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Lawyer Limelight: Richard J. Stark

By Nancy Stein

Congress is considering a number of substantial pieces of legislation addressing patents, including the Patent Reform Act and complex bills addressing follow-on biologics. It takes a real expert to be able to understand and explain the significance of these proposed laws and how they will impact patents. With clients like Qualcomm, Bristol-Myers Squibb, IBM and GlaxoSmithKline, Richard J. Stark is just such an expert. He's a partner in the litigation department at Cravath, Swaine & Moore, focusing on intellectual property and other technologically intensive litigation for both plaintiffs and defendants. Recently Stark talked to Lawdragon about the House and Senate proposed bills, clarifying their terms and explaining their significance. He also shared some practical patent litigation management strategies.

Lawdragon: New legislation has been proposed in both the House and the Senate to address patent reforms, including reforms related to "follow-on biologics." Would you explain for the uninitiated what follow-on biologics are?

Richard Stark: Biologics are medicines derived from biological processes, in contrast to traditional pharmaceuticals, which are derived from chemical reactions. With traditional pharmaceuticals, we have the concept of generic products, which have an abbreviated FDA approval process. The new legislation aims to create a class of "follow-on" biologics—analogous to generic pharmaceuticals—by giving them a shorter route to FDA approval.

The active ingredient in a generic pharmaceutical must be identical to the pioneer's active ingredient. This approach doesn't work with biologics because two biologics will rarely, if ever, be exactly the same. The proposed legislation deals with this issue by allowing for follow-on biologics that are not identical, but rather "biosimilar" to pioneer products. A "biosimilar" product that meets additional, more stringent standards may be approved as "interchangeable" with the pioneer.

LD: Why has this legislation become so important?

RS: To date the law has not allowed follow-on biologics. As concerns about the cost of health care have become more pronounced, interest in providing a mechanism for rapid approval of cheaper versions of biologics has grown. President Obama's 2010 budget plan includes funding for the FDA to create a system for approval of follow-on biologics, and with a Democratic Congress, I think we will see legislation passed in the near term.

LD: What are the most important features in the new biologics bills?

RS: There are three critical issues. First is the

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issue of how the FDA will define "biosimilarity" and "interchangeability." The precise boundaries of these tests have yet to be decided. How easy or hard it will be for a follow-on maker to establish "biosimilarity" or "interchangeability" will have important implications for public health and safety and a tremendous impact on the economics of both pioneer and follow-on biologics. This will be a contentious issue, which may take quite a while to resolve.

Second is the question of how long a period of statutory (non-patent) exclusivity will be provided for pioneer products. At one end of the spectrum, the [Henry] Waxman (D-CA) bill provides only 3-5 years. The [Anna] Eshoo (D-CA) bill provides for 12-14 years. In economic terms, the difference is enormous.

Third is the procedure for initiating patent infringement litigation. The Waxman and Eshoo bills require similar disclosures of patents by innovator companies, but the Waxman bill goes much farther in seeking to tie the hands of patentholders.

LD: Which biologics bill do you favor?

RS: As between the Waxman and Eshoo bills, I prefer Eshoo's (H.R. 1548, the "Pathway for Biosimilars Act"). This bill recognizes the complex nature of biologics and strikes a more appropriate balance between competing interests. The complexity and long development times of biologics warrant longer exclusivity periods for pioneers. In the long run, the public will benefit from a law that provides a reasonable and predictable period of exclusivity to innovators.

LD: How about the proposed Patent Reform Act? Which aspects will have the most significant impact?

RS: The most significant aspects of the proposed Patent Reform Act relate to damages and post-grant review of patents.

As to damages, the current proposal would require judges to determine the factors that juries may consider in calculating reasonable royalty damages. This is a compromise proposal intended to moderate damages awards by invoking judges' discretion, in contrast to prior proposals that would have imposed strict, formulaic limits on reasonable royalty damages.

The current proposed legislation would also broaden opportunities for alleged infringers to seek reexamination or cancellation of patent claims in the PTO. This aspect of the bill could expose patents to multiple attacks and thus favors alleged infringers.

Two other noteworthy aspects include shifting from a "first-to-invent" to a "first-to-file" patent system, and also a change to permit appeals of claim construction rulings. The first-to-file system would simplify some thorny issues and would put a premium on companies being able to identify patentable inventions early. The change in the appealability statute would permit more interlocutory appeals, potentially slowing cases substantially.

LD: Why did prior proposals for patent reform fail? What's new or different this time?

RS: Past bills failed in large part due to controversy over limitations on damages. Patent reform bills have largely been championed by certain companies who rely on manufacturing operations and tend not to leverage their intellectual property. These entities favor strong measures to reduce damages verdicts and licensing fees.

Other entities, both manufacturers and non-manufacturers, whose business strategies emphasize enforcing and/or licensing out their patents, oppose measures that would impair the value of their intellectual property. Prior incarnations of patent reform legislation tilted strongly in favor of the former group and drew a lot of opposition from the latter.

The modified version of the bill, introduced in the Senate this year, attempts a compromise on the damages provisions. As a result, this bill may stand a better chance of enactment. But this is still a controversial subject, and I would expect to see further revisions before anything is passed.

LD: How did you get into this type of law?

RS: Cravath has a long history of handling major patent actions, dating back to its representation of Thomas Edison. One of the first cases I worked on, almost 20 years ago, was a patent case involving monoclonal antibodies—some of the earliest biologic products. Over the years, I have worked on a range of intellectual property cases, including a massive case involving computer architecture for IBM. I happen to enjoy science and technology as much as I like a good legal fight. It continues to be a great fit for me.

LD: Are there some patent litigation management strategies you can share?

RS: The main thing I preach is doing things right the first time. It's tempting for companies to act in a "penny wise and pound foolish" way. At best, this leads to having to spend twice as much money trying to fix problems after the fact. At worst, it can lead to disastrous, unsalvageable results. These cases require careful thought and preparation, preparation, preparation.

There are some effective ways to keep costs under control in complex patent litigation, such as keeping teams lean and judiciously choosing which issues you pursue. But mostly I urge clients to think in terms of cost effectiveness. Losing is very expensive. Hiring the best lawyers you can find from the outset will save money in the long run.