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Inside Views: The Biosimilars Pathway: An Invitation To Litigation

By Lynn C. Tyler [1]

The litigation provisions of the recently-enacted legislation establishing a pathway to bring biosimilars to market contain "patent" ambiguities in key areas, particularly whether the various lists of patents to be litigated are exclusive. Courts will have to resolve these issues over the next several years, likely at great (and unnecessary) expense and uncertainty to litigants.

The massive federal health care reform legislation in the United States, HR 3590 [2] [pdf], the "Patient Protection and Affordable Care Act" (the "Act"), includes provisions for bringing "generic" versions of biotech drugs to market, commonly known as the "biosimilar pathway." The majority of the relevant provisions are contained in Section 7002 of the Act. Unfortunately for both branded and generic drug companies, referred to in the Act as the "reference product sponsor" ("sponsor") and the "subsection (k) applicant" ("applicant"), respectively, the legislation is unclear on several key issues and thus certain to lead to costly litigation in the next several years until the courts settle these issues.

This article is not a comprehensive review of the statute, but some review is necessary to understand the more important areas of ambiguity. The Act prescribes a rather elaborate dance in which sponsors and applicants must engage before commencing any patent infringement litigation. The dance begins when the applicant submits to the FDA an application for approval of a biosimilar drug. The statute states that "[w]hen a subsection (k) applicant submits an application" to the FDA, the applicant will give a copy of the application to one in-house lawyer for the sponsor and to outside counsel for the sponsor, subject to certain confidentiality restrictions. Later, the statute states that the copy of the application must be provided to the sponsor "[n]ot later than 20 days after the Secretary [through the FDA] notifies the subsection (k) applicant that the application has been accepted for review." In addition, at that point the applicant must also provide "such other information that describes the process or processes used to manufacture the biological product that is the subject of the application."

The next step is that, within 60 days after the receipt of the application and process information, the sponsor must provide the applicant with a list of patents which the sponsor believes "could reasonably be asserted" and identify any that are available for license. Sixty days after receiving the sponsor's list of patents, the applicant must provide the sponsor with (1) its own list of patents that it believes could be asserted, and either (2) a detailed statement, on a claim by claim basis, of the factual and legal basis why each patent on the sponsor's and applicant's (if any) list(s) is invalid, unenforceable, or would not be infringed, or (3) a statement that the applicant does not intend to market the product before the patent expires.

The applicant must also provide a response to the sponsor's indication of patents that are available for license. The final step in this phase is that, within 60 days of receiving the applicant's detailed statement, the sponsor must provide its own detailed statement, again on a claim by claim basis, of the factual and legal basis why each patent will be infringed and a response to the applicant's statement on validity and enforceability.

After providing a relatively brief period for the parties to agree on patents to be litigated, if the parties cannot agree the statute goes on to prescribe another set of steps in the pre-litigation dance. The first

of these is that the applicant notifies the sponsor of the number of patents the applicant will include on a list of patents to be litigated. Five days later, the parties simultaneously exchange lists of patents that each believes "should be the subject of an action for patent infringement." The number of patents on the sponsor's list cannot exceed the number on the applicant's list, unless the applicant's list does not include any patents, in which case the sponsor can list one patent.

Whether the parties agreed on a list of patents to be litigated or exchanged lists, within 30 days of completing the applicable process the sponsor must file an infringement suit. If the parties agreed on patents to be included, the sponsor's suit must include those patents. If the parties did not agree, the sponsor's suit must include all the patents on the respective lists.

At this point, we confront one of the key ambiguities. Recall that by now two sets of lists have been generated, the first (referred to as a "Paragraph 3" list based on its place in the statute) identifying all patents that either party thought "could reasonably be asserted," and the second (a "Paragraph 5" list) identifying the patents that the parties thought should be involved in litigation. What happens if the Paragraph 3 list is longer than the Paragraph 5 list? Can the sponsor bring suit on patents that were included on the Paragraph 3 lists, but not the Paragraph 5 lists? This portion of the statute does not say that the sponsor cannot include such patents, only that the sponsor must include the patents on the agreed list or the patents on both parties' lists if the parties did not agree.

Further, section 271(e)(2) of the Patent Act has been amended to provide that an applicant infringes each patent on a Paragraph 3 list by filing an application for approval of the product (and recall that the lists are not generated until after the application has been filed). If the Paragraph 5 lists are exclusive, Congress would have eliminated key property rights of sponsors in some cases. These considerations make it appear that the statute does not limit patent infringement suits to patents on a Paragraph 5 list.

