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Intellectual Property Protection for Biologics

Summary

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- Biologics are a rapidly evolving area within biotechnology, and having the proper intellectual property (IP) protection is crucial to safeguarding inventions.
- IP protection of genetic material can be traced back to the early 1900s, though biologics themselves are fairly new.
- All forms of IP, including trademarks, copyrights, trade secrets, and patents can protect biologics, though most current issues have to do with patent protection.
- The U.S. government grants two types of protection against competition: patents through the U.S. Patent and Trademark Office (USPTO), and regulatory exclusivity through the U.S. Food and Drug Administration (FDA).
- There are many challenges related to obtaining IP protection of biologics, including cost, difficulties in characterization, and the uncertain nature of laws currently in place.
- Patent attorneys with experience in biotechnology and the university technology transfer office (TTO) can work with the inventors to ensure that the biologic is properly protected.

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Intellectual Property Protection for Biologics

Megan Brewster, MRA,¹ and Pallab Singh, JD, PhD²



Topic Relevance by Timeline

Summary

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- There are many challenges related to obtaining IP protection of biologics, including cost, difficulties in characterization, and the uncertain nature of laws currently in place.
- Patent attorneys with experience in biotechnology and the university technology transfer office (TTO) can work with the inventors to ensure that the biologic is properly protected.

Introduction

As technology evolves in our commercial world, the protection of the technology can be just as important as the technology itself. Though they are a fairly new area of research, biologics have extremely promising possibilities as therapeutics for many conditions. Over the past few decades, we have seen the first biologic get approved, and, years later, the first biosimilar. The introduction of biologics into the marketplace has required intellectual property law to develop new standards

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and rules for obtaining intellectual property protection of biologic material. However, in some ways intellectual property law remains ambiguous when applied to the area of biological products. In this chapter, we will provide an overview of biologics and some key differences between biologics and small molecules. We will discuss the intellectual property protections that are available for biologics, as well as how we got to the legal state we are in today.

Biological Products

Biological products, often referred to as biologics, are used in the diagnosis, prevention, treatment, or cure of disease (Center for Drug Evaluation and Research, “About Biosimilars and Interchangeable Products”). Unlike traditional small molecule drugs that are created through chemical synthesis and are fairly small in size, biologics are usually proteins, which means they are larger and more complex (Tanaka). They may exist in the form of therapeutic proteins, monoclonal antibodies, gene therapies, or vaccines, and are usually derived from living cells (Center for Drug Evaluation and Research, “About Biosimilars and Interchangeable Products”). Biologics are more expensive to produce than small molecule drugs, and, because they are complex, are often difficult to characterize, making the manufacturing process more difficult (Globerman et al.) (see Table 1). While small molecule drugs have generics, biologics have biosimilars. However, unlike generics, biosimilars are not exact copies of the original product, due to the heterogeneity of the structure and the small variations that occur during design and manufacturing (Tanaka). Further, biologics are derived from natural products, which creates a unique consideration in terms of obtaining protection on biologics when compared to traditional small molecules.

Table 1. Challenges Presented by Biologics Compared to Small Molecules.

Small Molecules	Biologics
Made through chemical synthesis	Made from living cells
Usually inexpensive	Very expensive to develop
Small, simple compounds	Large and complex proteins, difficult to characterize
Generics- exact copies	Biosimilars- highly similar, but not identical
Identical products between different lots	Variation of products
Have been in use for years, laws more detailed	Fairly recent, not many laws developed
Straightforward manufacturing process	Very complicated manufacturing process

As mentioned in another chapter, intellectual property can be divided into four broad areas: copyrights, trademarks, patents, and trade secrets (“Intellectual Property (IP) Policy”) (see the chapter “Intellectual Property: Ownership and Protection in a University Setting”). Trademarks

may apply to biologics in terms of name, branding, logos, and designs, while copyrights can be used to protect written publications or presentations. Trade secrets may be relevant to secrets held about a specific manufacturing process, such as a cell growth condition or a vector used to make a biologic (Price and Rai; Stim). Patenting biologics is especially interesting, as biologics have been around only for the past few decades, and their complexity, variation, and unpredictability sometimes make them difficult to characterize to the extent that is required for patents to be awarded (Globerman et al.).

