

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

Miscellaneous Docket No. 927

BAYER HEALTHCARE, LLC,

Plaintiff-Respondent,

v.

NORBROOK LABORATORIES, LTD. and NORBROOK, INC. USA,

Defendants-Petitioners.

On Petition for Permission to Appeal pursuant to 28 U.S.C. § 1292(b) from the United States District Court for the Eastern District of Wisconsin in consolidated case nos. 08-CV-953 and 09-CV-108, Chief Judge Rudolph T. Randa.

ON PETITION FOR PERMISSION TO APPEAL

Before MICHEL, Chief Judge, FRIEDMAN and LINN, Circuit Judges.

LINN, Circuit Judge.

ORDER

Norbrook Laboratories, Ltd. and Norbrook, Inc. USA (Norbrook) petition for permission to appeal orders certified by the United States District Court for the Eastern District of Wisconsin as ones involving a controlling issue of law as to which there is substantial ground for difference of opinion and for which an immediate appeal may materially advance the ultimate termination of the litigation. Bayer Healthcare, LLC opposes.

Norbrook seeks Federal Drug Administration (FDA) approval to market a generic version of BAYTRIL 100 on a multi-day, low-dose treatment regimen. BAYTRIL 100 is a name brand drug sold by Bayer to treat bovine respiratory disease and is made up of

fluro-quinolones. Bayer's patent relates to the use of fluro-quinolones in a single high dose. Norbrook filed an Abbreviated New Animal Drug Application (ANADA) for its generic version of BAYTRIL and a so-called Paragraph IV certification stating that Bayer's patent was invalid or not infringed.

Based on Norbrook's ANADA, Bayer brought this suit in the United States District Court for the Eastern District of Wisconsin, alleging patent infringement and also seeking declaration of patent infringement. Norbrook filed its answer and counterclaimed noninfringement and patent invalidity, but later amended its answer explaining that it had withdrawn its Paragraph IV certification and ANADA with the FDA and in its place filed a Section I statement that certifies to the FDA that the generic manufacturer is seeking to market the drug for a use other than the one encompassed by the patent. Norbrook also counterclaimed that the patent is invalid based on inequitable conduct.

Norbrook filed a motion for judgment on the pleadings seeking to dismiss Bayer's infringement complaint for failure to state a claim and for lack of subject-matter jurisdiction. On September 23, 2009, the district court denied the motion, making several determinations why Bayer's complaint set out a plausible showing that Norbrook's actions could constitute infringement. First, the court held that there was a material issue of fact as to whether Norbrook could validly withdraw its paragraph IV certification and whether the FDA will approve the amended ANADA. Second, the court held that even assuming that Norbrook could withdraw its Paragraph IV certification, Bayer's complaint set out a plausible claim for infringement because a Paragraph IV certification is not necessary to state a cause of action under 21 U.S.C. § 271(e)(2) as

long as the purpose of the submission to the FDA is to obtain approval to engage in the manufacturer or sale of a product, "the use of which is claimed in a patent." Third, the court held that "use," as defined in § 271(e), means the disease treated rather than the dosage used. Fourth, the court held that there was an issue of material fact as to whether Norbrook's multi-day, low-dose treatment regimen treatment would induce or contribute to infringement. Finally, the court held that it could not determine as a matter of law that Bayer's declaratory judgment action should be dismissed for lack of case or controversy or subject matter on essentially the same grounds that it could not dismiss Bayer's infringement complaint.

In a separate order, the district court certified the September 23rd order for permissive appeal pursuant to 28 U.S.C. § 1292(b). Pursuant to that section, Norbrook seeks review of the order containing the above-mentioned issues. Ultimately, this court must exercise its own discretion in deciding whether it will grant permission to appeal interlocutory orders certified by a trial court. See In re Convertible Rowing Exerciser Patent Litigation, 903 F.2d 822 (Fed. Cir. 1990); 28 U.S.C. § 1292(c)(1). We determine that granting the petition in these circumstances is not warranted.

Accordingly,

IT IS ORDERED THAT:

The petition for permission to appeal is denied.

FOR THE COURT

MAR 23 2010

Date

/s/ Jan Horbaly

Jan Horbaly
Clerk

cc: Kenneth R. Nowakowski, Esq.
Aaron P. Maurer, Esq.

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JAN HORBALY
CLERK