Whitepaper

Chemical Analysis & Consultation for Intellectual Property Disputes in Biopharmaceuticals

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Analytical chemistry — the science of breaking down matter and identifying its composition — plays an important role in biopharmaceutical/drug patent disputes. When the matter in hand involves two companies that are making products that are seemingly identical, small variations in chemical composition (or the lack thereof) can make a big difference in the eyes of the courts.

The fundamentals of biopharmaceutical patents are the mechanisms at play between the time that a new brand-name drug is developed and the time that generic drug companies are allowed to create bioequivalent or similar products. The role of chemical analysis and consultation in the outcome of potential intellectual property (IP) litigation are pivotal to the role of chemical analysis in litigation.

How Is a New Drug Developed?

To understand the key aspects of intellectual property (IP) litigation for biopharmaceuticals, it is imperative to comprehend how a pharmaceutical company develops a new drug, acquires the patent for it, and has it approved by the U.S. Food and Drug Administration (FDA).

Biopharmaceutical companies devote a significant amount of funding to continuing research and development (R&D) on new pharmaceutical technologies. When this technology or outcome of the technology yields a promising formula for a new drug, the company applies for the composition, proprietary technologies, formulas or processes used to prepare the drug to be patented with the U.S. Patent Office. A patent for a new pharmaceutical or biopharmaceutical product or technology is valid for 20 years, but there is still a long road for these companies between the time that a patent is issued and the time the company can release these new pharmaceutical products to consumers.

It is because FDA regulations demand a rigorous process of determining the safety and potential risks of new pharmaceutical products. First, the pharmaceutical company has to submit a New Drug Application (NDA)[1] or similar application with the administration, a policy which has been in place since 1938. To be approved, the application must establish the following, based on a body of research and, often, many clinical trials:

- There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate there is no degradation of the product for the normal or expected period of use.
- Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed.

After the application is approved, the

pharmaceutical company has to market the product to physicians, pharmacies, and health insurers, which can take many years and cost millions of dollars.

During this time, the lifetime of the patented product is shortening, thus limiting the practical lifespan of the patent.

Brand-Names vs. Generics

When the patent lifespan expires, generic pharmaceutical companies can enter the market. The 1984 Hatch-Waxman Amendments gave generic drug makers an easier path to getting their products to market in order to promote competition and lower prices for consumers. The result is that a generic pharmaceutical company doesn't need to file an NDA, but rather an ANDA: an Abbreviated New Drug Application.

Under the ANDA, a generic pharmaceutical company only has to show that the pharmaceutical product for which it is applying to have approved is bioequivalent to the previously approved brand-name variety, or, in the words of the FDA[2], "comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use."

The Hatch-Waxman Amendment

The process for approval of brand-name and generic pharmaceuticals was put into place by the Food, Drug, and Cosmetic Act (FDCA) of 1938, which established the FDA as the governing body over products that impact the user's health. However, when the competition in the market for medications was reviewed in the 1980s, government researchers noticed that generics weren't flooding into the market at the end of a patent's lifespan as per the goal of the FDCA.

Accordingly, they drafted an amendment to the legislation that would become informally known as the Hatch-Waxman Act. This legislation, signed by President Ronald Reagan in 1984, was intended to make it easier for generic products to enter the market.

Litigation for Pharmaceutical IP Disputes

The Hatch-Waxman Act also ushered in an increase in pharmaceutical litigation by making it easier for patent-holders to sue ANDA applicants on the grounds of patent infringement. The prevalence of patent litigation between pharmaceutical developers and generic drug manufacturers continues to increase today. For example, Lex Machina[3] reports that patent litigation for ANDA applications increased by 30 percent in 2017 alone.

Litigation costs a lot of money for both sides, but the practice continues its upward trend for reasons such as the following:

- Patent litigation when the FDA involved is different from other IP cases. If a patentee challenges an application for a generic drug, it holds up the approval process for all versions of that drug by up to 30 months, giving the patent-holder market control for a

longer time frame.

- Generic drugs are inherently cheaper because these companies do not have to complete the R&D or marketing side of development, thus lowering their overhead and enabling them to offer the pharmaceutical product at a lower cost point.

In a different scenario, a pharmaceutical company can also make the case that the applicable patents should be extended based on the following grounds, according to :

- A new formulation of the product
- A new method of use for the product
- Combinations of the given product with other products

In this case, a pharmaceutical company must have ample evidence (including chemical analysis, expert witnesses, etc.) to show that the pharmaceutical product in question can be used in a new way, or that the formula can be changed without changing the integrity or use of the substance.

Pharmaceuticals vs. Biopharmaceuticals

While pharmaceutical litigation is mostly straightforward, the same is not so with biopharmaceuticals, wherein additional expert testimony is needed due to the complicated nature of these biopharmaceutical formations.

The FDA has been slow to adopt regulations on Biologic License Applications (BLAs) for biopharmaceuticals because these substances are inherently more complicated than standard pharmaceuticals. While many drugs are completely synthesized, biopharmaceuticals are derived from biological sources, usually living organisms. This makes the process of developing these actives difficult to reproduce, thus creating an absence of bioequivalence, the deciding standard of the ANDA for generic medications.

As a result, biopharmaceutical patent law can get into some lengthy and complicated litigation. Each side has a particular burden: the challenger (often the patent-holder) has to prove infringement on the behalf of the applicant, while the applicant has to defend itself from these allegations.

The Role of Chemical Analysis in Litigation

While chemical analysts are employed to help in litigation for all types of pharmaceutical products, their services are needed particularly often in litigation concerning biopharmaceuticals. This is because the chemical makeup of these products tends to be more complex, and to explain their mechanism and efficacy takes a deeper understanding of pharmaceutical science than that of the layperson.

In a court case, analytical chemistry can be used by both sides, from something as simple as analyzing the layers used to release a drug into the system to the advanced chemical makeup of a formulation.

When patent-holders try to prove infringement on

their patents, the grounds can be highly specific to a single chemical process or proprietary technology, such as the use of a certain extended-release characteristic, for example. A chemical analysis would show that the manufacturing processes for the generic medication are the same as the processes used to create brand-name medication and have, therefore, violated a protected patent.

Generic pharmaceutical companies enter into litigation similarly: chemical analysis can be used to disprove claims of patent infringement by showing that the composition of a generic pharmaceutical product doesn't directly mirror that of the brand-name drug with the same Active Pharmaceutical Ingredient (API).

Finally, chemical analysis can be used to extend the life of a patent. A brand-name drug company can use the testimony from chemical analysts to support the claim that a given drug can be used in a different way, formulated differently, or combined with other active pharmaceutical ingredients safely.

What Do Analytical Chemists Do?

In the context of understanding of what a pharmaceutical product is composed, a chemical analysis would involve breaking down the composition and classifying the constituents that make up the product. This separates the Active Pharmaceutical Ingredient (API) from the rest of the composition and makes definitive claims about the state of the substances in question. The roles of analytical chemists in litigation include:

- Perform qualitative and quantitative analysis
- Sample, define, isolate, concentrate, and preserve sample
- Validate and verify results through repeat testing and standardization
- Perform separations based on different properties
- Create new methods to make measurements
- Interpret data in a given context
- Communicate their conclusions to juries and other scientists

In a court case, these chemists have to communicate their findings clearly to a jury, making it important that the results are easily understood and clearly valid from a scientific standpoint.

Avomeen Life Sciences

Contact Avomeen to learn how our scientists can provide litigation support for your case.

Call us at 800-930-5450 or email us at scientist@avomeen.com to request a Litigation Support proposal.

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