United States Court of Appeals for the Federal Circuit

SCIELE PHARMA INC. (NOW KNOWN AS SHIONOGI PHARMA INC.),
Plaintiff-Appellee,

and

ANDRX CORPORATION, ANDRX PHARMACEUTICALS INC. (DOING BUSINESS AS WATSON LABORATORIES INC. – FLORIDA), ANDRX PHARMACEUTICALS L.L.C., ANDRX LABORATORIES (NJ) INC., ANDRX EU LTD., AND ANDRX LABS L.L.C.,
Plaintiffs,

v.

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,
Defendants-Appellants,

and

MYLAN INC. AND MYLAN PHARMACEUTICALS INC.,
Defendants.

2012-1228

Appeal from the United States District Court for the District of Delaware in consolidated case no. 09-CV-0037, Judge Robert B. Kugler.

Decided: July 2, 2012

DAVID B. BASSETT, Wilmer Cutler Pickering Hale and Dorr LLP, of New York, New York, argued plaintiff-appellee. With him on the brief were DAVID A. MANSPEIZER and CHRISTOPHER R. NOYES; and MARK C. FLEMING, of Boston, Massachusetts.

DOUGLAS C. HOCHSTETLER, Kelley Drye & Warren LLP, of Chicago, Illinois, argued for defendants-appellants. With him on the brief was BETH D. JACOB, of New York, New York. Of counsel was CLIFFORD KATZ.

Before LOURIE, PROST, and MOORE, *Circuit Judges*.

MOORE, *Circuit Judge*.

Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively Lupin) submitted an Abbreviated New Drug Application (ANDA) to the Food and Drug Administration seeking approval to market a generic version of Fortamet, an extended-release tablet of metaformin hydrochloride. Shionogi Pharma Inc.[1] (Shionogi), which markets Fortamet, sued Lupin for patent infringement under 35 U.S.C. § 271(e)(2)(A) asserting, among others, U.S. Patent No. 6,866,866 ('866 patent), which is listed in the Approved

[1] Sciele Pharma Inc. is now known as Shionogi Pharma. For simplicity we will refer only to Shionogi in this opinion.

Drug Products with Therapeutic Equivalence Evaluations (Orange Book) entry for Fortamet. Lupin attempted to launch its generic Fortamet "at risk," i.e., without a final judgment on the merits in the litigation. Shionogi moved for a preliminary injunction to stop Lupin from selling its generic Fortamet and the district court granted Shionogi's request for injunctive relief. For the reasons discussed below, we *vacate* the preliminary injunction and *remand* for further proceedings consistent with this opinion.

BACKGROUND

The '866 patent is entitled "Controlled Release Metformin Compositions" and describes and claims, *inter alia*, dosage forms with "a mean time to maximum plasma concentration (T_{max}) of the drug which occurs at 5.5 to 7.5 hours after oral administration on a once-a-day basis to human patients." '866 patent, at [57]; *see also* col.21 ll.48-59. Other claims narrow the T_{max} range to, for example, between 5.5 and 7.0 hours after the administration of the dose of metformin. '866 patent col.21 ll.64-67. Shionogi asserted claims 1, 3, 4, 5, and 25 in this litigation. Claim 3 is the only asserted claim explicitly limited to a narrower T_{max} range.

The claimed T_{max} range reflects a quirk in the '866 patent's prosecution history. During prosecution, the examiner rejected a number of pending claims as obvious in light of WO99/47125 (Cheng) in view of U.S. Patent No. 3,845,770. J.A. 2634. In a subsequent examiner interview, the applicant discussed the "importance of T_{max} . . . and the relationship to gluconeogenesis," and the examiner indicated that the "closest prior art"–Cheng–"suggest[s] the general teaching of a T_{max} of 8." J.A. 2643. In response, the applicant cancelled a number of claims including claim 1, which had an upper T_{max} range of 7.5 hours, and rewrote then-pending

claim 5, which had an upper T_{max} range of 7 hours, into independent form. J.A. 2668. The applicant indicated that the examiner agreed during the interview "that [pending] claim 5, which had an upper T_{max} of 7.0 hours and which value is directly supported by the working examples, is patentably distinct over the Cheng, et al. reference." J.A. 2675.

Despite cancelling the rejected claims including claim 1, the applicant received a notice of allowance for pending claims 1, 4, 5, 7-27, and 29. J.A. 2645. The applicant contacted the Patent Office and explained that the notice of allowance mistakenly allowed cancelled claims, including the previously cancelled claim 1. J.A. 2650. The applicant provided "a listing of the pending claims," which once again indicated that claim 1 was cancelled. *Id.* The examiner issued a supplemental notice of allowance acknowledging the amendment after the interview, removing the cancelled claims, and allowing the amended claims. J.A. 2686. The supplemental notice of allowance thus accurately reflected the applicant's prior submission: the pending claims directed to a T_{max} with an upper limit of 7.5 hours (including claim 1) were "[c]ancelled," J.A. 2668, and claims 5, 7-27, 29, 30, and 43 (with an upper T_{max} of 7 hours) were allowed, J.A. 2668-73.

After this, the '866 patent issued with a surprise; the issued patent contained the cancelled claims from the first notice of allowance – not the supplemental notice of allowance. Hence, the patent issued with claim 1's original upper T_{max} limit of *7.5 hours*, the exact T_{max} limit that the examiner found problematic, and that the applicant sought to avoid by cancelling pending claim 1. J.A. 2675. After issuance, the patentee did not pursue further action, and claim 1 of the issued patent continues to recite the higher T_{max} limit of 7.5 hours. Because claim 1 is the only inde-

pendent claim in the patent, many of the dependent claims also include the limitation that the upper end of the T_{max} range is 7.5 hours.

The '866 patent was eventually listed in the Orange Book entry for Fortamet. When Lupin filed its ANDA seeking permission to sell a generic version of Fortamet, the application included a Paragraph IV certification that the '866 patent was invalid, unenforceable, and/or would not be infringed by Lupin's ANDA products. Shionogi filed a suit for patent infringement within the requisite time period, thereby triggering the statutory 30-month stay of FDA approval of Lupin's ANDA. Although the patentee previously sought on several occasions to cancel what essentially issued as claim 1 in the '866 patent, Shionogi nevertheless asserted claim 1, along with claims 3-5 and 25, in the present litigation. Claim 3 is the only asserted claim limited to dosage forms with an upper T_{max} of 7 hours. The other claims have an upper T_{max} limit of 7.5 hours. The litigation progressed but remained unresolved when the 30-month stay expired. The expiration of the 30-month stay allowed the FDA to give final approval to Lupin's ANDA on June 29, 2011, and Lupin launched its ANDA product on September 30, 2011. Shionogi moved for a preliminary injunction and a recall of Lupin's generic products on October 12, 2011.

On December 6, 2011, the district court granted a preliminary injunction that prohibited Lupin from "further importation and sales of its generic version of . . . Fortamet." J.A. 1. After reviewing the standard for a preliminary injunction, the court held that Shionogi was likely to prevail on its infringement claim based primarily on Lupin's proposed labeling. J.A. 11. The court then rejected Lupin's argument that the claims of the '866 patent were improperly issued. J.A. 12. Although the court did not reach the merits of Lupin's obviousness arguments, it did note that in light of

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