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Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Effects Of Biosimilars Legislation On Patent Litigation

Law360, New York (October 07, 2009) -- Intellectual property protection may not immediately come to mind when one considers health care reform, but it should.

Those interested in patent protection should pay special attention to provisions in this pending legislation that would authorize the Food and Drug Administration to approve follow-on versions of biotech medical products ("biosimilars").[1]

These provisions would establish a complex dispute resolution scheme for biotech medicine patents that departs significantly from the rules of civil litigation.

If enacted, the legislation threatens to convert the U.S. patent system into a two-tiered regime in which biotech medicine patent holders would have fewer rights to enforce their patents. This could diminish the value of biotech patents.

The Legislation

Two biosimilar bills currently before Congress would establish new rules to govern biotech medicine patent disputes between the party that developed and secured approval of a biotech medicine (hereafter, "innovator") and the manufacturer that seeks to market the follow-on or similar version of the innovator product (hereafter "biosimilar applicant").

On the Senate side, the Committee on Health, Education, Labor and Pensions approved a biosimilar amendment to the "Affordable Health Choices Act" ("HELP bill")[2] On the House side, Congressman Waxman introduced H.R. 1427, the "Promoting Innovation and Access to Life-Saving Medicine Act" ("Waxman bill").[3]

A third biosimilar bill, the "Pathway for Biosimilars Act" (H.R. 1548), was introduced by Congresswoman Eshoo.[4] This bill (including the patent provisions) has largely been incorporated into the House Energy and Commerce Committee bill on health care reform by a strong bipartisan vote of 47 to 11.

The Eshoo bill is not discussed here because it builds upon the existing patent system rather than adopting entirely new and different rules to govern certain fundamental aspects of litigation involving biotech medicine patents alone.[5]

Both the HELP legislation and the Waxman bill would create a bifurcated scheme in which certain innovator patents may be litigated early in the biosimilar application process ("early litigation"), while other patents may not be litigated until much later when the biosimilar product is close to approval or is on the market ("later litigation").[6]

To determine which patents are litigated and when, both proposals would establish a scheme governing the exchange of information between the parties.

If enacted, these legislative proposals would impact key aspects of any litigation surrounding biotech medicine patents. Indeed, as described below, the legislation would establish inefficient and unbalanced rules to control key phases and actions in a biotech patent case.

Pre-Litigation Information Exchange

Frequently, before parties resort to litigation, they may of their own volition attempt to resolve a dispute through the exchange of information and their respective positions on a matter.

Whether through a "demand letter" or a "cease-and-desist letter," these exchanges put the alleged offending party on notice and may serve to avoid the costs and expense of full-blown litigation. This exchange may be especially important for patents since IP litigation is complex, protracted and expensive.

The biosimilar bills would create a much different process for the exchange of information before litigation. They would establish strict procedures and timelines for exchanging patent information before a lawsuit may be filed by an innovator. This process appears to be unbalanced and may carry severe penalties for innovators.

For example, if the innovator omits a patent from its response to a biosimilar applicant's request for information — either inadvertently or because it believes a patent would not be implicated — it is precluded from enforcing that patent against the biosimilar applicant at any time.[7]

In any other setting, no such penalty accompanies the exchange of information between parties before a civil lawsuit is filed. This severe penalty would be unique to biotech medicine patents and out of line with other civil suits, including those involving nonbiotech patents.

Shifting the Focus of the Complaint

If a lawsuit is commenced, the first step in any civil case is, of course, the filing of a complaint. Subject to the pleading requirements of the Federal Rules of Civil Procedure ("FRCP"),[8] the plaintiff is the "master of the complaint."

The plaintiff chooses what the complaint will say, when it will be filed, what issues it will raise and what relief it will seek.

Although the defendant may raise defenses and add its own counterclaims to the action, and even move to dismiss certain claims or file its own declaratory judgment action, it may not dictate the content of the complaint filed by the plaintiff.