Trade Secrets

Anytime a biologic is made, the company or individuals involved must decide what they want to patent, and what they want to keep a trade secret. A trade secret can relate to various types of information—from a specific cell growth condition to a purification process, a vector used to make a particular biologic, or the methods for making a specific type of media—so long as it has potential economic value, and the knowledge is not disclosed publicly (Price and Rai). Because even small variations in manufacturing can have detrimental effects on the safety and efficacy of a biologic, it is crucial that these practices are well controlled. This makes trade secrets of the manufacturing process even more valuable, giving a greater competitive edge to the company. However, there is one extremely important caveat regarding trade secrets in the biologics industry: all biologics are regulated by the FDA, and some information disclosed to the FDA during the regulatory process may eventually be accessible to the public (see the chapter “FDA Device Regulation: 510(k), PMA”). While there are mechanisms to request nondisclosure of any trade secrets divulged to the FDA, the FDA has ultimate discretion as to how they will treat information requested to be held secret. This is an important aspect to consider when determining what to patent and what to keep a trade secret: if something will end up being disclosed during the regulatory process, it will no longer be a trade secret, and needs to be patented if the inventors plan to prevent others from using it. Trade secrets have their limitations, but are especially useful when an invention does not meet the criteria for a patent—for example, if it is difficult to demonstrate its novelty, or if the patent is too costly to enforce (Price and Rai).

Patenting Biologics: A Brief History

Within biologics, oftentimes the structure of the biologic, the methods of using the biologic, and the process for manufacturing the biologic can be patented (Globerman et al.). Patenting for biologics is more nuanced than the usual patent requirements of novelty, utility, and nonobviousness (Sherkow and Greely). For one, it has long been debated what types of innovations within biotechnology and medicine are considered patentable. The USPTO is responsible for evaluating patent applications within the U.S., and it declares that the laws of nature, physical phenomena, and abstract ideas are not patentable (“General Information Concerning Patents”). So where does that leave biologics, which are made or derived from living cells? The answer lies within a plethora

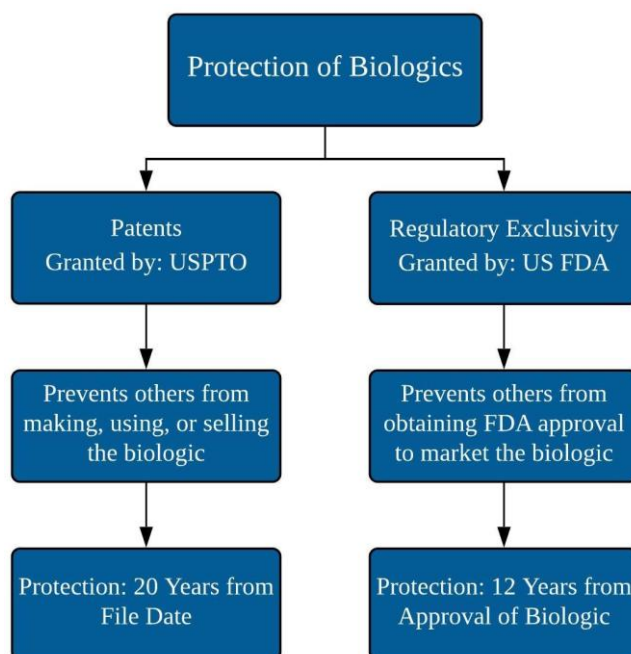
of court cases over the past century, which will be distilled here. It is important to understand how current laws got to be where they are now, and that there are still uncertainties within this field.

First, in 1900, a chemist identified epinephrine from the adrenal gland. His company, Parke-Davis, was awarded a patent on the chemical compound, and they began enforcing their patent by filing patent infringement lawsuits on their competitors who were using the chemical. Though the competitors argued that the patent was not valid because it was a product of nature, the court ruled that because the compound was isolated and purified from its natural surroundings, it was considered patentable (Sherkow and Greely; *Parke-Davis & Co. v. H.K. Mulford Co.*).

