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Biotechnology in the Courts Subcommittee Report

Summaries of Recent Decisions of Interest to the Biotechnology Community

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C O N T R I B U T O R S

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The AIPLA Biotechnology in the Courts Subcommittee Report is a forum for members of the subcommittee to present summaries and commentary on recent judicial decisions of interest to the biotechnology community. Any view of a contributor expressed in a summary should be understood to reflect only the present consideration and views of the contributor, and should not be attributed to the AIPLA or any of its committees, the contributor's firm, employer, or past or present clients, to other contributors, or to the editor. To request an electronic copy of the Report, or if you are interested in summarizing a case for a future edition, please contact Melanie Szweras at mszweras@bereskinparr.com.

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Mr. Tyler is listed in *Best Lawyers in America*® and *Indiana Super Lawyers*®. He is the author of several published articles on issues of intellectual property or federal procedure in a variety of peer-reviewed publications. In 2010, one of his articles won the prestigious Burton Award for Legal Achievement. The first of his two articles on inequitable conduct has been cited by two Federal Circuit Judges in published opinions.

Mr. Tyler graduated *summa cum laude* in 1981 from the University of Notre Dame and in 1984 received his J.D. *magna cum laude* from the University of Michigan Law School. In 2007, he received a M.S. in Biology from Purdue University (Indianapolis campus).

Mr. Tyler's civic activities include being a co-founder, past president, and volunteer for the Neighborhood Christian Legal Clinic. For his work on behalf of the Clinic, he received the Indianapolis Bar Association's Pro Bono Award in 2002 and was a co-recipient of the firm's inaugural Joseph A. Maley Pro Bono Award in 2009.

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Mr. Brunelle received his B.S. in chemical engineering from Purdue University in 2004. He received his J.D. magna cum laude in 2008 from Indiana University School of Law – Bloomington. During law school, Mr. Brunelle served as a managing editor of the Indiana Law Journal, as executive problem editor of the Sherman Minton Moot Court Board, and was selected for membership in the Order of the Coif.

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Case Summaries

I. *Wyeth v. Abbott Labs.*, Case No. 2012-1223, -1224 (Fed. Cir. June 26, 2013)

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Summary

Wyeth and Cordis Corporation ("Wyeth") appealed the U.S. District Court for the District of New Jersey's grant of summary judgment that Wyeth's patent claims related to methods of treating or preventing restenosis by the use of rapamycin were invalid for lack of enablement. The Federal Circuit affirmed, finding that the patent claims covered tens of thousands of compounds, that only one such compound was disclosed in the patents at issue, and that synthesizing and identifying those compounds with the claimed immunosuppressive and anti-restenotic effects constituted undue experimentation.

Background

The claims at issue in Wyeth's appeal were claims 1 and 2 of U.S. Patent No. 5,516,781 and claim 1 of U.S. Patent No. 5,563,146. Each claim recites a method of treating or preventing "restenosis in a mammal . . . which comprises administering an anti-restenosis effective amount of rapamycin to said mammal." Restenosis is the re-narrowing of an artery, which is a potential adverse event to endovascular surgery.

The parties agreed that the shared specification of the patents at issue disclosed only one rapamycin species called sirolimus, which is naturally produced by a bacterium called *Streptomyces hygroscopicus*.

Defendants market stent products that elute everolimus and zotarolimus, drugs that have the same macrocyclic ring as sirolimus but different substituents at the C-42 position. The district court adopted Wyeth's proposed construction of "rapamycin" as "a compound containing a macrocylic triene ring structure produced by *Streptomyces hygroscopicus*, having immunosuppressive and anti-restenotic effects." The district court granted defendants' motion for summary judgment of invalidity for non-enablement and lack of written description based in part on this construction.

Decision

The focus of the Federal Circuit's opinion was whether practicing the full scope of the claims required excessive, and thus undue, experimentation. The Court began its analysis by noting that the scope of the claims at issue was broad. "Under the district court's unchallenged construction of 'rapamycin,' the invention is a new method of use of a known compound (sirolimus) *and* any other compounds that meet the construction's structural and functional requirements."

The Court agreed with Abbott that there was no genuine dispute that the specification's guidance was limited to disclosure of the immunosuppressive and anti-restenotic properties of sirolimus and assays to screen for those properties. Wyeth argued, based on expert testimony, that while there may be millions of compounds made by varying the substituent groups outside of sirolimus's macrocyclic ring, one of ordinary skill in the art would know that the number of compounds that exhibit the recited functional effects would be significantly smaller. In particular, Wyeth argued that those of skill would know (1) that to exhibit the recited functional effects, a compound must be permeable across cell membranes and (2) that such permeability typically occurs in compounds having molecular weights below 1,000-1,200 Daltons. Thus, Wyeth reasoned that the universe of potential rapamycin compounds was much more limited by these known criteria.

Even accepting as true for purposes of summary judgment Wyeth's claims regarding the knowledge of a person of skill in the art, the Court found that practicing the full scope of the claims would still require more than routine experimentation. First, the Court noted that even if potential rapamycin candidates must have a molecular weight below 1,200 Daltons, there would remain tens of thousands of compounds. The specification was also silent as to how to structurally modify sirolimus in a way that would preserve the recited utility. Second, the Court found that one of skill would be required to first synthesize and then screen each of the tens of thousands of candidate compounds to determine whether each had immunosuppressive and anti-restenotic effects.

In conclusion, the Court found that synthesizing and screening tens of thousands of compounds was outside the bounds of routine experimentation described in precedent cases. And, this was particularly the case where the specification at issue "disclose[d] only a starting point for further iterative research in an unpredictable and poorly understood field."

Commentary

Once again, the Federal Circuit has found that broad claims require broad disclosure. In the past we have reported on high profile biotech cases, such as *University of Rochester v. Searle*, *Ariad v. Eli Lilly*, and *Centocor v. Abbott*, in which similarly broad claims were found invalid based on § 112 grounds. *Wyeth* demonstrates that an enablement defense to broadly construed claims is also viable in the more traditional chemical arts. The opinion also stands as an example of when the application of known techniques to recreate a patented compound may lie outside the limits on permissible experimentation for enablement purposes due to the sheer amount of labor necessary to employ those techniques.