

Written Comments to the PTO Genetic Diagnostic Testing Study

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Thank you for the opportunity to provide written and oral testimony for these important questions. This comment concerns the quality assessment of patented technology related to genetic diagnostic testing. I have written about this issue in more detail in a recent article, *Patent Cover-Up*, 47 Hous. L. Rev. 1299 (2011), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1599893. In this comment, I focus on the need for an exception to infringement to allow for quality assessment.

Permitting quality assessment strikes a reasonable balance between the normal exploitation of the patent and the legitimate interests of the public. Most research use of patented technology is overlooked until it is disseminated or results in an improvement or alternative means. As such, the question of the purpose of the research is likely to be an issue only after the research culminates in an improvement or alternative means. The proposed exception protects dissemination of information, regardless of whether the research results in improvement, but it does not protect designing around a patented technology. Because the exception does not protect alternatives that could supplant demand for the patented invention, it is less likely to be opposed based on proprietary interests.

To the extent quality assessment resulted in an improvement of the patented technology, the proposed exception would apply to the research but not to the improvement. Under the doctrine of blocking patents, the improver of a patented technology can receive a patent on a significant improvement but has no rights in the underlying patented technology. The patent holder of the initial invention similarly has no claim to the improvement. To practice the improvement, the improver would have to obtain a license from the patent holder of the initial invention. Without the proposed quality assessment exception, improvers would be subject to infringement liability for their use of the patented technology in inventing the improvement.

The proposed exception would not apply to research that results in an alternative means of practicing the invention, unless the alternative means provides information about some limitation of the patented technology or can be used to evaluate the patented technology. For example, quality assessment resulting in a more accurate method of detecting mutations in genetic sequences would be protected under the proposed exception, if the more accurate method were useful in evaluation of the existing methods used in genetic testing of patented sequences. The more accurate methods also would be protected if they provided an objective assessment of existing methods, such as by producing information related to mutations that existing methods failed to detect. Such a proposal might provide the needed incentive for patent holders in this space to continue developing testing methods related to their patented sequences.

A quality assessment exception would permit independent parties to analyze the limitations, accuracy, validity, and weaknesses of patented technology, but would not protect experimentation to create an alternative to the patented invention. By refusing to protect substitutes for the patented invention, the proposed exception is substantially narrowed and less likely to raise appropriation concerns.

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