

PATENTS, Product Patenting Strategies ...

1. What is a “product patent”?

A “product patent” is a patent giving protection to a product as such, e.g. as an apparatus, a device or a chemical compound. If the patented product is a chemical compound, the patent is also called a “substance patent”. In the field of pharmaceutical inventions, a product patent gives protection to a chemical/biological compound (The active component of a medicine), also called a “New Chemical Entity” (NCE) or Active Pharmaceutical Ingredient (API).

2. What is a second generation patent?

A novel compound is patentable *per se* if its use is novel and inventive. A novel compound fulfilling these requirements may be protected *per se* by a “product patent” also called a “basic (compound) patent”.

“Secondary” or “second generation” patents are patents directed to “new developments” or “improvements” of the subject-matter of the “basic patent”.

If patenting strategy is carefully managed, secondary patents may bring, in some circumstances, extension of the term of protection around the product of interest. Basic patents and secondary patents may not belong to the same owner, sometimes having the effect that the owner of the basic patent is prevented from practicing certain embodiments falling into his own patent. However, careful management of patenting strategy around your product of interest can minimize the risk of being blocked by competitors’ second generation patents (see items 5 and 6).

3. What kinds of protection are available around a product?

A product of interest may enjoy different types of protection, each of which may impact your intellectual property rights and your competitive advantage.

3.1 Different types of protection

Different types of protection may be obtained around a product, such as:

- Product (compound *per se*/composition of matter)
- Process (methods of manufacturing it)
- Product by process (if the compound is novel)
- Use of the product or method of use protection (utility of the compound)
- Formulation of the product (e.g. cosmetic or pharmaceutical formulations)



-First and second medical use (for compounds found to be useful as a pharmaceutical).

The type of protection may differ from one country to another and therefore your Patent Attorney should give you advice on the type of protection you may aim at, based for example on your territorial commercial interests.

3.2 Some specific cases

Known compounds never used (or anticipated for use) in a medical indication

A compound that is known for use in a non-medical indications may still be patented for any medical indication and for a specific medical indication, in some countries (first medical use) if the inventor finds that it is useful as a pharmaceutical.

“Natural” products

Natural products may still be protected by patent claims framed in such a way as to distinguish the claimed product from the product as found in nature.

4. “Basic” patents

A basic patent generally protects a chemical (and eventually salts thereof) or a biological compound per se (composition of matter). It may further protect formulations of this compound, methods of using such a compound and methods of manufacturing it.

5. “Secondary” (follow-on) patents

Secondary patents protect “new developments” or “improvements” of the subject-matter of the basic patent. Depending on when the secondary patent is filed (before or after the publication of the basic patent), the patentability requirements for the subject-matter of the secondary patent are (i) novelty only with respect to the basic patent or (ii) both novelty and inventiveness (non-obviousness) with respect to the basic patent.

Secondary patents may be for example directed to:

- Purity/purified form of the compound
- New salts, esters etc...
- Species from the genus or sub-genus (selection invention)
- Metabolites
- Crystalline form
- New formulation
- Combination formulation (with another substance)
- New manufacturing process



- Delivery route
- Dosage regimen
- New therapies/Indications (not predictable).

If the basic patent is published, the patentability of the subject-matter for secondary patents as referenced above will depend on the non-obviousness of its subject matter with respect to the basic patent. Support for its non-obviousness can be found by answering some questions with respect to the general state of the art including the basic patent (if the basic patent is published), such as:

How predictable was the result?, Which unexpected benefits were found?, What were the problems which had to be overcome?, Do the new findings it contradict existing wisdom? Etc...

Patentability may depend on the amount of support you can provide to support the “beneficial” effects of the subject-matter for this secondary patent.

6. When to file secondary patents?

- In the decision for filing secondary patents should carefully balanced several -**
- The full use of the Paris Convention (20 years protection);
 - The risk of filing too early in the scientific process: enablement/sufficiency and technical effect objections may arise during prosecution;
 - The competitive advantage of filing secondary patents, especially when you do not own the basic patent;
 - The risk of filing too late: competitors may file secondary patents that may affect your freedom-to-operate on your product under development;
 - The risk of filing too late: your own disclosures or those from third parties may destroy the patentability of secondary patents by rendering their subject-matter non-novel or obvious.

7. Patent term extension

Although the legal term of a patent is normally 20 years from filing the “effective patent term”, defined as the length of time in which a product (pharmaceutical and agrochemical products) is marketed with the benefit of enforceable patent protection, may be very much shorter due to lengthy regulatory processes.

Patent term extensions and the like are available in some countries to compensate for regulatory delays.

Deadlines for applying for such patent term extensions are quite short and are triggered by the market approval from the regulatory authorities.



