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ARIAD PHARMACEUTICALS, INC. V. ELI LILLY AND COMPANY

—- F.3d ——, 2009 WL 877642, C.A.Fed. (Mass.), April 03, 2009 (NO. 2008-1248)

I. STATEMENT OF THE FACTS

Defendant-Appellant Eli Lilly and Company ("Lilly") appeals the district court's ruling that the patent at issue was both valid and infringed by two of Lilly's pharmaceuticals. Plaintiff-Appellee Ariad Pharmaceuticals, Inc. ("Ariad") held a patent which claimed a method of artificially reducing the activity of NF-KB, a DNA transcription factor (the patent did not claim any molecules which achieved the claimed reduction). Lilly argued that the patent was invalid for anticipation, lack of enablement, or lack of written description. Lilly also argued that the patent was unenforceable due to Ariad's inequitable conduct. The jury determined that the patent was valid and infringed by Lilly's drugs, and that Ariad had not been guilty of inequitable conduct.

II. HOLDING

The Federal Circuit reversed, holding that the jury lacked substantial evidence to support a determination of adequate written description. Thus, the patent was invalid. The court upheld the district court's finding of no inequitable conduct.

III. REASONING

Ariad argued that because it did not claim any molecules that could reduce NF-KB activity, its written description could not be held invalid for failure to designate specific molecules which would effectuate the method (the description mentioned three vague classes of molecules as possibilities). The court disagreed, holding that Ariad must describe some way of performing the claimed method to establish possession. Ariad argued that one of ordinary skill in the art could have performed the method given the suggested categories of molecules. However, at trial, the jury had determined an early effective filing date for the patent, rendering much of the evidence Ariad cited to establish the level of skill of an ordinary practitioner

unavailable, having been published after the effective filing date. Because the inventors of the patent had discovered NF-KB, the court found, one of ordinary skill in the art at that time was, at best, 'ignorant'. Therefore, the scope of the asserted claims went far beyond the disclosure provided in the specification.

In a concurring opinion, Judge Linn reasserted his disagreement with the Federal Circuit's current doctrine which requires a separate written description above and beyond the claims. The separate requirement, he argues, has generally caused confusion over what actually defines the scope of the claim. Judge Linn criticized the court for deciding the case on the written description element, as it foreclosed analysis of the important issue of enablement of broad claims.

IV. RECENT COMMENTARY

Judge Linn's concurring opinion questions the value of a separate written description requirement in analyzing patent validity. Kevin Noonan believes that the requirement aligns patent law with its constitutional mandate, which requires that patents be granted only if they "promote the progress" of the useful arts. He argues that requiring a separate written description prevents patentees from over-claiming, and prevents patent claims from becoming invitations to research, rather than fully enabling the invention. (Kevin Noonan, *Ariad Decision Voids Attempts to Use Broad Claiming to Avoid the Written Description Requirement*, Patent Docs, Apr. 14, 2009, http://www.patentdocs.org/2009/04/ariad-decision-voids-attempt-to-use-broad-claiming-to-avoid-the-written-description-requirement.html). On the other hand, as Andrew Williams points out, the requirement of a separate written description left unresolved the question of whether a claim encompassing any method to achieve a particular result could ever be valid. (Andrew Williams, *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, Patent Docs, Apr. 6, 2009, http://www.patentdocs.org/2009/04/ariad-pharmaceuticals-inc-v-eli-lilly-and-co-fed-cir-2009.html).

WYETH V. DIANA LEVINE

129 S.Ct. 1187 (March 4, 2009)

I. STATEMENT OF THE FACTS

Plaintiff-respondent Levine sued defendant-appellant Wyeth in Vermont state court under strict liability and negligence standards. Levine had received treatment for symptoms of nausea, including Wyeth's drug Phenergan, an antihistamine. The drug was known to cause gangrene when injected into a patient's arteries. Gangrene caused by the drug necessitated the amputation of Levine's arm. Levine alleged that the drug's labeling had failed to adequately warn of the risks of ''administering the drug via IV-Push. Wyeth argued that Levine's claims were preempted by Food and Drug Administration (FDA) regulations governing labeling requirements. At trial, the jury found Wyeth negligent and Phenergan defective as a result of inadequate warnings and instructions, and awarded damages. The trial judge rejected Wyeth's preemption defenses, a ruling later upheld by the Vermont Supreme Court.

