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A Proposal to Curb Misuse of ‘Exceptional Case’ Allegations Against ANDA Applicants

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On December 8, 2008, the United States Court of Appeals found *Takeda v. Mylan* to be an exceptional case and ordered Mylan to pay attorneys fees of over 16 million dollars. The “exceptional case” pleading is a boilerplate accusation in Hatch-Waxman cases and part of a Brand Pharma litigation strategy resulting in increased costs of litigation and the delay of generic drugs coming to market. To curb the overuse of the exceptional case accusation in Hatch-Waxman cases, Brand Pharma plaintiffs should be required to plead with particularity, similar to the pleading requirements for fraud.

The exceptional case statute at 35 U.S.C. § 285 provides that courts in “exceptional cases” may award attorney fees to the prevailing party. Exceptional case claims can be grounded on “inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement.” A finding of “exceptional circumstances” is the first step in a two step analysis of a motion for attorneys’ fees pursuant to 35 U.S.C. §285. Once the court has determined that the case is “exceptional,” the prevailing party seeking an award of attorneys’ fees must prove “exceptional circumstances” by clear and convincing evidence.

In *Takeda v. Mylan*, the Court determined that Mylan and Alphapharm each lacked a good faith basis for their Paragraph IV letters and engaged in misconduct throughout the litigation. At trial Alphapharm and Mylan each changed the focus of their invalidity arguments from those in their certification letters. Alphapharm pointed to a compound referred to as “compound b,” which Takeda had previously disclosed, as evidence that pioglitazone was structurally obvious at the time the invention was made. Mylan advanced an inequitable conduct argument based on alleged misrepresentations by Takeda to the U.S. PTO. The Court held that, due to the change in invalidity arguments, Alphapharm’s Paragraph IV certification letter was devoid of merit and failed to establish a prima facie case of invalidity and was baseless. Similarly, the court held that Mylan’s certification letter was filed with no reasonable basis to claim Takeda’s patent was invalid.

The awarding of attorney’s fees in *Takeda* has encouraged Brand Pharma plaintiffs to make the allegations in their pleadings and use the discovery process to identify any change in the ANDA applicant’s litigation position in order to obtain an “exceptional case” ruling.

“Exceptional Cases” are Very Rare.

Unlike the *Takada v. Mylan* case, Brand Pharma can rarely show that an ANDA applicant engaged in behavior that would constitute an “exceptional case” justifying the sanction of awarding attorney’s fees against the ANDA applicant. In fact, a recent survey of all decisions of the U.S. District Court for the District of New Jersey in which the Court determined that a case was “exceptional” and granted attorney’s fees under 35 U.S.C. § 285 revealed that there has not been a single such case under Hatch-Waxman. However, the survey did find eight non-Hatch Waxman cases in which the court awarded attorney’s fees

under this statute, suggesting that exceptional case pleading is overused, at least in a Hatch-Waxman context.

The “exceptional case” allegation by Brand Pharma puts into motion several discovery-related mechanisms and has immediate and serious cost and delay consequences. First and foremost, it results in extra discovery of the ANDA applicant to which the patent holder is normally not entitled. For example, by alleging a case is “exceptional”, the patent holder can seek to determine who was responsible for signing the FDA patent certification and drafting the patent notice of the certification, and who made the decisions to select the particular drug and develop the Paragraph IV basis, which, in turn, may infringe upon the attorney-client privilege. Another consequence of Brand Pharma’s assertion of “exceptional case” status includes wasted ANDA applicant resources and increased costs of litigation as the defendant endeavors to respond to such expanded discovery demands.

“Exceptional Case” Pleading Delays Generics from Entering the Market.

The overuse of exceptional case designations by Brand Pharma also delays the litigation, ultimately preventing the entry of the generic drug onto the market. Such tactics contribute to the 30 month stay of approval by the FDA and can cause the stay to run out, forcing the generic drug company to decide whether to launch its product at risk. Finally, such efforts by Brand Pharma harm the public, as the exceptional case pleading holds up the release of the generic drug into the marketplace and keeps drug prices artificially high.

A Proposed Solution.

A solution to the boilerplate use of the exceptional case pleading and its abusive consequences is to require Brand Pharma plaintiffs to plead “exceptional case” status with particularity similar to the requirements for pleading fraud. Federal Rule of Civil Procedure 9(b) provides that “in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” This higher pleading standard acts as a safeguard against frivolous claims charging the commission of a fraudulent act. To plead with particularity the plaintiff must show that (1) the defendant has made a false representation of or failed to disclose a material fact; (2) the defendant has knowledge of or a belief in the falsity of the statement by the person making it; (3) a belief in the truth of the false statement or the completeness of the representations by the person to whom the representation is made; (4) an intent on the part of the defendant that the statement or the failure to disclose should be acted upon by the plaintiff; and (5) the detrimental reliance upon the false representation or the fullness of the disclosure by the person claiming to have been deceived. While the pleading for “exceptional case” status need not be co-extensive with all types of fraud, requiring particularity would reduce the misuse (and overuse) of exceptional case pleading, while appropriately protecting the ANDA defendant.

Conclusion.

Exceptional case pleadings have become a crucial element of Hatch-Waxman litigation, especially in reaction to ANDA filings similar to those presented by Alphapharm and Mylan in the Takeda case. However, exceptional case pleadings should not be used as an intimidation tool to keep generic drug companies from filing ANDA and Paragraph IV certifications for fear of being found culpable for litigation misconduct. Safeguards, such as pleading with particularity, must be put in place to give an ANDA defendant some protection and confidence when they reasonably believe that their drug is a bioequivalent and does not infringe the patent holder’s rights. This safeguard, if implemented, has the real potential of significantly reducing ANDA litigation delays and costs, and benefits the public through the quicker availability of generic drugs.

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1. Takeda Chem. Indus., Ltd. v. Mylan Lab., Inc., 594 F.3d 1381, 1384 (Fed. Cir. 2008)
 2. Joyal Prod., Inc. v. Johnson Elec. N. Am., Inc., 2009 WL 512156 (D.N.J.)
 3. Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1034 (Fed. Cir. 2002)

4. J. P. Stevens Co., v. Lex Tex Ltd., Inc., 822 F.2d 1047, 1050 (Fed Cir. 1987)
5. Reactive Metals and Alloys Corp. v. ESM Inc., 769 F.2d 1578, 1582 (Fed. Cir. 1985)
6. Takeda Chem. Indus., Ltd. v. Mylan Lab., Inc., 492 F.3d 1350 (Fed. Cir. 2007)
7. Takeda, 594 F.3d at 1384.
8. Id.
9. Id.
10. Id. At 1385
11. Id.
12. 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure §1296 (3d ed. 2004)
13. Id.
14. 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure §1297 (3d ed. 2004)