On the other hand, the provisions governing the creation of the Paragraph 5 lists would arguably be meaningless if they did not limit the potential patents-in-suit. What is the point of allowing the applicant to limit the number of patents on the Paragraph 5 lists if the sponsor can sue on any and all patents it chooses? One principle of statutory construction is that statutes are to be construed as a whole, giving meaning to all the provisions. This consideration suggests that the statute does limit litigation to patents on one of the Paragraph 5 lists, at least initially (as will be explained immediately below).

Another section of the statute addresses preliminary injunctions and creates further issues. This section provides that the applicant must give the sponsor 180 days advance notice of its intention to begin commercial marketing of the biosimilar. Between its receipt of the notice and the expiration of the 180 days, the sponsor can seek a preliminary injunction against sales of the applicant's biosimilar based on any patent that (1) was included on a Paragraph 3 list but (2) was not included on either an agreed list of patents for litigation or a Paragraph 5 list (or, under another section of the statute, based on a patent that issued or was licensed after the sponsor created its Paragraph 3 list).

One issue raised by this section is exclusivity again. Can the sponsor only seek a preliminary injunction based on a patent that falls into one of these categories? What if there is pending litigation involving the agreed or Paragraph 5 list patents? Can a patentee seek a preliminary injunction based on those also? The statute does not expressly say that the sponsor cannot. If the answer is that the patentee can seek a preliminary injunction based on such patents, however, what is the point of the provision limiting the requests for preliminary injunctions to patents on Paragraph 3 lists but not the later lists?

The statute also does not address the procedure for seeking a preliminary injunction. Must the sponsor seek the preliminary injunction in any pending case? What if the deadline for amending the pleadings (often fairly short) has passed? Will courts conclude that the applicant's notice of intent to market satisfies the "good cause" required under Federal Rule of Civil Procedure 16 to amend pleadings after any applicable deadline, except in extraordinary circumstances? Can the sponsor start an all new suit on the patent(s) for which it is seeking a preliminary injunction? If so, does it have to be before the same court as the pending suit? If the sponsor chooses to file a new suit before a different court, will the new court transfer the case to the court handling the earlier case? The statute does not address these and other possible issues, so that task will fall to the courts.

Another question is whether the provisions on preliminary injunctive relief provide clues to the earlier question about whether the agreed list or Paragraph 5 lists of patents limit the patents that the

sponsor can assert. The preliminary injunction provisions give the applicant an incentive to include on its Paragraph 5 list any and all patents that could reasonably be asserted against the proposed biosimilar. Otherwise, it would expose itself to the risk of being hit with a preliminary injunction at or near the time of its proposed launch of the biosimilar (a time at which considerable investment would have been made). This suggests that Congress may have intended the agreed list or the Paragraph 5 lists to be exclusive for any initial litigation.

On the other hand, an applicant willing to run the risk of a preliminary injunction could force the sponsor to seek such relief, perhaps on an incomplete record with limited time to prepare and/or for the hearing itself. Further, the sponsor would have to satisfy the additional evidentiary burdens of irreparable harm, the balance of the harms, and that the preliminary injunction would not disserve the public interest. The sponsor would have to post a bond, potentially quite large, to enforce the preliminary injunction. What if the court does not rule on the motion for preliminary injunction before the stated date for the applicant to begin commercial marketing?

One would not necessarily expect Congress to have answered in the statute all the questions raised in this article. The issues about the exclusivity of the initial litigation and the preliminary injunction provisions, however, would leap off an exam page to a second or third year law student taking a course in patent law, and it is hard to imagine why the statute is not clearer about the answers. As a result of the lack of clarity, both branded and generic pharmaceutical companies can look forward to at least a few years of unnecessarily risky and costly litigation while those procedural issues are decided, along with issues going to the merits of their cases.

Lynn C. Tyler is a partner and registered patent attorney in the Indianapolis (US) office of Barnes & Thornburg LLP. He concentrates his practice in patent litigation.

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[1] Lynn C. Tyler: **#bio**
[2] HR 3590: **http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf**
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[5] Biotech Legislative Agenda: Healthcare, Energy, Patents And Capital: **http://www.ip-watch.org/weblog/2009/10/05/biotech-us-legislative-agenda-healthcare-energy-patents-and-capital/**