7.1 Patent term extensions (PTE)

Patent term extension is available in the US, Japan, Israel, Australia, Taiwan, Korea and in some other countries for products subject to a regulatory approval.

7.2 Supplementary Protection Certificates (SPCs)

In Europe, the possibility of extension of the term of a patent to compensate for regulatory delays is offered by a Supplementary Protection Certificate.

The aim of the supplementary protection certificate is to give 15 years of “effective patent protection”, defined as being the period during which a product can be sold while benefiting from the protection of either a patent or an SPC. The idea is to ensure that a patent holder can, if desired, market a patented product exclusively for at least 15 years.

The SPC duration is such that it offers a maximum term of 15 years after the first market authorization for the product in the European Economic Area (EEA) and can give up to a maximum of 5 extra years from the normal patent expiry (“basic patent”) in respect of a medicinal or plant protection product.

The SPC does not extend the entire scope of the patent on which it is based but is limited to the product covered by the marketing authorization and for any medicinal use of the product that has been authorized. An SPC may be granted for more than one compound per patent.

Although SPCs are governed by an EU regulation, since patents are national, SPCs are national too. Therefore SPC applications should be nationally filed for on a country-by-country basis.

Deadlines for applying for SPCs are triggered by the market approval by the regulatory authorities (either through centralized procedure via the European Medicines Agency (EMA) or the approval in each country) or by the patent grant date whichever expires later.

Switzerland and Norway have their own patent extensions provisions which are similar to the SPC regulations existing in Europe.

7.3 Other types of exclusivity

Other ways of extending competitive advantage in the Biotech and pharmaceutical industries include Data exclusivity protection, Orphan drug protection and Paediatric exclusivity.

8. Strategies for optimizing patent product life



Complementary strategies to optimize product patent life require good communication, between Intellectual Property professionals, marketing decision-makers and regulatory professionals.

8.1 Close follow-up of product development is essential

It is of utmost importance that patent attorneys/professionals are provided with the necessary information that may be crucial in the decision for filing “secondary” patent applications, for example. Relevant information can be provided through the following diligent process:

- Continuous monitoring of a product which is being developed;
- Monitoring the opportunities for matter that may support “second generation” patents (new process of manufacture, new formulation, new indications/new use, new regimen, new patient population, new route of administration etc...);
- Anticipating the possibilities opened to third parties seeking to work around your basic or secondary patents;
- Evaluating the competitive advantage of filing secondary patents, especially when you do not own the basic patent.

8.2 Active patent prosecution strategy

It is important to actively build-up your patent prosecution strategy. For example, a patent clustering strategy around your product of interest should be carefully managed through the timely filing of secondary patent applications and/or the filing of divisional applications, keeping in mind some country-specific provisions in terms of double-patenting, file-wrapper “estoppel” and restrictions on the filing deadline and content of divisional applications.

8.3 Diligent follow-up on marketing/regulatory status

In case of medicinal products or plant protection products subject to pending regulatory approval, coordinating marketing/regulatory approval information in all countries and patent strategy is crucial for optimizing patent life cycle management.

8.4 Careful follow-up on competition

Carefully sustained competitive intelligence around the product of interest is crucial to guide you in the decision to file secondary patents, particularly when you do not own the basic patent.



Analysis of the competitive landscape should take into account various strategies for optimizing patent product life mentioned above which are also available to your competitor.

8.5 Consideration of additional forms of protection in some countries

Other forms of protection may have to be considered, depending on your field of activity and on the countries where you are/intend to be commercially active.

For example, filing utility model and design patents directed to a delivery device and/or a product package for the product of interest may provide a competitive advantage, in addition to the filing of the composition of matter patent.

In China for example, failure to file such utility model and design patents may create a loophole for third parties who may file such utility model and design patents around your product of interest. This can cause lengthy, costly and uncertain invalidation proceedings for the owner of the product patent. These troubles could be avoided by using such additional types of protection which have the advantage to enable the owner of the product patent to stay one step ahead vis-à-vis potential competitors.

9. Role of the patent attorney

A patent attorney may come with a fresh eye on your projects and propose you possible patenting strategies, making use of a global view of patent life-cycle management.

By virtue of his/her international contacts with foreign patent attorneys, the patent attorney can guide you in building a worldwide patent strategy adapted to your commercial needs.

As mentioned above, detailed information on product(s) under development, new developments, marketing plans and regulatory status are crucial information you may want to share with your patent attorney in order to enable him/her to provide you with the best advice adapted to your needs. His/her objective is to ensure optimum protection and, if possible, to extend protection to other embodiments of the invention and optimize your Intellectual Property rights' life.

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