UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC., and GRUNENTHAL GBMH, Plaintiffs, – against – TEVA PHARMACEUTICALS USA, INC., and BARR LABORATORIES, INC. Defendants.	12-CV-8060 (TPG)
ENDO PHARMACEUTICALS INC., *et al.* Plaintiffs, – against – IMPAX LABORATORIES, INC. *et al.*, Defendants.	12-CV-8317 (TPG)
ENDO PHARMACEUTICALS INC., *et al.*, Plaintiffs, – against – IMPAX LABORATORIES, INC., Defendant.	13-CV-0435 (TPG) **(captions continued on the following page)**

ENDO PHARMACEUTICALS INC., *et al.* Plaintiffs, – against – ACTAVIS INC., *et al.*, Defendants.	:	13-CV436 (TPG)

OPINION

On February 18, 2015, defendants in these patent infringement actions moved for summary judgment with regard to three of the six patents in suit, U.S. Patent Numbers 8,114,383 ("the '383 Patent"), 8,309,060 ("the '060 Patent"), and 8,192,722 ("the '722 Patent"). Defendants argue that plaintiffs are collaterally estopped from litigating those patents here because they were invalidated in a case presided over by Judge Stein of this court. For the following reasons, the court grants summary judgment with regard to the '383 Patent, but denies summary judgment with regard to the '060 Patent and the '722 Patent.

Facts

The three patents at issue on this motion relate to co-plaintiff Grünenthal GmbH's "thermoforming" technology. The technology uses heat and pressure to make pills difficult to crush and snort. Grünenthal licensed a version of the technology, named INTAC®, to co-plaintiff Endo Pharmaceuticals Inc. Endo then used the technology to develop a crush-

resistant version of its oxymorphone painkiller OPANA®ER. The crush-resistant formulation of the drug is named OPANA®ER CRF.

From September through December of 2012, defendants filed applications with the Food and Drug Administration to market generic oxymorphone hydrochloride pills in extended release form. Plaintiffs responded by filing the instant lawsuits for patent infringement. Among other things, plaintiffs allege that defendants, in applying to make a generic oxymorphone hydrochloride product, infringe on several of the claims contained in the '383, '060, and "722 patents.

In September of 2013, Judge Stein of this court held a bench trial in a case titled *In re Oxycontin Antitrust Litigation*. 994 F. Supp. 2d 367 (S.D.N.Y. 2014). In that case, the plaintiff Purdue Pharmaceuticals alleged that the defendant, Teva Pharmaceuticals USA, Inc., would infringe on several of its patents if allowed to market a generic version of the drug OxyContin. *Id.* at 376. One of the patents asserted in that case was United States Patent Number 8,114,383. *Id.* That patent, the '383 Patent, is also asserted in this case.

Five claims of the '383 Patent were invalidated in *In re Oxycontin*. These were claim 1; claim 2; claim 5; claim 7; and claim 8. Judge Stein found that these claims were invalid because they were anticipated by the prior art, specifically by a publication known as the "McGinity Application." *See id.* at 421. Moreover, Judge Stein determined that even if not anticipated by the prior art, these claims were invalid for

obviousness, meaning that a "person of ordinary skill in the art would have had sufficient knowledge and motivation to make the invention claimed by the '383 Patent." *Id.* at 426.

Plaintiffs in the instant case assert four of the exact same claims of the '383 Patent invalidated in the OxyContin case. These are claim 1; claim 2, claim 5, and claim 7. Plaintiffs also assert claim 9 of the '383 Patent, which was not at issue in the OxyContin case. Claim 9 reads: "The dosage form according to claim **1**, wherein the active ingredient with abuse potential (A) is oxymorphone or a physiologically acceptable salt thereof." This language is identical to claim 8, which was asserted in the OxyContin case, except that the word "oxymorphone" is substituted for the word "oxycodone." *Compare* Claim 9, U.S. Patent No. 8,114,383 B2 *with* Claim 8, U.S. Patent No. 8,114,383 B2.

Plaintiffs also assert two patents, the '060 Patent and the '722 Patent, which were not asserted in the OxyContin case.

Discussion

The standard governing motions for summary judgment is well-settled. A court may grant summary judgment only when the moving party shows that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Cartrett*, 477 U.S. 317, 322 (1986). "When considering a motion for summary judgment, a court must construe the evidence in the light most favorable to the nonmoving party, drawing all

inferences in that party's favor." *Jeffreys v. City of New York*, 426 F.3d 549, 553 (2d Cir. 2005).

