The Importance and Valuation of Patents in Technology Transfer in the Animal Health Industry

PEER REVIEWED

What is Intellectual Property?
Following a definition of the World Intellectual Property Organization (WIPO), intellectual property (IP) is a protection by law, given as patents, copyright and trademarks. These enable the inventors to earn recognition and/or financial benefit. The IP system tries to foster an environment in which innovation can flourish whilst protection of inventions is given, but also the interest of the public is considered1. In research-intensive industries like animal health, patents are by far the most important type of IP and this article will therefore focus on them.

What is a Patent?
A patent is an exclusive right granted for an invention for a limited period of time in return for the public disclosure of the invention. Such inventions are, in general, products or processes and in the animal health industry they might frequently cover, among others, a (bio-)chemical compound, gene therapies, or a process for producing a specific (bio-) chemical compound or introducing specific genes. Many products in fact contain a number of inventions, moving from more general terms and going into much detail. There are a number of conditions that have to be met in order to get a patent:

- Novelty; characteristics that are not known by the public in the technical field (called "prior art").
- Non-obvious; the invention could not be deduced by a person having skill in the relevant technical field.
- Industrial application; beyond theoretical knowledge, it shall have the potential of being used for an industrial or business purpose.
- "Patentable"; in many countries, scientific theories, aesthetic creations, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods, methods for medical treatment (as opposed to medical products) or computer programs are generally not patentable. This part is very relevant for inventors in the animal health industry.
- Disclosure; clear and complete, to enable its replication by a person with skills in the relevant technical field.

Once a patent expires, the protection ends and the invention enters the public domain. At this point, anyone can commercially exploit the invention. To ensure that the granted exclusive rights for a period of time are balanced with a social benefit, technical information about the invention must be disclosed to the public in a patent application for ensuring the availability to society after the expiration of the patent.

It is important to understand that patents are territorial rights that are only applicable in the country or region in which the patent has been granted. The protection is granted for a limited period, generally 20 years from the filing date of the application. If there is an infringement, patents are usually enforced in a court which has the authority to stop patent infringement, but the responsibility for identifying and taking action against infringers of a patent lies with the patent owner.

Why are Patents Important in Technology Transfer?
Patents provide incentives and protection by offering a recognition for creativity and the possibility of earnings from the inventions for having a time of exclusive commercialisation. At the same time, the obligatory publication of patents facilitates the spread of new knowledge and accelerates innovation by the possibility of benchmarking to existing inventions. In the absence of protection of such knowledge, it would be easy to adopt this knowledge without any recognition of or contribution to the investments made by the inventor. As a consequence, companies driven by innovation would tend to keep their commercially valuable inventions as a secret. As the animal health industry is very regulated and transparent, keeping features and ingredients of products secret is close to impossible, showing the tremendous importance of a well-established patent system for this industry. Also it enhances research activities, not only by the public disclosure of the technical knowledge in the patent, but especially by the exclusive right granted by the patent, that provides incentives for competitors to search for alternative solutions. In this respect, most patents are not granted for major breakthroughs, but mostly for improvements to existing inventions that work in a more cost-effective or efficient manner.

Why should organizations with research & development activities patent their inventions?

Exclusive rights: Patents provide an exclusive right to prevent others from commercially exploiting an invention for twenty years from the date of filing of the patent application. To get access to this protection period, or the other way around – to obtain the freedom to operate, is a major driver of technology transfer.

Return on investments: In research-intensive industries like animal health, considerable sums and time are spent in developing innovative products. For the exclusive patent rights, companies are obtaining higher returns on investments for their time-limited monopoly. Technology transfer can be a welcome source of income for public institutions in order to ensure exclusivity to commercially active companies.

Opportunity to license or sell the invention: As a base for technology transfer, the patent owner can decide not to exploit the patent himself. Agreed licensing fees and royalties can be an interesting source of income.

Increase in negotiating power: Companies which are in the process of acquiring the rights to use the patents of another organisation through a licensing contract, shall have a close look at the owned patent portfolio. Patents that considerably restrict the applications of another patent could enhance the bargaining power.

