IP and innovation in biotechnology and pharmaceuticals

While the pharmaceutical sector relates to all the economic activity aimed at researching, manufacturing and marketing drugs, biotechnology refers to any technological application that uses biological material to make or modify products or processes (e.g. genetic engineering). Today, both pharmaceutical and biotechnological inventions can be the subject of patent protection. Furthermore, the categories of patentable biotechnology inventions in many OECD countries have expanded over the years to include genes, gene fragments, research tools and diagnostics, and genetically modified plants and animals. In particular, the number of gene patents granted has risen significantly since the second half of the 1990s, which has triggered concerns regarding the application of patentability requirements, the scope of protection of these inventions, the formation of patent thickets, licensing and litigation costs. In order to address those issues, different policy measures are available, including: providing subsidies to increase seed and start-up capital for small biotechnology firms, encouraging good licensing practices, clarifying and reinforcing research exemptions, exploring alternative access arrangements and knowledge transfer mechanisms, improving the quality of patents issued, and monitoring emerging access challenges.

What is the biotechnology and pharmaceutical industry?

Pharmaceutical

The pharmaceutical sector relates to all the economic activity aimed at researching, manufacturing and marketing drugs for human (or animal) medicine.

Since the 1900s, growing bonds between biology and engineering have led to the development of biotechnology as a science. The 1953 discovery of the deoxyribonucleic acid (DNA) molecule's structure by Crick and Watson, and the later development of a recombinant DNA technique by Cohen and Boyer in 1973, are the two key events that established the basis for new advances in biotech sciences (Bud, 1993; Vettel, 2006). Since then, biotechnology and pharmaceutical companies have established close links that have led to new innovation strategies (Galambos and Sturchio, 1998).

Biotechnology

Biotechnology can be broadly defined as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (Convention on Biological Diversity, 1992).

Biotechnological research can be classified into three main categories. In addition to "red biotechnology", which includes human and animal healthcare-related products, biotech research can be focused on "green biotechnology", which relates to applications in agriculture and stockbreeding, or "white biotechnology", which relates to industrial production processes, energy and the environment.

The potential of biotechnology to increase agricultural production, improve human and animal health, and protect the environment has been widely acknowledged, leading many governments to use the level of innovation in biotechnology sciences as an indicator of a country's competitiveness and economic performance. Today, biotechnology research is principally focused on genetic engineering, which includes the act of identifying what stretches of DNA in an organism correspond to what genes. This has been the grand pursuit of biotechnology research since the 1990s and will surely continue to be in years to come (Tudge, 2000). Most recent advances in biotechnology include protein engineering, DNA shuffling, gene therapy and synthetic biology.

How does intellectual property (IP) relate to biotechnology and pharmaceuticals?

The legal context of IP for biotechnology and pharmaceuticals

The 1980 US Supreme Court decision in Diamond v. Chakrabarty on the patentability of a genetically modified bacterium established the legal landmark by which inventions involving biological materials and some life forms were deemed patentable in the US and other countries (OECD, 2002). Although in some OECD countries the legal and commercial nature of biotech inventions is still under discussion, after the Chakrabarty decision the statutory situation of gene patents has been much clarified in most OECD member states, especially since the late 1990s. For example, in 1998 the US Patent and Trademark Office (USPTO) decided that gene fragments, such as expressed sequence tags (ESTs), were patentable if the patent application disclosed a genuine function. In 2001, the USPTO published revised guidelines on the examination of patent applications, which clarified that patent applications must disclose “a specific, substantial and credible utility”. In Europe, the EU Directive 98/44/EC on the legal protection of biotechnological inventions states that gene sequences with specified functions are eligible for patent protection. In 2001, the Japanese Patent Office (JPO) also issued examination guidelines for biological inventions, as well as examples of examinations for inventions related to DNA fragments, full-length cDNA and single nucleotide polymorphisms (SNPs) (OECD, 2002).

