The United States Patient Protection and Affordable Care Act of 2010: Perils of Mandatory Pre-Litigation Disclosure of Confidential Information

On March 23, 2010, the United States Patient Protection and Affordable Care Act (PPACA) was signed into law establishing, among other things, a preliminary Food and Drug Administration (FDA) approval pathway for "copycat" versions of protein based drugs. These copycat drugs are products shown to be biologically equivalent to a licensed reference product (e.g., an FDA approved drug already on the market), and are commonly referred to as biogenerics, follow-on biologics or biosimilars. Title 7 of the PPACA is similar in purpose to the Drug Price Competition and Patent Term Restoration Act of 1984 (i.e., the Hatch-Waxman Act[1]) in that both seek to improve public access to less expensive generic pharmaceuticals while maintaining the financial incentive for innovator companies to discover and develop new pharmaceuticals. While there are some similarities in the intent of the two Acts, there are significant differences in both form and function.

For example, while the Hatch-Waxman Act largely forbids patent infringement litigation based on methods of manufacturing a small molecule drug, the PPACA indirectly encourages patent litigation based on the manufacturing methods of protein-based drugs. Under the PPACA, there is a mandatory pre-litigation disclosure of confidential manufacturing information from the follow-on biologic company to the innovator (i.e., reference drug) company. The significant potential legal hazards associated with this disclosure cannot be overstated.

While some drug manufacturing protocols are nearly always included in patent applications, there is no statutory requirement for biologic drug manufacturers to include commercial grade manufacturing details in patent applications. Such proprietary manufacturing methods (e.g., chemistry, manufacturing and controls (CMC)) are nearly always kept confidential and may be legally protected as trade secrets if the methods have economic value because they are not generally known to the public, and are subject to reasonable efforts to maintain their secrecy. Unlike traditional small molecule drugs with easily defined and chemically static structures, any single biological drug (e.g., monoclonal antibodies, glycoproteins, vaccines, and recombinant proteins) is chemically variable and often best defined by the manner in which it was commercially manufactured, rather than by the end product. Indeed, it is common for minor differences to exist among various lots of the same biologic produced at the same manufacturing facility.

Reflecting the inherent high complexity and variability of protein based drugs, the PPACA requires follow-on biologic applicants to divulge proprietary manufacturing information not only to the FDA, but also to the innovator company holding the license for the reference drug.[2] The reference drug company is then charged with comparing both manufacturing protocols in evaluating the likelihood of patent infringement.

[1] 21 U.S.C. §355(j).
[2] 42 U.S.C. §262(l)(1)(B).

Unless otherwise agreed to, the receiving party must keep this information confidential and within the purview of the legal department.[3] Only "one or more" members of outside counsel, a single in-house attorney, and the patent licensor (if any) may review the information solely for purposes of "determining . . . whether a claim of patent infringement could reasonably be asserted . . . ." [4] All recipients of confidential information are forbidden from engaging in patent prosecution "relevant or related to the reference product." [5] In the event that the reference drug company does not initiate a patent infringement lawsuit, the reference drug company "shall return or destroy all confidential information." [6] It is evident that the new law clearly recognizes the financial significance of CMC and other proprietary biological drug manufacturing information, and understands the irreparable harm that may ensue if manufacturing trade secrets are illegally misappropriated. Indeed, the PPACA allows for immediate injunctive relief for violations of the confidentiality provisions.[7]

Practical Considerations For The Follow-On Biologic Company

To insulate oneself from being enjoined and/or vulnerable to lawsuits for trade secret misappropriation, it is imperative for both innovator and follow-on biologic companies to have strong written internal policies governing receipt and disclosure of all confidential information, including drug manufacturing trade secrets. Realizing the time and effort that goes into establishing an effective trade secret policy, follow-on biologic applicants may afford themselves an additional layer of intellectual property rights by clearly designating all confidential manufacturing methods as trade secrets when revealing this information to both the FDA and the reference drug company. It should be noted that all confidential information might not necessarily get the legal benefit of trade secret protection. Indeed, overuse of the trade secret designation for issues that are merely confidential can serve to undermine the legal potency of matters truly worthy of trade secret status.

Under United States laws, confidential information generally only acquires trade secret status when the information (1) can be shown to have economic value because it is not generally known to the public and (2) is subject to reasonable efforts to maintain its secrecy. Allegations of misappropriation are much more likely to be successful if trade secret protocols with a track record of success existed well before the time of information disclosure. Whenever necessary, trade secret policies should be updated on a regular basis to demonstrate continued diligence. In addition to the pre-litigation disclosure requirements of the PPACA, follow-on biologic applicants should, in any event, establish strong internal trade secret protocols to prevent accidental and/or intentional disclosure of proprietary manufacturing methods by both current and former employees.

Practical Considerations For The Reference Drug Company

In addition to the reasons described for follow-on biologic companies, reference drug sponsors will also clearly benefit from having a robust track record of adherence to well-crafted formal internal trade secret protocols. Without such written protocols, innovator drug companies risk charges of misappropriation if any future product appears to incorporate trade secrets disclosed during the pre-litigation formalities required by the PPACA.

[3] 42 U.S.C. §262(l)(1)(C).
[4] 42 U.S.C. §262(k)(D).
[5] 42 U.S.C. §262(l)(1)(B)(ii).
[6] 42 U.S.C. §262(l)(1)(F).
[7] 42 U.S.C. §262(l)(1)(H).

Specifically, reference drug companies must have a formal, written, and well-planned legal procedure for the secure receipt and confidential review of third-party proprietary information. This is particularly important for receipt of the pre-litigation follow-on biologic manufacturing information. Such a procedure will go a long way to rebutting charges of trade secret misappropriation long after the FDA review process has passed. Innovator drug companies need to guard themselves against the very real and unfortunate possibility of winning (or even worse, losing) a PPACA patent infringement lawsuit only to later find themselves defending against allegations of intellectual property infringement of another sort - theft of trade secret intellectual property.

If you have any questions about this article or would like to discuss this topic further, please feel free to contact:

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