Collateral estoppel prohibits a party from relitigating an issue that has already been decided in a previous proceeding. Collateral estoppel will apply where "(1) the identical issue was raised in a previous proceeding; (2) the issue was actually litigated and decided in the previous proceeding; (3) the party had a full and fair opportunity to litigate the issue; and (4) the resolution of the issue was necessary to support a valid and final judgment on the merits." *Ball v. A.O. Smith Corp.*, 451 F.3d 66, 69 (2d Cir. 2006). In a patent infringement action, it is not necessary that the claims asserted be identical to the previously adjudicated claims in order for collateral estoppel to apply. *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). Rather, "If the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies." *Id.*

The factors listed above indisputably apply to the four claims of the '383 Patent asserted in the trial before Judge Stein. The issue in *OxyContin* was whether claims 1, 2, 5, 7, and 8 of the '383 Patent were invalid. *In re OxyContin*, 994 F. Supp. 2d at 421. Judge Stein held that those claims were invalid because two scientists at the University of Texas had developed a "hot-melt extrusion process" for manufacturing extended-release pills years earlier, and that a publication relating to this process (the "McGinity Application") disclosed every required limitation of the

claims asserted. *Id.* at 425. Thus, those claims were invalid as anticipated by the McGinity Application. *Id.*

Judge Stein did not adjudicate the validity of claim 9 of the '383 Patent because that claim was not before him. However, he did adjudicate the validity of claim 8 of that patent. Claim 8 of the patent reads "The dosage form according to claim **1**, wherein the active ingredient with abuse potential (A) is oxycodone or a physiologically acceptable salt thereof." Judge Stein ruled that this claim was invalid because the McGinity Application disclosed to a person of ordinary skill in the art that the invention could be used with oxycodone. *Id.* at 425. Notably, claims 8 and 9 of the '383 patent are identical, except that they refer to different opioids: oxycodone and oxymorphone.

Although Judge Stein did not consider claim 9 of the '383 Patent, resolving the validity of that claim would involve questions, and answers to those questions, identical to those relevant to claim 8 of the '383 Patent. The McGinity application describes using the hot-melt extrusion of a high-density polymer and therapeutic compound to create controlled-release drugs. *See* International Application Published Under the Patent Cooperation Treaty (PCT) ("McGinity Application") at 2, 8. This process was expressly intended, among other things, to create analgesics in the form of "tablets, pills . . . and the like." *Id.* at 8, 11. Oxymorphone, like oxycodone, is an opioid analgesic. *See* Remington's Pharmaceutical Sciences 17 (Ex. G) at 1103–05 (describing oxymorphone hydrochloride as

one of several semisynthetic opiate analgesics). Consequently, a person of ordinary skill in the art would interpret the McGinity Application as disclosing the invention's use in creating controlled release tablets of oxycodone, *In re OxyContin,* 994 F. Supp. 2d at 425, *and* oxymorphone. Because there is no material difference between the questions of validity with regard to claim 8 and claim 9 of the '383 Patent, collateral estoppel applies. *See Ohio Willow*, 735 F.3d at 1342.

Defendants have satisfied their burden for obtaining summary judgment with regard to the '383 Patent. There is no dispute that claims 1, 2, 5 and 7 of the '383 Patent were litigated to final judgment in the OxyContin case, and that collateral estoppel applies to those claims. As discussed, collateral estoppel applies with equal force to claim 9 of the '383 Patent because trial on that patent would implicate questions of validity *identical* to those presented in the earlier case.

Defendants have also highlighted intriguing similarities between the other two patents at issue on this motion, the '060 and '722 patents, and the patent litigated to final judgment in the OxyContin case. *See* Defs. Mem. L. Supp. Mot. Summary J. at 9–11. However, unlike the '383 Patent, defendants have not shown that the claims asserted from the '060 and '722 patents are similar enough to (and raise materially identical questions as to validity) as the claims adjudicated in the OxyContin litigation. Indeed, the claims of the '060 and '722 patents recite limitations that were not considered or adjudicated by Judge Stein. *See, e.g.*, Claim 1 of U.S. Patent

Number 8,309,060 (referring to an "abuse-proofed" thermoformed dosage form). Because the '060 and '722 patents were not adjudicated in the OxyContin case, and because their claims recite different limitations, collateral estoppel does not preclude litigation of those claims here.

Of course, summary judgment does not require collateral estoppel. A party may also obtain summary judgment by showing that there is no genuine issue as to any material fact and that the party is entitled to judgment as a matter of law. But defendants, in their briefing in support of summary judgment, did not invoke summary judgment on the merits (validity/invalidity) of the '060 and '722 patents, but simply as a matter of collateral estoppel. *See* Mot. Summ. J. at 1 ("defendants will move the Court . . . for partial summary judgment of collateral estoppel as to [the three patents at issue].") Thus, absent collateral estoppel, there is insufficient evidence before the court to warrant summary judgment on the '060 and '722 patents.

Conclusion

For the reasons given above, defendants' motions for summary judgment are granted with regard to United States Patent Number 8,114,383. Summary judgment is denied with regard to United States patent numbers 8,309,060 and 8,192,722.

SO ORDERED

Dated: New York, New York
March 17, 2015

Thomas P. Griesa
U.S. District Judge