Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.

Nos. 07-1269, -1270, Fed. Cir. (Lourie,* Rader, Bryson)

ANDA applicants owe a duty of care under the Hatch-Waxman Act [and] applicants fail to meet this duty when they file "baseless" certifications [but this does not mean] ANDA applicants who are merely negligent can trigger § 285.

On December 8, 2008, the Federal Circuit affirmed the district court's award to Takeda of $16.8 million in attorney fees plus interest and expert fees after the abbreviated new drug applications by Mylan and Alphapharm for generic pioglitazone were held to infringe U.S. Patent 4,687,777, which related to the anti-diabetic drug that Takeda markets as ACTOS®. The Federal Circuit stated:

> When a patent has been infringed by the filing of an ANDA, 35 U.S.C. § 271(e)(4) provides for the grant of attorney fees under 35 U.S.C. § 285, which in turn allows the court to award reasonable attorney fees to a prevailing party in exceptional cases. Takeda contended that Mylan and Alphapharm each lacked a good faith basis for their Paragraph IV letters and engaged in misconduct throughout the litigation. [The district court held that Alphapharm's] Paragraph IV certification letter was "so devoid of merit and so completely fail[ed] to establish a prima facie case of invalidity that it must be described as 'baseless.'" The court discussed at length how Alphapharm's argument at trial focused on compound b as the lead compound for future research, whereas Alphapharm's certification letter focused on two other compounds and contained scientific errors. The court also analyzed what it saw as Alphapharm's litigation misconduct, which mainly consisted of a shifting theory of obviousness that did not explain why compound b would have been identified as the lead compound. . . . Similarly, the court held that Mylan's certification letter was filed in bad faith and with no reasonable basis to claim the '777 patent invalid. The court discussed how Mylan argued in its Paragraph IV letter that the invention of pioglitazone was obvious based on Takeda's disclosure of a compound in the '200 patent and Sohda II . . . only to abandon this theory entirely during the litigation. In addition, the court discussed Takeda's numerous allegations of litigation misconduct committed by Mylan in its pursuit of an inequitable conduct claim, which principally addressed Takeda's representations to the PTO regarding a different [prior art] compound. . . .
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> [The Amicus] Generic Pharmaceutical Association [argued] that failure to reverse the district court's finding of an exceptional case would deter generic applicants from presenting defenses at trial that were not included in their certification letters. Amicus asserts that changing defenses is normal conduct during litigation, especially in patent cases, when ANDA applicants prepare certification letters without the benefit of discovery. As a result, amicus argues, ANDA filers should be allowed to litigate the best available theories at trial, regardless of their inclusion in certification letters. Amicus asserts that if the district court decision stands, it will have a chilling effect on future ANDA patent challenges. [W]e find the "chilling" argument . . . to be unpersuasive . . . . In making a Paragraph IV certification, appellants are statutorily required to "include a detailed statement of

the factual and legal basis of the opinion of the applicant that the patent is invalid." It is clear from the district court's opinion that it was not faulting Alphapharm or Mylan for the act of filing an ANDA that challenged the pioglitazone patent, nor did it limit the filers to the theories raised in their certification letters. Rather, the district court found the case exceptional based on the specific circumstances involved in this case, viz., baseless certification letters compounded with litigation misconduct. . . .

Appellants argue that Takeda's award request was excessive for a litigation that lasted just two years and culminated in a nine-day trial. They point to Takeda's billing entries and expenses as excessive and inadequately supported in arguing that the district court abused its discretion by not reducing the award from the requested amount. Mylan also argues that the court abused its discretion in failing to consider opinions of Mylan's experts regarding the reasonableness of the award and that the court had no basis for its two-thirds allocation of the fee award to Mylan. Finally, both Alphapharm and Mylan assert that the additional sanctions of expert fees and expenses were unjustified because there was no evidence of fraud or abuse of the judicial process. . . .

Although the award of the total amount of a fee request is unusual, we have stated that such an award may be imposed and affirmed. That determination lies within the discretion of the trial judge, "who is in the best position to know how severely [a party's] misconduct has affected the litigation." Here, the district court left no doubt as to its opinion of the litigation and work performed by counsel. The court characterized the work of Takeda's counsel as "uniformly excellent" and determined that the attorney fee award was reasonable. Indeed, the court indicated that an even higher award would have been justified. The court found that none of the attacks on the size of the fee award had merit, and the court also gave specific reasons for disregarding Mylan's purported expert opinions, including a lack of experience on the part of the declarants with both the present litigation and patent litigation as a whole. Furthermore, the court explained its allocation of two-thirds of the fee burden to Mylan because it acted as lead defense counsel for discovery of the obviousness claims and then added considerably to the complexity of the case with an untimely assertion of an inequitable conduct claim. Given the court's reasoned analysis and familiarity with the litigation, we do not believe that the court abused its discretion with its award of attorney fees and related expenses.

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