousness she can only do a prior art search before July 26, 1996

In other words, the priority filing gives the patent applicant a chance to patent the invention ‘worldwide’ for one year.

Formal examination

The patent office verifies whether the documents submitted are in compliance with statutory requirements, e.g., that all relevant documentation is included in the application, and that the filing fee has been paid. This step usually takes place in all patent offices. In many patent offices in developing countries, unfortunately, this is the only sort of examination that is performed – often due to the lack of capacity and resources dedicated to the patent office and the overwhelming number of foreign patent applications.

Prior art search

In many countries (but not all), a search of “prior art” is carried out. Examiners are looking for any evidence that the invention is already known: they are trying to figure out if someone, somewhere, has already described or shown or made something that contains a use of technology that is very similar to the invention cover by the patent application filed. The search is conducted largely through online databases and leads to the compilation of a “search report” that evaluates the patentability of an invention. In some countries, this step is part of what is called “preliminary examination”; in China, for instance, the examiner checks whether the application contains any obvious and substantial flaws or defects, including whether the subject of innovation can be deemed to be patentable subject matter.

Publication of patent application

In most countries, the patent application is published 18 months after the priority date. The date of this publication can open a window of time for third parties to file pre-grant oppositions or submit third party observations in countries where this is provided by the law.

Pre-grant opposition

In some countries an opposition to the patent can be submitted as soon as the application is published (see factsheet X).

Substantive examination

During this phase, the examiners of the patent office determine whether to grant or reject the patent. Concretely they look to see if the patent application fits within the scope of matters that can be protected by patents as established by their patent law and if it meets the patentability criteria: whether it is novel and inventive (non-obvious), whether it is capable of industrial applicability. Examiners will also determine whether the patent application meets disclosure standards of their country; some countries require the patent applicant to disclose the best mode for working the patent. Examiners will also look at the claims made in the patent application – this is the section of the patent application where the patent applicant states what products and processes would be covered by the patent. Often there

are multiple claims and examiners will ensure that what is claimed is actually described in the patent application; some patent offices also charge additional fees for claims exceeding a certain number.

At times a patent application may disclose several inventions in order to pay the fee for only one patent filing while actually covering several inventions. In most countries patent offices will require that one application cover only one invention or a very closely related group of inventions or what is known as ‘unity of invention’; if this is not the case, they will direct the patent applicant to restrict the claims or pay additional fees or require the applicant to file divisional applications. Some countries also restrict the number and timing of divisional applications to prevent abuse of the patent filing process and avoid uncertainty over the patent status. In many countries prior art search and substantive examination are conducted consecutively (in the US they are conducted at the same time).

Some patent laws attempt to ensure that patent applicants reveal all relevant information to the patent office to assist in the examination process. The US imposes a duty of candour on patent applicants while the Indian patent law requires patent applicants to provide the status of their application in other countries – if there is a rejection or amendment required by another patent office, this information can be of tremendous use and importance to the patent examiner.

Not all countries conduct substantive examination – in jurisdictions where substantive examination of patent applications is not carried out, the validity of the granted patent is dealt with during infringement actions.

At the end of its examination the examiner can raise objections to the attention of the applicant who may respond to them and make amendments to the application.



Insert. Patenting process in developing countries

One of the problems for patients in developing countries is the absence of substantive examination. Due to the lack of expertise and investment and the overwhelming administrative burden created by the patent system, only a formal examination is performed in several countries. Instead of carrying out a substantive examination, countries rely on examinations performed by big patent offices (United States Patent and Trademark Office (USPTO) or EPO, for instance). Some outsource the examination to WIPO which in turn uses developed country patent offices. Many consider that this is better to ensure that an examination is performed. However, the big problem with this approach is that the patentability criteria, as established by the national law, is not necessarily the same, nor is there a uniform approach to the strictness with which patent applications should be examined. Several developing countries apply much stricter examination resulting in fewer patents being granted and greater space for production for their local industry while developed country patent offices may have a less strict approach in order to encourage the patents of their industry. Apart from outsourcing examination to developed countries, several developing countries also rely on the USPTO, EPO and Japan Patent Office (JPO) to train their patent examiners. In this way too developed country standards creep into developing country patent offices.

