

Legal aspects of the pharmaceutical and generics industry - protect your “Return on Innovation”

Patents in general and within the pharma industry

Generally, commercial enterprise is about finding profitable products or services that someone is willing to pay for. Through research and product- or business development companies invest in finding new solutions that provide an advantage over competitors and make the company more profitable in the long-term. As a process innovation is about taking an idea all the way to commercialization.

Much oversimplified, the innovation process may be divided into four steps.

1. The first step is to state the idea as a solution to something which customers ultimately seek and are willing to pay for.
2. The second step is to develop a concept, a workable solution or a prototype, which has the expected properties and performance.
3. The third step is to develop a finished product that satisfies the regulations that may apply on the market and which is also permissible, taking the IPR situation in account, for the company to produce and sell.
4. Finally, the fourth step is to produce, distribute and sell the product on the market.

Patent rights play an important role in this process. We must remember that the purpose of patents is to disseminate knowledge and encourage innovation and creativity. Those who share their knowledge are offered a time limited exclusive right to monetize their knowledge, but the field is left open for others to learn from and be inspired by the knowledge. Those who are granted a patent therefore have the exclusive rights to exploit their knowledge commercially, but for a limited time.

Patents may be granted in areas which are already covered by previous patents, especially when it comes to improvements or selection inventions within mature technologies. Thus, all companies launching a new product should verify that the new product does not infringe someone else’s patent. Similarly, the company itself has the opportunity to apply for patents for solutions they believe are unique and valuable enough, making the investment worthwhile.

This is particularly evident in the case of pharmaceuticals, as there are so many regulations and requirements for a new pharmaceutical to conform with. For companies developing new drugs (original preparations) the patent system is a way to “guarantee” a return on investments, or “Return on Innovation”, as we prefer to call it. During the term of the patent, the company must be able to recover a reasonable return on what they invested in the innovation process. Of all drug development projects, only very few that make it to launch as a new drug. Around 10% of the drugs in clinical phase 1 eventually make it to approval, and this figure does not even take into account the huge attrition at the preclinical stage. To develop and get new drugs approved is thus a process that requires huge investments. When this work is done, the cost of production of the drug is often extremely low in comparison. This creates a great incentive for manufacturers of generic products. Simply put, a company that develops proprietary pharmaceuticals invests in all of the four steps of the innovation process mentioned above, while a generic company only invests in the last step, taking advantage of the results of other’s research and development and, to some extent, also marketing of the original drug.

Thus, one can say that generic companies use the patent system as it was intended; to gather knowledge about innovation. This makes them extremely competitive, and profitable, since they do not make any investments in developing the drug. In addition, generic drug producers constantly monitor the IPR situation around original products to find weaknesses in the protection. If they find opportunities, they do not hesitate to challenge the patent protection in order to enable the earliest possible to launch of a generic product. Sometimes the exclusive right of the patent owner is challenged long before the patent expires, creating the conflicts we are seeing in courts today.

Trends and tendencies

A clear trend within the pharmaceutical industry is that the time and costs of developing new drugs, original preparations, have increased. The cost is now estimated to be 1-1.5 billion USD for a new drug.

Although the mapping of the human genome has led to novel methods for developing drugs, overall productivity in the global pharmaceutical industry's research has decreased; fewer new drugs are now approved per year than ten years ago. Another trend, visible for some time now, is that companies traditionally regarded as pharmaceutical companies to a larger extent purchase research and development from other, often much smaller companies. While large corporations have a well-developed marketing organization, the smaller companies are sometimes more creative and better at running the early steps of the innovation process.

Pharmaceutical companies as well as and generic drug companies are both focusing on the fourth step of the innovation process. They aim to produce, distribute and sell their products in the most cost efficient manner. At this stage, product branding is an additional competitive factor. We can clearly see how important the brand is as a signal of credibility, quality and - of course - the desired efficacy of the drug.

We can thus see that there are companies within the pharmaceutical industry that only work with one or a few of the early steps of the innovation process; we might call these research companies. There are also companies that only work within one or a few of the latter steps; we may call these brand companies. The pharmaceutical industry may very well transform towards networks of specialized players responsible for different parts of the innovation process where the principal player is a global "big pharma" company - a brand company - which launches, markets and sells the product. Already today it is not unusual for a project to pass from, say, a university, to a biotech company and further on to a "big pharma" before it reaches the market. In addition, other participants in the network may contribute with formulating the drug, toxicology studies, pre-clinical and clinical tests, etc. A consequence of this, besides an increased complexity in regulating and controlling intellectual property rights (IPR), may be that patent protection is sought by research companies earlier in the innovation process. This is because without IPR it is difficult, if not impossible, to participate in such a network in a manner that secures your "Return on Innovation".

The future

The importance of IPR is growing because it plays such a central role in the transfer of the project between the different participants in the network. It is crucial that rights are defined correctly, are transparent, and that ownership is regulated. Issues that are not addressed at an early stage may otherwise develop into intractable problems later on. The assignment of the rights to the invention is a typical example here.

For the same reason and because more parties are involved, we expect the importance of formalized agreements to increase. It is crucial to address questions of ownership, transfer and creation of IPR correctly in agreements during all steps of innovation. The brand company, ultimately consuming the exclusivity generated from the IPR, will continue to request safely enforceable legal rights in order to secure "Return on Innovation".

We expect traditional pharmaceutical companies and generic companies to become more similar. Already, traditional "big pharma" produce and sell generic drugs. Generic companies are filing patents and are moving into the "specialty pharma" market. Today there is a tendency for companies with the greatest margins to minimize their risks while the small companies take the big risks. This raises the question of who will finance innovation in the future.

Even in such a scenario, a brand company will have its own very valuable knowledge which sometimes is not recognized. This includes experienced staff, knowledge and experience of regulatory issues, feedback from patients using the products (knowledge banks), and GMP manufacturing capability. This takes years to obtain. It provides competitive advantages even after any patent has expired. For the research companies IPR might be the only value they can show, and their only route to "Return on Innovation".

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