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RESEARCH TOOL PATENTS COME BACK TO LIFE TO STOP INFRINGING DRUG DISCOVERY ACTIVITIES

SUMMARY

On June 6, 2003, the Court of Appeals for the Federal Circuit (CAFC) reinvigorated research tool patents when it held that the use of patented peptides for drug discovery research constituted infringement and was not exempt under the safe harbor provided by 35 USC §271(e)(1). *Integra Lifesciences LTD et al. v. Merck KgaA et al.,* 02-1052, -1065 (CAFC, 2003).

After earlier judicial decisions of lower courts that first permitted the importation of products derived from the off-shore use of patent research methods[1] and then protected from infringement liability the use of patented intermediate compounds to discover other compounds,[2] the CAFC emphatically found that early stage discovery research activities were not "solely for uses reasonably related to the development and submission of information under a Federal law" and thus not protected by the safe harbor afforded by §271(e)(1).

THE CAFC DECISION

Integra owns five U.S. Patents relating to a short tri-peptide segment of fibronectin having the sequence RGD. Merck & Co., in collaboration with The Scripps Research Institute, worked on a project to identify potential drug candidates and utilized peptides claimed in the five Integra patents. Integra sued Merck and Scripps for patent infringement. In rejecting Merck's claim that these activities were protected under §271(e)(1), the Court concluded that §271(e)(1) was enacted to permit generic drug manufacturers to conduct testing in advance of a patent's expiration so as long as those activities were reasonably related to securing FDA approval. The Court noted that the intent of the statute is to facilitate the immediate entry of safe, effective generic drugs into the marketplace upon expiration of a pioneer drug patent, and activities that do not directly produce information for submission to the FDA do not qualify for exemption under the safe harbor provision. The Court stated that the "FDA has no interest in the hunt for drugs" that may or may not later undergo clinical testing for FDA approval. Thus, the Court concluded that Merck's work was not reasonably related to clinical testing to obtain FDA approval.

[1] *Bayer AG v. Housey Pharmaceuticals, Inc*., 169 F. Supp.2d 328, 61 U.S.P.Q. 2d 1051 (D. Del, 2001).
[2] *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.,* (WL 1512597 (SDNY 2001)

POSSIBLE IMPLICATIONS

In its analysis, the CAFC considered the RGD peptides to be "research tools" that could be used to facilitate the identification of new therapeutic drugs. The decision in *Integra* provides owners of research tool patents with some comfort that unless the research tool is used for clinical testing, infringement of the patents may result. From a practical standpoint, the *Integra* decision provides some breadth to research tool patents and may cause potential users of the patented tool to steer clear of the patents, or take a license. In addition, holders of research tool patents may now assert their patents against potential infringers, even if the infringing use is related to drug development activities that at some indeterminate time in the future may be used for development of data for regulatory approval.

The Court also discussed issues surrounding the valuation of the "reasonable royalty" measure of damages. Although no definitive conclusion was made, the Court mentioned several factors that should be considered, including (1) the time at which the infringement took place; (2) the purpose of using the research tool in the drug development continuum (e.g., identification of a new drug versus confirmation of a recognized drug's safety or efficacy); and (3) royalty stacking (e.g., the number of patent licenses needed to develop or commercialize a drug). Moreover, the Court's discussion of royalty stacking suggests tacit approval of reach-through royalties.

Thus it appears that the courts are willing to address issues relating to research tools, research methods, and license valuations surrounding the tools and methods. With the prevalent use and patenting of research tools, more decisions on these issues are likely to follow.

This document is intended as in informational reminder and does not constitute legal advice. If you have any questions or would like to discuss a particular situation, you should contact your usual W & D attorney or one of us.

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