

Patent & Regulatory Summary Document for Industrial and Tologix

NOTE:

The term innovator refers to the company bringing an innovative drug to market. The term patentee refers to the holder of a patent. In some cases, an innovator may not have any patents in force but may still qualify for regulatory exclusivity, as discussed below.

The terms application for marketing approval, regulatory approval submission or regulatory filing may be used interchangeably.

Drug Development

It is estimated that for every 5,000-10,000 compounds under research, only 1 will be approved and brought to market.

It takes **over a decade of work and billions of dollars** to bring that 1 new drug to market.

The pre-market drug development stages are:

Discovery & Development - Research for a new drug begins in the laboratory.

Preclinical Research - Drugs undergo laboratory and animal testing to answer basic questions about utility and safety.

Clinical Research - Drugs are tested on people to make sure they are safe and effective.

Regulatory Review - Government agencies examine all submitted data related to the drug and decide whether or not to grant market approval in their country.

Market Exclusivity

Once a new drug enters the market, the goal is to **maximize the period of market exclusivity**.

This period of market exclusivity is critical to:

- recoup the investment it took to get the drug to market
- recoup the cost of research that did not lead to commercial products
- fund future research
- fund litigation against generic competitors
- run the company
- make a profit

Once a generic competitor enters the market, the innovator loses **80% of their market share** within months. This is a significant loss of revenue for the company.

Every extra day on the market without generic competition is extremely valuable to the company. Therefore, every company must track the date of **LOE: loss of exclusivity**.

Market Exclusivity

The main forms of protecting market exclusivity are:

- Patent protection, including
 - o Patent term adjustment
 - o Patent term extension
 - o Linkage Regulations

- Data protection (for new chemical entities), including
 - o Extensions for research in certain disease areas
 - o Extensions for research in certain patient populations

The particular provisions available to innovators vary by jurisdiction.

Patents

A patent grants a limited period of monopoly to a patentee in exchange for a full disclosure of their invention to the public.

During the term of a patent, a patentee has a right to “exclude others” from making, using or selling the patented invention.

Patents right are jurisdictional, meaning you must apply for a patent in each jurisdiction where you want to have patent protection.

Every country has their own unique patent laws.

Obtaining a Patent:

- A patent application is drafted and filed in any jurisdiction where the patentee wishes to have patent protection.

- The application is examined in a government Patent Office in each jurisdiction where the application is filed.

- A negotiation (patent prosecution) takes place between the Patent Office and the patentee's legal representative, during which time the application may be amended to comply with the legal and formal requirements of the jurisdiction.
- A patent is granted or the application is dropped.

The patent prosecution phase generally takes 3-5 years. Some countries are faster than others.

Patent Term

Once granted, the basic term of a patent is **20 years from the filing date**. However, in some cases the term can be extended, as described below.

Patent Term Adjustment

Some countries, notably the USA, grant patent term extensions for delays caused by the Patent Office during patent prosecution.

The calculation of extra term is performed by the Patent Office and may be disputed by the patentee if they believe they are entitled to additional term.

Patent Term Adjustment (Restoration)

A drug company cannot bring a product to market without conducting lengthy (and expensive) clinical trials and undergoing extensive regulatory review.

By the time a drug product finally gets to market, a patent typically only has 3-8 years of term left. This problem is unique to the drug industry.

In order to address the problem, an innovator can apply for patent term adjustment in certain jurisdictions to compensate for the time lost during the regulatory approval process.

The length of time by which the patent term can be extended, if at all, varies by jurisdiction.

In order to take advantage of patent term restoration, an innovator must apply and make strategic decisions regarding which patent rights to extend. The process and requirements vary by jurisdiction.

Linkage Regulations

Some countries have regulations that "link" the patent system to the regulatory approval system for new drugs.

When an innovator files an application for marketing approval (regulatory approval submission), they can list any relevant patents on a public register to ensure that no generic competitor can receive marketing approval for a 'copycat' version of the drug without first addressing those patents.

In order to take advantage of linkage regulations, an innovator must list the patent on the patent register and meet all eligibility and timing requirements. These requirements vary by jurisdiction.

Special litigation proceedings have been developed to deal with patents listed on these public registers.

Data Exclusivity

In order to get a new drug approved, an innovator must file a regulatory approval submission with a government regulatory authority (e.g. FDA in USA, Health Canada in Canada, EMA in Europe).

The regulatory submission contains extensive clinical and manufacturing data in order to prove that the drug is safe and effective.

When a generic competitor wants to bring a 'copycat' version of the product to market, they are not required to conduct their own clinical trials. They can rely on the innovator's data.

This is why generic companies can sell their drugs much cheaper than innovators. The generic does not have to invest billions of dollars in research.

To incentivise innovators to continue the costly endeavor of drug research, many jurisdictions offer data protection for new chemical entities, i.e. new drug molecules that have not previously been approved as a medicine.

During the data protection period, a generic competitor is prohibited from relying on the innovator's data in order to expedite approval of a generic version of the drug. Accordingly, the innovator enjoys market exclusivity during the data protection period.

Some countries offer an additional term of data protection to incentivise innovators to conduct research in certain areas, e.g. rare diseases or pediatric populations.

Data protection begins on the date of market approval and is entirely independent of having a patent. In some cases, the period of data protection can extend beyond patent expiry.

In order to take advantage of data protection provisions, an innovator must apply and meet all eligibility and timing requirements. These requirements vary by jurisdiction.

Problem

LOE can be complicated to track as there are multiple legal systems to protect innovators from premature generic competition, each system with its own regulations and associated eligibility and timing requirements.

To make matters worse, each country has its own unique systems and regulations, so the type and length of additional exclusivity an innovator can be granted varies.

Furthermore, different teams inside the company are responsible for dealing with the different legal systems and there is a general lack of information flow between the teams.

There is often no central place where all of the patent and regulatory information is stored related to market exclusivity.

In addition, certain critical information must be inputted by and/or shared with external counsel and commercialization partners in various countries.

Companies must rely on external counsel to advise them on the unique provisions available in each country, as well as the application processes, and the timing and eligibility requirements.

Solution

Build a program where critical patent and regulatory information related to a particular product is stored and can be easily accessed by anyone who has permission to access it.

Build the legal regulations into the program to make it easier for teams to be aware of, and take advantage of, the exclusivity provisions available in each country.

Effectively track LOE.

This will enable teams to be more informed, prepared and proactive in developing global strategies for protecting market exclusivity. It will also minimize risk of premature loss of market. It will also enable companies to effectively plan for LOE and any associated litigation.

Users

This primary users of this product will be patent and regulatory teams within a company developing commercial drug products.

Additional users will include internal legal teams, external service providers (e.g. law firms, consultants) and external commercialization partners in various jurisdictions.

NOTE: I have not included price control regulations here as they do not relate to exclusivity per se, but these will also be built into the software at some stage.