II. HOLDING

A majority of the Supreme Court affirmed, holding that FDA's drug labeling regulatory regime did not preempt state law tort claims involving questions of inadequate labeling, in an opinion by Justice Stevens, joined by Justices Kennedy, Souter, Ginsburg and Breyer. Justice Breyer filed a concurring opinion. Justice Thomas concurred in the judgment. Justice Alito dissented, joined by Chief Justice Roberts and Justice Scalia.

III. REASONING

The majority declined to debate the merits of the state 'tort claim, and addressed only Wyeth's preemption claims. It noted generally that preemption of state law does not lie unless Congress clearly intended such preemption. It first dismissed Wyeth's argument that it was impossible to comply with both federal labeling duties and the state law duties imposed here. Wyeth argued that it was barred from proposing labeling changes by FDA regulations unless it possessed 'new information' about the drug's safety. However, the majority found that Wyeth was permitted to change it's labeling without prior FDA approval. Furthermore, under FDA

regulations, the manufacturer retains primary responsibility over labeling, not the FDA. Regarding Wyeth's argument that requiring it to comply with state tort law duties would obstruct the purposes and objectives of federal drug labeling regulation, the majority found that Congress had never explicitly preempted state law claims, and had implicitly preserved state court remedies over a long period of time and several statutory amendments. Wyeth's strongest argument hinged on a recent (2006) preamble to a FDA regulation governing prescription drug labels, which opined that state law judgments threaten the FDA's role as the expert agency responsible for regulating drugs. However, the majority held that no deference was owed to this statement, because it was only contained in a preamble, because the rule's validity was in question given procedural failures in its promulgation, and because it was contrary to the intent of Congress.

Justice Breyer concurred, emphasizing that pre-emption might apply in some circumstances, given that the FDA had some authority consistent with its statutory mandate to comment on or define the preemptive scope of its regulations.

Justice Thomas concurred in the judgment, arguing that the Supreme Court's jurisprudence on "'purposes and objectives"' preemption was not consistent with the Constitution. He would severely restrict the power of the courts to find implied preemption, because it often results in the unconstitutional invalidation of state laws, and is premised on dubious guessing as to Congress' intent.

Justice Alito would have held the state tort law claims preempted, because no state should be able to countermand the FDA's determination of drug safety. Such action upsets the careful regulatory balance already determined by Congress and the federal agency. Because the FDA had considered Phenergan's labeling in light of the known risks, and because the labeling had provided adequate warning of those risks, state court adjudication of labeling requirements should be barred. Finally, juries were ill-equipped to adequately replicate the FDA's cost-benefit analysis.

IV. RECENT COMMENTARY

The *Levine* decision will exact sweeping changes in pharmaceutical company drug applications and regulation. Jim Beck and Mark Herrmann point out that *Levine* makes preemption much more unlikely, though not impossible. They note that the Court declined to require formal rulemaking as a prerequisite to

preemption, and that an express rejection of a proposed warning label would probably suffice. (Jim Beck and Mark Herrmann, *Wyeth v. Levine – First Real Thoughts,* Drug and Device Law, Mar. 4, 2009, http://druganddevicelaw.blogspot.com/2009/03/wyeth-v-levine-first-real-thoughts.html). However, this begs the question as to how precise the rejection must be. Anthony Sebok sees two possible rules: either the court requires that the FDA expressly rejects the exact warning whose absence created liability, or the court requires only that the FDA rejects the reasoning behind a proposed warning. (Anthony Sebok, *The Day after Levine: Analyzing the Supreme Court's Recent Ruling that FDA Approval of Label Warnings Does Not Preempt State Tort Law*, FindLaw, Mar. 17, 2009, http://writ.news.findlaw.com/sebok/20090317.html). The former rule would multiply FDA workload and require companies to try to predict sources of litigation, while the latter would require that these companies establish a clear record upon which a court could find that their reasons for a warning had been rejected. Either way, as Craig Wylie points out, these firms will face increased risks of litigation, and they ought to ensure strict oversight of regulatory compliance at every step of production. (Craig Wylie, *Wyeth v. Levine: Disrupting the labeling process*, PharmExecBlog, Apr. 1, 2009, http://blog.pharmexec.com/2009/04/01/wyeth-v-levine-disrupting-the-labeling-process/).