In contrast, both biosimilar bills would effectively shift control of the complaint from the plaintiff to the defendant in any patent litigation involving a biosimilar product.

Specifically, the biosimilar applicant gains this control through the information exchange process, which gives the applicant the final word on which patents are subject to early litigation and which may only be disputed in later litigation (which may take place only after the biosimilar product has gone to market).

By vesting this authority with the biosimilar applicant, the bills allow the presumptive defendant in patent infringement litigation to dictate how many patents (in the case of the HELP bill)[9] and which patents (in the case of the Waxman bill)[10] may be included in the innovator's complaint in actions brought both in early litigation and later litigation.

The division of biotech patent litigation by the alleged infringer into two distinct phases does not advance judicial economy and may hinder enforcement of patent rights.

Additional Factors to Govern Venue

The location of the litigation is an important strategic consideration for the parties and one that is also generally controlled by the plaintiff. The law requires that the geographic location for the litigation have some relationship to either the parties or the issues in dispute.[11]

Choice of venue is important because of convenience to the parties and the differing temperaments of the courts. A defendant may request transfer of the lawsuit to a different venue, and the court is required to decide whether to transfer based on the evenhanded criteria of "convenience of parties and witnesses" and "justice."

Although the courts have for many years routinely applied the foregoing criteria in myriad cases, the Waxman proposal would establish two additional factors to which a court must give "greatest weight" if a biosimilar applicant moves to transfer venue.[12]

One of these additional factors would appear to impose a bias in the choice of forum in favor of the biosimilar applicant.

As set forth in the Waxman bill, that factor requires the court to consider "[t]he strong public interest in obtaining prompt judicial resolution of patent disputes so that the biological product which is the subject of the patent dispute may be brought to market as expeditiously as possible, consistent with fair and prompt resolution of patent disputes."[13]

Limits on Representation by Counsel

Not surprisingly, the FRCP allow and, in fact, encourage reliance on counsel by all litigants.[14] Courts recognize that litigants have a right to select counsel of their own choice and that disqualifying a litigant from use of an attorney should only be required when failing to disqualify poses significant risks to fairness.

Notwithstanding this basic principle, the HELP bill would significantly limit the ability of innovators to rely on important in-house counsel and outside counsel in patent litigation, thereby potentially hindering the innovator's ability to mount an effective case.

The bill limits disclosure of confidential information about the biosimilar product to only one of the innovator's in-house attorneys.[15]

Moreover, neither the in-house lawyer nor any outside counsel may access such information if they have been engaged in patent prosecution related to the products at issue.

Thus, the HELP bill would preclude meaningful involvement of counsel for the innovator who may be most familiar with the patents at issue. Protective Orders that contain prosecution limits typically restrict in-house lawyers from prosecuting after, not before, receipt of the other side's confidential information.

Restricting Declaratory Judgment Actions

In recognition of the importance of clarifying the legal rights of parties to a dispute, Congress passed the Declaratory Judgment Act ("DJA") to allow "any interested party" to seek an authoritative declaration by a federal court of "the rights and other legal relations" of the party where an actual dispute exists.

A party need not wait for some violative action to take place before seeking relief from a federal court under this statute.[16] Rather, declaratory judgment actions ("DJ actions") are intended to "minimize the danger of avoidable loss," remove threats of impending litigation, prevent violations of law or breaches of contract and avoid unnecessary multiple lawsuits.[17]

Although a party in a typical civil case may unilaterally seek clarification of its legal rights by filing a DJ action, the Waxman bill would allow the biosimilar applicant to restrict the rights of an innovator to bring such actions.

A biosimilar applicant could, for example, choose not to include a patent in its initial notice to the innovator during the information exchange process.

Under the Waxman proposal, that omission would bar the innovator from filing a DJ action on that patent until after the biosimilar product is actually on the market.[18] This prohibition is inconsistent with the DJA, which allows parties to bring actions in anticipation of a product coming to market.

