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# How proposed act would affect biotech industry

## Five subsections of the patent reform act might have significant impact.

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THE COST OF LITIGATION is crippling the industry. Certain companies are taking advantage of administrative rules to further their own ends. Damage awards are out of control. So go the typical rationales trotted out to suppaort new legislation; so go the rationales for supporting the proposed Patent Reform Act of 2005. There is almost always at least a grain of truth in such rationales, and the ones underpinning the proposed act are no exception. The difficult part is determining the percentage of truth in particular statements, which can only be approached by closely examining the various legislative subsections in view of a particular industry sector.

This article will take an in-depth look at five different subsections of the proposed act that potentially affect the biotechnology industry: "Reasonable and Effective Accessibility," which seeks to limit references that can be cited against a patent to those that can be found without undue effort; "Eliminating the Best Mode Requirement," which is directed to modifying current law that requires an inventor to disclose the best way to make, use and practice his or her invention; "Enforceability and Claim Invalidity," which redefines the penalty for obtaining a patent through fraud on the U.S. Patent and Trademark Office (PTO); "Damages Related to Inventive Contribution," which provides instruction on how one should determine damages resulting from infringing a patent claim embracing a combination invention; and, "Limiting Continuation Applications," which would eliminate an inventor's right to file as many patent applications off of a "parent" application as he or she wishes.

The first subsection relates to a proposed requirement that prior art be reasonably and effectively accessible before it can be cited against a patent or patent application. It is primarily driven by litigation fears. Imagine the development of a biologic-based new chemical entity: Three years of research before a lead compound was obtained; two years of optimization and another two for preclinical and formulation studies; six or seven years for clinical studies; and finally it reaches the market. Imagine further that a patent was filed during the optimization phase, and extensive literature studies were performed using worldwide databases. With everything in order, sales begin to peak, and that is the time when a generic company decides to sue.

The generic company has a lot to gain from challenging the validity of the patent embracing the new chemical entity. A successful challenge means that it can "free-ride" on the hundreds of millions of dollars spent by another for clinical development. The generic goes beyond electronic searching; it hires searchers to scour the card catalogs of Eastern European science libraries in an attempt to find that one piece of invalidating prior art. Finally, after $300,000 in searching fees, a master's thesis is found on a back shelf. The thesis discloses a chemical entity structurally similar to the marketed biologic. This reference is used to invalidate the subject patent. (For a discussion of public availability, see *Cooper Cameron Corp. v. Kvaerner Oilfield Products Inc.*, 291 F.3d 1317, 1332, (Fed. Cir. 2002).)

The "reasonable and effective accessibility" subsection is meant to prevent this scenario. There is no doubt that some published documents are not really publicly available. As such, they do not represent knowledge that is in the public domain; granting a related patent would accordingly not commandeer public property for an entitled few. Conversely, it would mean that the information would finally be presented to the public.

A problem, though, exists with respect to defining "reasonable and effective accessibility": The definition begs for clarification. As such, rather than curtailing certain litigation efforts, the subsection may simply spin a significant portion of a patent litigation toward elucidating the phrase. The cost of such litigation would likely increase relative to the average rather than decrease.

The elimination of the best-mode requirement again derives from a litigation concern. An inventor must include the method he or she subjectively believes to be the best for making, using and practicing an invention in a patent application at the time of filing. If such a method is not included, a patent issued from the application may be invalidated during litigation.

### Method of making an invention could be kept as trade secret.

A problem with best mode is that there may be people connected with a patented process or chemical entity—even joint inventors—who do not communicate effectively with one another. Should the claims of an entire patent be rendered invalid simply because one inventor did not timely convey an improvement to another? Should the claims of an entire patent be invalidated because an inventor forgot to convey a new process step to a patent attorney? Those scenarios appear terribly unfair.

One might pause for a moment, however, and consider a different unfairness that would result from eliminating the best-mode requirement. If eliminated, an inventor at a biotechnology company would only have to disclose a single method of making a chemical entity within a patent application. The method might be inefficient and inordinately expensive, rendering it unusable in a commercial setting. A commercially viable method, even if known at the time of patent filing, could be kept as a trade secret by the company. In other words, the company could receive a limited monopoly (i.e., a patent) to make, use and practice the invention while ensuring that no one else could ever come to market without investing the time needed to independently discover the commercial manufacturing process. (For a discussion of the interplay between best mode and trade secrets, see *Chemcast Corp. v. Arco Industries Corp.*, 913 F.2d 923 (Fed. Cir. 1990).)

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### Enforcement and claim invalidity

With regard to claim invalidity, the existing duty of candor is essentially a codified version of common law fraud that is specific for patent practice: No one should be able to obtain patent protection for a method, composition or article of manufacture if he or she withholds publicly available information from the PTO that could render the patent invalid. Under the current system, a patent can be held unenforceable due to fraud on the PTO even when the withheld art would not invalidate any of its claims. Thus the proposed subsection poses the question: Should a patent be unenforceable due to fraud on the PTO when the withheld art would not invalidate any of its claims? (For a discussion of the evolving nature of the duty of candor, see Thomas Lee, "Introduction: Evolution and Future of New Rule 56 and the Duty of Candor," 20 AIPLA Q. J. 131 (1992).)