Decades later, in 1980, another prominent case occurred when a scientist at General Electric tried to patent a recombinant bacterium he had made, but the patent was denied. When the case was eventually brought to the U.S. Supreme Court, it was decided that “anything under the sun that is made by man” is patentable (“*Diamond v. Chakrabarty*”; Sherkow and Greely).

Several decades later, the Supreme Court heard another landmark case, *Association for Molecular Pathology v. Myriad Genetics Inc.*, that has drastically altered the standards for patent eligibility of biologics. Myriad Genetics had the license for seven patents related to *BRCA1* and *BRCA2*, which are genes found to be involved in breast cancer. These patents included the isolated forms of *BRCA1* and *BRCA2*, the cDNA primers and probes used in the sequencing, and the methods of sequencing for the prediction of breast cancer risk. Myriad then began enforcing their patent, which led to a lawsuit with a group that did not believe the claims at issue were related to patent-eligible subject matter. After a court case, appeals, more court cases, and more appeals, the Supreme Court ruled that genes, even if used for diagnostics, are not patent eligible, because they are a product of nature. However, cDNA, primers, and probes are patent eligible because they do not exist naturally, but they are only eligible if they can be separated from the unpatentable genes (“*Association for Molecular Pathology v. Myriad Genetics*”; Sherkow and Greely).

Together, these court cases have shaped much of the way biologics are interpreted in patent law. As a result, individuals, universities, and companies must carefully consider during the design and development of natural products the effective ban on patenting of such products. For example, there now may be a greater emphasis on designing and patenting nonnatural mutants or variants, nonnatural combinations, or specific formulations, all of which, it can be argued, are not directly related to products found in nature and are thus patent eligible.

Figure 1. Contrasting Intellectual Property Protection Authorizations.

Patents vs. Regulatory Exclusivity

There are two types of government-granted rights when it comes to a monopoly on a biologic and protecting it from competition: patents and regulatory exclusivity (Kesselheim et al.) (Figure 1). Though not necessarily considered IP, regulatory exclusivity can be just as important in protecting the biologic invention, and it is important to understand what both entail. A patent, which can also be termed market exclusivity, prevents others from making and using the invention, and thus defines the period of time in which the inventors can exclude others. Utility patents, which protect the composition of matter, process, or manufacture of the biologic, are valid for 20 years from the filing date in the U.S. (Kesselheim et al.; “Nonprovisional (Utility) Patent Application Filing Guide”). In the biotechnology realm, and especially when it comes to biologics, patents are essential to excluding others from using or producing the product, and they provide time to recoup the massive investment put forward during the drug discovery and clinical trials process. While 20 years may seem like a long time, it must be noted that developing biologics is a lengthy process, and by the time the product actually comes into the market, the patent life may have already been decreased by years (Globerman et al.; Kesselheim et al.). There are, however, certain circumstances when the life of a patent can be extended. Since the Hatch-Waxman Act of 1984, companies have the ability to petition the government to extend one patent. The maximum amount of time added is five years, and the actual time added is calculated by taking the amount of time from the initiation of clinical trials to when the product is submitted for an FDA Biologics License Application (BLA), and dividing by two (Kesselheim et al.). Though this act was originally created for drugs and uses the term “drug product” to describe eligibility, the FDA has defined this term

to include human biologic products (Kesselheim et al.; Center for Drug Evaluation and Research, “Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program”).

While the patenting of biologics is granted through the USPTO, the second form of governmental protection against competition, termed regulatory exclusivity, is governed by the FDA (Kesselheim et al.; Center for Drug Evaluation and Research, “Reference Product Exclusivity for Biological Products Filed Under”). However, this was not always the case. Up until 2010, when the Biologics Price Competition and Innovation Act (BPCIA) was passed, there were no specific details on regulatory exclusivity for biologics. The Hatch-Waxman Act defined it as five years for small molecule drugs, but the regulatory exclusivity length for biologics was not specified (Kesselheim et al.). This was a major issue within the industry, because there was no abbreviated pathway put into place for biosimilars, the “generic” versions of biologics. Decades later, the BPCIA gave originator biologic manufacturers a period of 12 years after approval (Center for Drug Evaluation and Research, “Reference Product Exclusivity for Biological Products Filed Under”). Though biosimilar manufacturers can submit their applications as early as four years after the original product was approved, the FDA will not grant marketing approval for the biosimilar until 12 years have passed for the original biologic (Carrier and Minniti; Center for Drug Evaluation and Research, “Reference Product Exclusivity for Biological Products Filed Under”).