Furthermore, the USPTO, the European Patent Office (EPO) and the JPO co-operate through a trilateral commission to reach agreement with respect to their patent examination practices for [illegible] inventions whose commercial exploitation would be contrary to public order or morality (OECD, 2002).

Evidence on IP use in biotechnology and pharmaceuticals

Each year, thousands of biotechnology patents are issued worldwide, leading to the successful development of new products, services and tools in fields as diverse as agriculture, pharmaceuticals, environmental clean-up, and industrial products and processes (OECD, 2004). The categories of patentable biotechnology inventions in many OECD countries have expanded over the years to include genes, gene fragments, genetic-based tools and diagnostics, genetically modified plants and animals, and a host of inventions derived from the revolutions in genomics, proteomics and pathway engineering (OECD, 2004). In particular, the number of gene patents granted has risen significantly since the second half of the 1990s (OECD, 2002; OECD, 2004).

Biotechnology patent statistics show that since the boom in biotech patenting in the 1980s (Zucker and Darby, 1997), there has been a rapid rise in patent grants. From 1990 to 2000, the number of patents granted in biotechnology rose by 15% a year at the USPTO and by 10.5% at the EPO, compared with a 5% increase in overall patents (OECD, 2004). However, more recent statistics show changes in those trends. For example, between 2008 and 2012, the number of PCT applications that were published concerning biotechnology inventions had only grown in four applications, while the number of PCT applications published in the pharmaceutical field decreased in more than 1,000 applications (WIPO, 2013).

In addition, the public sector has also played an important role in the growth of patents for biotechnological inventions. For example, US and European public research organisations (PROs) own 30% of all the patents for DNA sequences filed between 1996 and 1999 (OECD, 2004). Finally, start-up companies have a higher share of biotechnology patents than do large, established pharmaceutical companies (OECD, 2004). On the other hand, it can also be noted that both pharmaceutical and biotech companies also show high levels of open innovation (OECD, 2009).

Regarding types of IP [1] used by the sector, pharmaceutical trademarks play an especially important role in pharmaceutical and bio-pharmaceutical innovation. While generic names have their role in providing consistent terminology for certain compounds around the world, it is trademarks that enhance public health by assisting health professionals in reducing medication errors, enabling consumers to choose the medications that are right for them, and providing manufacturers with the incentive to both develop new drugs and monitor the safety of existing drugs (INTA, 2007).

Evidence on the link between IP and innovation in biotechnology and pharmaceuticals

Most biotech firms are small, research-led enterprises that rely on pre-seed investments to develop their projects. In order to secure continuous research and innovation, firms use patent applications as a means to guarantee investors that they will recover their investments. As in other R&D intensive industries like the pharmaceutical sector (Levin et al., 1987; Cohen et al., 2000), biotechnology companies find patents to be an irreplaceable means for appropriating innovation returns (Mansfield, 1986; Levin et al., 1987). Most of the small- and medium-sized firms in the US biotechnology industry would not have come into existence without the prospect of patents to help them make profits and attract capital investors (Mazzoneli and Nelson, 1998).

In the pharmaceutical and bio-pharmaceutical sectors - where innovation costs are very high, regulatory approval substantially delays market entry and few R&D projects result in marketed drugs - patents are considered an essential factor in protecting competitive advantage (OECD, 2004). Patents have a role to play for start-ups and university spin-offs in the biomedical field because both rely on protected IP as their main asset in raising capital for development (OECD, 2004).