Requests for Preliminary Injunctions

A plaintiff may also seek a preliminary injunction ("PI"), asking the court to preserve the status quo until it decides whether the defendant's alleged acts are permissible.

This is a critical litigation tool that allows plaintiffs to prevent the irreparable harm that may flow from a defendant's actions. In patent litigation involving drugs, innovators frequently rely on PIs to prevent harm from an at-risk launch of an allegedly infringing product.

The HELP bill would limit the conditions under which an innovator may seek a PI. In fact, the bill appears to preclude the possibility that an innovator may obtain a PI with respect to any patent that is the subject of the early litigation process.[19]

It only authorizes PI applications for those patents that are the subject of later litigation and, thereby, creates the inference that this remedy is not available for patents that are disputed in early litigation.

If that were the case, then an innovator may be especially disadvantaged since it presumably would seek to litigate its strongest patents during the early litigation process.

No Forgiveness for Minor Mistakes

Deadlines and disclosure requirements are common in ordinary litigation. It should, therefore, not be surprising that, occasionally, even conscientious litigants make mistakes and miss deadlines or make other minor errors.

The rules governing civil litigation acknowledge this reality and frequently provide ways for litigants to recover from mistakes — sometimes even enormous mistakes — without penalty.

For example, the FRCP allow a court to provide relief, upon a finding of "good cause," for defendants that default by failing to respond in a timely manner to a complaint.[20]

Other provisions reflect the flexibility of the civil justice system and allow a court to correct a mistake or error made by a party in the case.[21]

No latitude for error is permitted in either the HELP or Waxman bills. Rather, both bills would impose stiff penalties on innovators who make minor mistakes and they would not permit courts to redress such mistakes upon a finding of good cause.

Thus, if an innovator were to make a clerical error and fail to timely include a patent in its response to a biosimilar applicant's request for patent information or omit the patent because of an incorrect belief that a patent would not be implicated, the innovator would forever be barred from bringing an infringement action relating to that patent.[22]

Moreover, if an innovator were to fail to file suit in a timely manner against a biosimilar applicant, it would be limited solely to a royalty in any infringement action, rather than an injunctive relief.[23]

These penalties for innovators can hardly be said to fit the crimes nor do they comport with the standard rules that apply to other litigants, including all other patent holders.

Conclusion

In light of the foregoing, the following conclusions can be drawn about the Waxman and HELP bills currently before the Congress.

First, these bills would impose unique patent dispute resolution rules which deviate significantly from the procedures governing other patent suits and nonpatent civil litigation.

Second, altering the basic rules could have a material impact on the outcome of any litigation involving patents on biotech medicines.

And, third, were that to be case, biotech medicine patents may ultimately hold less value than other patents for which enforcement is routinely available under traditional principles of civil litigation rules.

As Congress considers health care reform, it must be mindful of these possible consequences. Surely, any patent dispute scheme adopted for biotech medicines must be fair and balanced and encourage judicial efficiency.

--By Bruce S. Manheim and Denise L. Loring, Ropes & Gray LLP

Bruce Manheim is a partner with Ropes & Gray in the firm's Washington, D.C., office. Denise Loring is a partner with the firm in the New York office. The authors were assisted in the development of this article by Joseph Pull, an associate with Ropes & Gray.

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[1] FDA is authorized to approve generic versions of drug products under Section 505 of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. § 355(j) ("Hatch-Waxman Amendments"). Unlike most drugs, biological products are derived from living organisms and they include medicines derived from biotechnology. The FDA is authorized to review and approve biological and biotech products under the Public Health Service Act. 42 U.S.C. § 262.

[2] See "Biologics Price Competition and Innovation Act of 2009" This Amendment appears as Subtitle A of Title VI of larger bill approved by the committee, which is available at: help.senate.gov/BAI09I50_xml.pdf. (See pg. 774, line 13 to pg. 820, line 11).