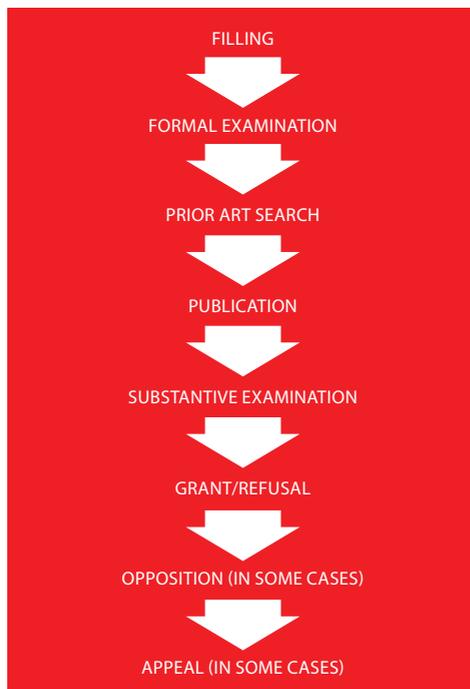


FIGURE 1 Patent granting procedure.

Source: WIPO, *Guide to Using Patent Information*, [http://www.wipo.int/edocs/pubdocs/en/wipo_pub_1434_3.pdf].

Most developing countries are almost exclusively importers of goods covered by intellectual property rights. It is also more difficult for them to face excessive prices. Their interest is even more than in other countries to make use of the room of manoeuvre in the TRIPS agreement regarding the definition of patentability requirements, apply strict patentability criteria and limit the granting to high quality patents – when in countries such as the US, rather lax criteria are applied and some balance may be achieved through litigation in court.

Developing countries usually consider that they could not develop proper examination competencies. Several examples prove that this is not true and that strict examination of pharmaceutical patents can be developed in countries with limited resources. The Egyptian Patent Office (EGYPO) is one example: with several dozen of examiners active in the field of pharmaceuticals, it performs substantive examination of patent application and may refuse some patent (as it was the case recently with the patents covering the treatment against hepatitis C, sofosbuvir). In Argentina, after the introduction of new guidelines for the examination of pharmaceutical patents in 2012, the number of patents granted was 54, while in Mexico, a similar-sized market to Argentina, the number of patents granted in 2012 for pharmaceutical products was 2500.

Even without a large number of examiners, patent office in developing countries can allocate targeted resources on area with high social impact such as health in order to protect key rights and needs. South-South collaboration and regional cooperation can also be a way for countries with limited resources to avoid a risk of monopoly for years for matters that are not inventive.

Grant/refusal

If the examination process concludes that the application deserves to be approved, possibly after its amending, the patent is granted and the office issues a certificate of grant. Otherwise, the patent application is rejected and the patent is refused.

Opposition

Within a specified period, many patent offices allow third parties to oppose the patent granted on the grounds that it does not in fact satisfy patentability requirements or meet other requirements of the patent law.

Appeal

In general, decisions of grant or refusal of a patent and decisions of opposition boards can be challenged before an administrative body or a court.

Insert. PTC

The World Intellectual Property Organization is managing the Patent Cooperation Treaty (PCT) that established an international filing system. 152 countries are contracting States. The PCT makes it possible for applicants to introduce patent application simultaneously in a large number of countries by filing an "international" patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national (or regional) patent Offices in what is called the "national phase"; patents remain territorial rights applying only in the territory of the office that granted it.

The PTC procedure includes:

The Filing: the applicant files an international application with a national or regional patent Office or with WIPO.

International Search: an "International Searching Authority" (ISA)¹ identifies the published patent documents and technical literature ("prior art") which may have an influence on whether the invention is patentable, and establishes a written opinion on the invention's potential patentability. International Publication: as soon as possible after the expiration of 18 months from the earliest filing date, the content of the international application is disclosed.

Supplementary International Search (optional): a second ISA identifies, at the request of the applicant, published documents which may not have been found by the first ISA – due for instance to the diversity of prior art in different languages and different technical fields.

International Preliminary Examination (optional): one of the ISAs, at the request of the applicant, carries out an additional patentability analysis, using the same standards on which the written opinion of the ISA was based. During this phase amendments and arguments can be submitted and an interview of the applicant with the examiner is possible. At the end of the procedure, an international preliminary report on patentability is issued by the examiner. National Phase: at the end of the PCT procedure, usually at 30 months from the earliest filing date of the initial application (from which the applicant claim priority), s/he start to pursue the grant of the patent directly before the national (or regional) patent Offices of the countries in which s/he wants to obtain them.

1. One of the patent offices among the following, appointed by the PCT Contracting States: the national Offices of Australia, Austria, Brazil, Canada, China, Chile, Egypt, Finland, India, Israel, Japan, the Philippines, the Republic of Korea, the Russian Federation, Singapore, Spain, Sweden, Turkey, Ukraine and the United States of America, and the following regional Offices, the European Patent Office, the Nordic Patent Institute and the Visegrad Patent Institute.