Positive image: Business partners, investors and shareholders may perceive patent portfolios as a demonstration of the high level of expertise, specialisation, and technological capacity of a company. A public institution could justify its research grants and public funds with the generated public knowledge. This is used for raising additional funds and finding business partners.

How is the licensing of a patent done in technology transfer?

Licensing a patent simply means that the patent owner grants permission to another party to manufacture, use or commercially exploit the patented invention. The elaboration of terms and conditions is of crucial importance and shall be well thought out (amount and type of payment, defined purpose, defined territory, agreed period of time), as this will have an impact on the further commercial success of the product in the given field of application or a different field, that intentionally could be excluded from a licence.

In the fragmented value chain of today's animal health industry, a patent owner can grant a licence to a third party for many reasons. Oftentimes, speaking about an academic and SME environment, the patent owner may not have the necessary manufacturing facilities and therefore opts to allow others to manufacture and commercialise the finished product in return for "royalty" payments. Alternatively, a patent owner may have very specialised development and manufacturing facilities, but they may not be large enough to cover market demand or bring up very innovative research. Another possible situation is one in which the patent owner wishes to concentrate on one geographic market and may choose to work with distributors in other geographical markets. Entering into a licensing agreement can therefore help to build a mutually-beneficial and fruitful business, partnering between inventors and parties with complementary resources that are needed to have a commercially viable and exploited product.

Research-intensive institutions such as universities are major producers of patent applications. Many of these institutes are funded by public money and requested to produce results for the public. Whilst the knowledge inserted into patents is publicly available, the technology transfer based on patents is an important income source, whether it be via a scientific spin-off company or a straightforward transaction with a larger company. For these transactions it is important to be able to put a value to the patented technology.

How Can the Value of Patents be Measured?

First of all, it is important to understand that the patent is not an asset by itself and cannot be considered as a positive indication that an organisation is innovative. The value of the patent only exists when it is strategically managed depending on the skills of the inventors and the organisation itself, and when there is a demand in the market.

Therefore, thinking about the value of a patent is thinking about a particular context, both internally to the organisation and externally, as it will depend on the circumstances and environment of the market that is being considered.

The WIPO defines the valuation of intangibles as "The process of identifying and measuring financial benefit and risk of an asset, in a particular context." In this definition, risk is representing both the money and time that are needed for this technology to arrive to the market, with the value of the asset increasing as the necessary money and time to the market decreases[2].

One of the main concepts to have in mind is that the value of an intangible asset is not its cost of getting granted or maintaining the patent, or "real" market value of sales of the finished products. It should consider the financial benefit that this technology will generate in a given context, never forgetting to consider the existing risk of taking this asset from the point it is at a particular moment until it is ready to be marketed.

Several methods can be used to perform patent valuation, and all of them have advantages and disadvantages. These methods can be divided mainly into two categories: qualitative and quantitative valuations. For a proper valuation, it is important to understand the specific context and choose the best method in each situation, considering even using a combination of different methods[3].

Qualitative methods aim to provide a non-monetary value guide for the asset. For that, specific factors are chosen for the analysis (value drivers). These factors are then rated and scored, based on facts that can influence the asset´s value. It can take into consideration both micro- (quality of asset, importance within the industry and competitors) and macro-economic indicators, depending on the approach used.

Quantitative methods calculate the monetary value of the patent (including, for example, cost, market, income and other methods).

In cost methods, the valuation takes into consideration the cost of development of the technology itself, and it is especially useful in cases when the future benefits from the use of this technology are not yet evident. The main issue is that there is not a direct correlation between the potential future benefits generated by a technology and its developmental cost, which makes it a very limited valuation method On the other hand, market-based approaches use a similar situation (a similar asset licensed in the same industry, for example) to make comparisons and adjust to another specific situation. It is a very accurate method in theory, but it depends on the availability of the required information, benchmarks, for the comparison.