[3] See "Promoting Innovation and Access to Life-Saving Medicine Act" available at: frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1427ih.txt.pdf

[4] See "Pathway for Biosimilars Act" available at frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1548ih.txt.pdf

[5] See Eshoo Amendment, available at: energycommerce.house.gov/Press_111/20090731/hr3200_eshoo_2.pdf The patent provisions in this bill were subsequently dropped out of the legislation with the consent of Congresswoman Eshoo to avoid points of order against the bill, but she expects to reincorporate her patent provisions when the bill comes to the House floor for a vote. Meanwhile, Mr. Waxman has vowed to return his bill's patent provisions to whatever biosimilar legislation is passed by the House.

[6] See HELP Bill, at pg. 792, line 4 to pg. 800, line 16. See Waxman Bill, at pg. 30, line 14 to pg. 36, line 2.

[7] See HELP Bill, at pg. 808, lines 10-16; see Waxman bill, at pg. 45, line 22 to pg. 46, line 4.

[8] See, e.g., Fed. R. Civ. P. 8(a), 9(b), 10(a)-(b), and 11(a)-(b).

[9] See HELP Bill, at pg. 797, line 21to pg. 798, line 9 (restricting right of innovator to list more patents than those listed by biosimilar applicant; if applicant lists none, then innovator may list one patent).

[10] See Waxman bill, at pg. 34, lines 1-8 (limiting right of innovator to bring an infringement action only with respect to patent(s) included in the notice received from the biosimilar applicant).

[11] See, e.g., 28 U.S.C. § 1391(b); and 28 U.S.C. § 1404(a). In Hatch-Waxman litigation involving generic drugs, because there is no actual infringing product on the

market, venue is limited to jurisdictions where the generic is incorporated, resides or has a principal place of business.

[12] See Waxman Bill pg. 41, line 24 to pg. 43, line 16.

[13] See Waxman Bill pg. 43, lines 4-10.

[14] For example, see Fed. R. Civ. P. 5(b)(1); Fed. R. Civ. P. 11(a); Fed. R. Civ. P. 16(c)(1); Fed. R. Civ. P. 26(b)(5); and Fed. R. Civ. P. 54(d)(2).

[15] See HELP Bill, at pg. 788, lines 9-16.

[16] See e.g., Medimmune Inc. v. Genentech, 549 U.S. 118 (2007) (finding that a patent licensee does not have to breach the terms of the contract in order to meet the actual controversy requirement and challenge the licensed patent in court).

[17] 10B Wright, Miller & Kane, Federal Practice and Procedure § 2751, at 457-58 (3d ed. 1998).

[18] See Waxman Bill, at pg. 34, lines 9-19. The HELP bill provides that DJ actions may not be brought by either party before 180 days of first commercial marketing of the biosimilar product as long as the applicant complied with the relevant information exchange requirements. If not, then an innovator may file a DJ action when it chooses to do so. See HELP Bill, at pg. 802, line 5 to pg. 803, 15. While more even-handed, this provision still allows the biosimilar applicant to control the timing of a DJ action by the innovator.

[19] See HELP Bill, at pg. 801, lines 1-21.

[20] Fed. R. Civ. P. 55(c) and 60(b).

[21] Fed. R. Civ. P. 15(a), (c); Fed. R. Civ. P. 26(b)(5)(B); and Fed. R. Civ. P. 36(b).

[22] See HELP Bill, at pg. 808, lines 10-16; see Waxman bill, at pg. 45, line 22 to pg. 46, line 4.

[23] See HELP Bill, at pg. 807, line 11 to pg. 808, line 9; see Waxman bill, at pg. 44, line 18 to pg. 45, line 21. This contrasts sharply with the Hatch-Waxman scheme governing litigation of patents involving generic drug products. If an innovator were to fail to file suit in a timely way, it would only lose its right to a 30 month stay on FDA approval of the generic drug. 21 U.S.C. § 355(j)(5)(B)(iii). The innovator would not be forever foreclosed from injunctive relief.