Biosimilars

Biosimilars (sometimes referred to as “follow-on biologics”) are important to understand, because they are what comes after an original biologic and they may affect the IP. When an initial biologic is created and approved, and it is the first of its kind, it is referred to as a “reference product” (Center for Drug Evaluation and Research, “About Biosimilars and Interchangeable Products”). Biologics that come after the original that are based on the reference biologic and will be used to treat the same indications as the original can be considered biosimilars (Sarpatwari et al.). Unlike small molecule drugs, where identical copies of the same product can be made to create generics, biologics often have a more complicated structure and require a more complex manufacturing process, and therefore products can be variable (Globerman et al.; Center for Drug Evaluation and Research, “About Biosimilars and Interchangeable Products”). If the new biologic is considered “highly similar,” meaning, it has been characterized to be very close in its properties to the reference, then it can look to the safety and efficacy data of the reference product. The FDA then classifies some biologics even further into a higher regulatory standard: if the new biologic is expected to produce the same clinical effect as the reference, then it can be considered an interchangeable product. When considered an interchangeable product, a biologic can be substituted for the reference product, and vice versa, without the involvement of the patient’s doctor (Center for Drug Evaluation and Research, “About Biosimilars and Interchangeable Products”). One may be wondering why all of this matters, as an academic entrepreneur is likely at a university, and will therefore probably be the inventor of the initial biologic, not the biosimilars

that come after it. However, the creation and presence of biosimilars in the market can have a large impact on the IP and marketability of the reference product, and therefore can potentially affect the success of the biologic.

It is also important to know that the BPCIA does not just determine the regulatory exclusivity of biologics but that it serves two other major functions relevant to our topic. The BPCIA also covers the regulatory pathway for biosimilar approval (though this will not be discussed here) and the mechanism for identifying and resolving patent disputes. According to the BPCIA, when a biosimilar application has been sent to the FDA, that company must send a copy of their application to the maker of the reference product within 20 days. Within 60 days of receiving that information, the company of the reference product has to respond with a list of patents that they believe may have been infringed. The biosimilar company has an opportunity to respond, and if an agreement is not reached, they will go to court to dispute the validity of the original patents, as well as potential infringement. This entire process is termed the “patent dance” (Minniti).

Over the past few years there has been much controversy over the requirements of conducting this exchange. One of the first major issues to arise out of the BPCIA was between two biotechnology companies: Amgen, the creator of a reference biologic, and Sandoz, the creator of the biosimilar for that reference product (“Sandoz Inc. v. Amgen Inc”). According to the BPCIA, Sandoz had 20 days after submitting their biosimilar application for FDA review to send a copy of their application to Amgen, but they did not. Because the patent dance was not initiated, Amgen filed suit against Sandoz in an attempt to require them to provide the information for their new biosimilar. Sandoz argued that the statements in the BPCIA could be interpreted in two different ways (Minniti; “Sandoz Inc. v. Amgen Inc”). The first, which is the way that the BPCIA was initially interpreted by many, and is likely the way the document was originally intended to be interpreted, is that the biosimilar company must submit the application and manufacturing information to the reference company, which initiates the patent dance (Tanaka). However, the second interpretation of the BPCIA, which is the way Sandoz argues to have interpreted it, is that the biosimilar company does not have to share their application information with the reference company, thus going straight to a declaratory judgment suit. In 2015, a ruling in favor of Sandoz was issued, which stated that a company could forgo the patent dance and instead immediately face a lawsuit (Minniti; Sarpatwari et al.; “Sandoz Inc. v. Amgen Inc”).