Income-based methods value the potential income that a patent can generate when the protected technology reaches the market. It is a complete and more detailed valuation, that considers the income (by sales, royalties, licensing, etc), the duration of the patent and the risks involved. Income methods are particularly useful for patents that actively generate incomes. A very well-used technique in the animal health industry is the calculation of a risk-adjusted net present value.

What about Patents in the Animal Health Industry?

The animal health industry faces the same challenges as the human health industry when it comes to patents, having to deal with generic products, counterfeiters and, as discussed in this article, the necessity of valuating and protecting new products in technology transfer deals.

In most cases, the patent law is applied in the same way to human or animal products, but there are some specific exceptions that should be taken into consideration when navigating the field of veterinary medicine[4]. It is extremely important for inventors in the animal health field to keep these few special situations in mind, in order to be able to explore them correctly and know how to behave if they present themselves at any point in time.

A comprehensive review of that topic was performed in 2008[4] and our objective is to show a summary of the specific exceptions in different areas of patent law applications regarding animal health invention. We believe that many other points may exist.

Issue of Obviousness and Cross-species Situations

The issue of obviousness has been discussed in several cases,

both in the US and Europe. The definition of obviousness is different when comparing the US patent law (35 U.S.C. § 103) and the European Patent Convention (EPC), leading to different evolutions of the issue between these two regions.
When considering topics specifically related to animal health, cross-species situations can generate exceptions that need to be taken into account carefully when developing and patenting new animal drugs. Imagine a situation where an active ingredient is already known and used in species "1", and a new drug is developed using the same active ingredient (or another member of the same class of active ingredients) for species "2". Would that be considered as obvious and the new drug not be able to be patented?

In a situation like this, some key points need to be considered:
If there is prior art showing that other active ingredients from the same class do not work in species "2", the novelty of the invention can be more easily claimed. This is the easiest scenario that can happen on the cross-species issue.

In cases that the new drug (or another from the same class) has never been tested on species "2", the situation gets more complicated. In this case, the patent applicant has to demonstrate that the claimed invention is surprising and unexpected, by identifying reasons by which the drug was expected not to work in species "2". The main point here is to prove the unpredictable character of the discovery, considering the cross-species situation studied.

Issue of the Generic Animal Drug and Patent Term Restoration Act (GADPTR)
In 1984 the Hatch-Waxman Act was implemented, in which the generics company were given the benefit of earlier entry possibilities, in exchange for the fact that the originator company would retreat some of the lost years of patent life due to regulatory processes. This act is specific to human health-related inventions. A few years later, in 1988, this act was extended to the animal health field, with some important differences, by the Generic Animal Drug and Patent Term Restoration Act (GADPTR).

In the human health field, the restoration act makes very clear that a patent can only be extended once, based on its first approved use. In a different way, in the animal health area there is a unique provision that gives to the patentee the option of deferring the one-time patent extension until the food-producing animal indication is approved. That takes into consideration that food-producing animal products are much more lucrative than companion animal products in respect of patents, and therefore allows the applicant to have the full time extension for the most profitable product opportunity.

- Another important difference from the human health restoration act is that the GADPTR excludes a restoration period for genetically engineered animal products.

An important point to have in mind when dealing with animal patents regarding the restoration act is the situation when a company has two different patents for the same active ingredient, one covering its use on humans and another covering its veterinary application. In spite of the fact that the restoration act does not allow a second patent term restoration for the same active ingredient, a special scenario can be found when these two patents are completely separated and two patent extensions could be granted. It is important that both patents do not extend in scope to each other, so that they are considered independent.

Issue of Minor Use and Minor Species Animal Health Act (MUMS)

In animal health patent law there is no orphan drug designation, as known for human rare diseases drugs. On the other hand, an act was signed in 2004, in the US, intending to make more drugs available for veterinarians and animal owners for treatment of minor animal species and uncommon diseases in the major species[5]. The major difference between both of them is that the MUMS designation only gives the patentee more exclusivity time, but does not provide patent extension rights or tax reductions, as the orphan status does.

References

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