Debates regarding IP and innovation in biotechnology and pharmaceuticals

While a rise in the number of patents for genetic inventions can certainly be a sign of dynamism in a new technological sector, questions have been raised about the potential impact of the growing web of gene patents on the research environment, the market dynamics for new product development, and the clinical uptake of new tests and treatments. Since gene patents have existed for several years, the concerns they raise are increasingly about the way the patents are used and licensed (or not licensed) by their owners (OECD, 2002). Some believe that, in a number of cases, the criteria of novelty and inventive step are not being met, and that broad patents are issued that could give patent holders an overly-strong negotiating position vis-à-vis possible licensees (Nuffield Council on Bioethics, 2002; OECDc, 2003; Walsh et al., 2003). Moreover, the rapid proliferation of gene patents may increase commercial uncertainty, owing to possible dependency between granted patents. In this case, too much litigation could again slow progress, raise end-product costs or discourage entry to certain fields of enquiry (OECD, 2002). Furthermore, because only licensed entities can offer patented genetic tests, if a patent-holder decides not to license, or licenses exclusively, other clinical testing services are excluded from using (and developing) the test (OECD, 2002).

The trend in areas like biotechnology is to consider as patentable only those research discoveries whose usefulness and value lie in performing further research (Mazzoneli and Nelson, 1998). This is likely to foster the growth of markets based on patent licenses for research tools and ideas that would have otherwise been in the public domain (Mazzoneli and Nelson, 1998). Moreover, patents over research tools may increase the difficulty of obtaining the necessary tools and materials for basic research, and increase its cost (Guellec and van Pottelsberghe, 2007). This has been subject to discussion in the wider context of debates regarding the use intellectual property rights (IPR) by universities and PRIs.

Other concerns about the effect of biotechnology and pharmaceuticals patents on innovation relate to excessive patenting [1], patent thickets and royalty stacking. Nonetheless, despite these concerns, empirical surveys conclude that, on the whole, the patent system as applied to biotechnology inventions has not produced a widespread breakdown in the licensing of biotechnology patents. Examples of license stacking, restricted access and poor quality patents do exist, but in the majority of cases industry and universities have found workable solutions to mitigate their effects. Diffusion occurs through license negotiations, inventing around and alternative access solutions, such as the creation of public databases. Nevertheless, continued vigilance is necessary to ensure that licensing practices do not overtly restrict access (OECD, 2004).

What IP-related policies are relevant to support innovation in biotechnology and pharmaceuticals?

Challenges

OECD member countries are trying to balance the need to keep information and access to genetic data open in order to encourage the diffusion of research results, with the commercial need to protect inventions in order to create revenue from investments in R&D (OECD, 2002). In other words, the main policy issue is whether large investments in biotechnology are producing equivalent public benefits (Arundel, 2003).

Policy instruments

Policy makers in several OECD countries believe that firms in their countries lag behind the US in their ability to commercialise national biotechnology research efforts. The result has been the development of a variety of policies to encourage commercialization of biotech research results, with a focus beyond IP matters.

Several EU countries, including Austria, Belgium, Germany, Denmark, Finland, France, Italy, the [illegible] "Bio-Regio" programme (Arundel, 2003).

Other policies in support include:

- Encouraging good licensing practices in the public and private sectors. The licensing of [illegible] biotechnology. Good practice guidelines can encourage their further development and use (OECD, 2004).
- Clarifying research exemptions. A useful step would be to assess how research exemptions [illegible] technologies for research, while offering adequate protection for those who create novel research tools (OECD, 2004).
- Exploring alternative access arrangements. Understanding how patent pools, patent [illegible] would help move these access arrangements closer to reality (OECD, 2004).
- Conducting economic analyses of knowledge transfer mechanisms. Technology diffusion [illegible] occurs in these structures, and how market and non-market transactions are affected by various features of the patent system (OECD, 2004).
- Improving the quality of patents issued. Governments could compare how examiners in different jurisdictions interpret the criteria of patentability for biotechnology inventions, and whether these criteria are applied with sufficient rigour (OECD, 2004).
- Monitoring emerging challenges. New challenges may emerge in interdisciplinary fields such as biotechnology. Governments need to anticipate where the next generation of challenges will emerge (OECD, 2004).

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Links
[1] https://www.innovationpolicyplatform.org/content/types-ipr?topic-filters=12056
[2] http://www.nuffieldbioethics.org