So what does this mean for the creators of the initial biologic? This decision sets forth the framework for all future litigation regarding biosimilars. With this ruling that the patent dance is optional, it means that the company of an original biologic may not know of another company submitting a biosimilar application, leaving them temporarily unaware of the existence of upcoming competition. It also means that the company holding the reference biologic does not have the advantage of accessing the biosimilar application and manufacturing information. This decision may quicken the start of potential patent infringement cases, and may also lead to biosimilars being able to reach the market more quickly (Minniti; Tanaka).

Challenges of IP Protection for Biologics

There are many challenges to protecting biologics. Biologics are extremely complex in their structure and manufacturing process, and the laws surrounding the protection of biologics, and what exactly within biologics can be patented, are both still uncertain. Over the coming years, it is likely that these rules and regulations will become less ambiguous, as court cases defining their interpretations play out. However, there are still other challenges in maintaining the intellectual property protection of biologics; specifically, there is a massive cost for obtaining and maintaining IP protection (see the chapter “Intellectual Property: Ownership and Protection in a University Setting”). Applying for and maintaining a patent involves payment of various official fees (e.g., an application fee, a search fee, an examination fee, an issue fee, and maintenance fees) (“General Information Concerning Patents”), and considerable attorney fees for drafting the patent application and prosecuting the patent application before the USPTO. Also, if the patent faces any sort of litigation over the span of its lifetime, the fees continue to add up, making the entire process a very costly endeavour.

Obtaining Expert Counsel

Securing IP protection for biologics is a complicated process, but, fortunately, the university likely has a technology transfer office that will aid inventors in filing for intellectual property protection, and is very useful for answering questions the inventors may have (see the chapter “Working with the University Technology Transfer Office”). Any information that will need to be patented must be disclosed before being publicly reported, and the individuals in the office can help the inventors determine what is and is not patent eligible. There are also patent attorneys who specialize in biotechnology, having strong backgrounds in patent law and molecular biology, biochemistry, and medicine. These attorneys are an important resource for helping inventors distill claims and interpret legal jargon related to the IP protection process. There are many other resources available online as well to help inventors understand IP in the context of biologics, and some helpful references are listed below in the Resources section.

Conclusion

In this chapter, we have reviewed valuable information regarding the IP protection of biologics. We have discussed the rapidly evolving therapeutic area of biologics, and how these compounds inherently differ from traditional small molecules. These differences—including greater size and complexity, a more involved manufacturing process, and the very recent creation of applicable laws—all contribute to the complicated nature of biologics. Both patents, issued by the USPTO, and regulatory exclusivity, provided by the FDA, allow forms of protection for the biologic. As biologics have developed over the past few decades, we have seen a plethora of court cases around the specifics of biologics patenting, and while some issues have been clarified, many areas of how

to interpret protections are still vague. The advent of biosimilars also brings another layer of complexity to an already complicated area. However, the protection of biologics is crucial, and there are many resources available to assist inventors in this process.

Resources

1. Intellectual Property Rights and the Promotion of Biologics, Medical Devices, and Trade in Pharmaceuticals (Globerman et al.)
 - a. This review provides a detailed discussion of the changing face of IP law in the world of biologics. It discusses the basics of biologics and their production, their importance as therapeutics, IP protection and costs, as well as IP in a global market.
 - b. <https://www.fraserinstitute.org/studies/intellectual-property-rights-and-the-promotion-of-biologics-medical-devices-and-trade-in-pharmaceuticals>.
2. Biologics: The New Antitrust Frontier (Carrier and Minniti)
 - a. This article provides an extremely comprehensive review of biologics and the important laws and regulations surrounding their protection.
 - b. <https://illinoislawreview.org/print/vol-2018-no-1/biologics/>.
3. USPTO
 - a. The U.S. Patent and Trademark Office has an abundance of information about qualifications for IP protection, how to go about filing, and details about the different types of protection.
 - b. <https://www.uspto.gov/>.
4. Center for Biologics Evaluation and Research
 - a. The FDA website, specifically the section about the Center for Biologics Evaluation and Research (CBER) provides information on biologics, biosimilars, and regulatory exclusivity.
 - b. <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/>.

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