**With combination inventions, damages may be hard to set.**

The Patent Reform Act of 2005 answers the above question with a resounding "no." When a determination of misconduct has been made, and no claims of the subject patent are held invalid, the patent holder would pay a fine of up to $5 million per relevant reference withheld. At first blush, this provision appears equitable. If a patent has not been obtained by keeping an invalidating piece of prior art secret, then why should the patent be rendered unenforceable in its entirety? A different view, however, relates to whether the threat of a $5 million fine is a substantial deterrent to bad behavior when hundreds of millions of dollars are at stake—a typical value for a patent covering a leading biotechnology product. A close, relatively obscure reference might threaten patentability of a new chemical entity before a patent examiner holding a doctorate in biochemistry, but it might not appear invalidating to a juror who took one chemistry course during freshman year in college. To some, that could be a chance worth taking.

The proposed subsection on an inventive contribution focuses on a damage award as opposed to other features of a combination invention. This is presumably directed to mechanical or electromechanical inventions, where the addition of a single element within a multielement combination might represent a slight improvement over prior commercial embodiments. Most would agree that a patent covering the single element, if infringed, should not enable the patent holder to obtain a damage award that primarily involves profit from nonpatentable subject matter. What, however, would implementation of this subsection look like in the biotechnology area? (For a discussion of "causation" and "whole market value" damage theories for improvement inventions, see *Kori Corp v. Wilco Marsh Buggies & Draglines Inc.*, 761 F.2d 649, 656 (Fed. Cir. 1985), cert. denied, 474 U.S. 902 (1985).)

One could envision a situation in which a 100-amino acid polypeptide exhibiting interesting pharmacological activity was known in the scientific literature. A biotechnology company performs research and finds that the addition of three specific amino acids to the terminus of the polypeptide increases activity fivefold; that is enough to take the polypeptide into development and eventually onto the market. After two years, sales are high enough to generate interest from the generic side, and one such company markets a knock-off. Patent infringement litigation ensues; the biotechnology company wins; and damages must be determined.

The invention is a combination of a three-amino acid sequence and a 100- amino acid sequence. The 100-amino acid sequence exhibited very good activity, just not enough to commercialize. Is the inventive contribution accordingly 3/103 amino acids (e.g., 3% of profit)? Is it the increase in activity, even if the subject patent claim does not mention activity? Is it the complete molecule, since the compound could not have been commercialized without the additional amino acids? The answer to those questions is not clear, which means clarification would be left to the federal courts on a patent-by-patent basis.

### Continuation applications

Under the current statute and rules, after an inventor has filed a patent application—often called the parent application—he or she can file as many identical patent applications (i.e., continuation applications) claiming priority to it as he or she wants. That is, as long as the parent application is pending and the claims of the various applications are differentiated. Each continuation application requires a standard fee, which is supposed to cover the cost of examination.

The PTO, however, has alleged that allowing one to file unlimited continuation applications is overburdening the administrative capability of the office. It further puts forth the notion that patent examiners, through the continual harassment of having to review the same application again and again, may be effectively forced to issue at least one of the many applications, even if it is not worthy of patentability. The PTO accordingly believes that certain entities are misusing administrative resources for their own competitive advantage. (For a discussion of proposed rules governing the filing of continuation applications, see 71 Fed. Reg. 61 (2006).)

Still, there are legitimate reasons for filing several continuation applications, especially in the context of emerging biotechnology companies. Emerging companies must worry about funding, and venture firms want to see issued patents. If an emerging biotech company receives a notice from the PTO that some, but not all, of its presented claims are patentable, the company can let the allowed claims issue and pursue the others in a continuation application. This scenario might repeat itself several times over the course of three or four years, giving the fledgling company an opportunity to quickly build a presentable patent portfolio.

Furthermore, biotechnology inventions are often fundamental, representing a paradigm shift in the industry. One may file a patent application directed to the fundamental invention but may not be able to appreciate all of its commercial applications at that time. (It is, after all, changing an industry or even spawning new ones—e.g., polymerase chain reactions.) The ability to file multiple continuation applications provides the inventor with an opportunity to present and obtain different claims that embrace developing commercial applications. In short, he or she has an opportunity to extract full value for the societal contribution.

**Some provisions may hinder emerging biotech companies.**

The proposed Patent Reform Act of 2005 is premised on good policy statements: reducing litigation costs, closing administrative loopholes and putting decisions at the technology/legal interface in front of those who understand technology. It is unclear, though, whether it is premised on sound practical grounds. Some of the proposed subsections may actually spur litigation rather than curtail it; some may decrease the amount of useful knowledge society receives in exchange for granting a patent on a particular technology; and some may negatively effect emerging biotechnology companies. Unfortunately, proof regarding the effect of this legislation comes with implementation rather than theory. NLJ