United States Court of Appeals for the Federal Circuit

ENDO PHARMACEUTICALS INC.,
Plaintiff-Appellant,

v.

ACTAVIS, INC. AND
ACTAVIS SOUTH ATLANTIC, LLC,
Defendants-Appellees.

2013-1658

Appeals from the United States District Court for the Southern District of New York in No. 12-CV-8985, Senior Judge Thomas P. Griesa.

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ENDO PHARMACEUTICALS INC.,
Plaintiff-Appellant,

v.

ROXANE LABORATORIES, INC.,
Defendant-Appellee.

2013-1662

Appeal from the United States District Court for the Southern District of New York in No. 13-CV-3288, Senior Judge Thomas P. Griesa.

Decided: March 31, 2014

MARTIN J. BLACK, Dechert LLP, of Philadelphia, Pennsylvania, argued for plaintiff-appellant. With him on the brief were ROBERT D. RHOAD and JONATHAN D. LOEB. Of counsel were VINCENT AUGUST GALLO and JOSEPH RAYMOND HEFFERN.

CHARLES A. WEISS, Holland & Knight LLP, of New York, New York, argued for defendants-appellees, Actavis, Inc., et al. With him on the brief were ERIC H. YECIES and NICHOLAS P. CHIARA.

ALAN B. CLEMENT, Locke Lord LLP, of New York, New York, argued for defendant-appellee, Roxane Laboratories, Inc. With him on the brief were KEITH D. PARR, HUGH S. BALSAM, and MYOKA KIM GOODIN, of Chicago, Illinois.

Before NEWMAN, DYK, and MOORE, *Circuit Judges.*

Opinion for the Court filed by *Circuit Judge* MOORE.

Opinion dissenting in part filed by *Circuit Judge* DYK.

MOORE, *Circuit Judge.*

Endo Pharmaceuticals, Inc. (Endo) appeals from the district court's order denying its motions for a preliminary injunction to prevent Roxane Laboratories, Inc. (Roxane), Actavis Inc., and Actavis South Atlantic LLC (Actavis) from marketing and selling their respective generic drug products during the pendency of this litigation. Because

the district court erred in concluding that Roxane and Actavis (Appellees) had an implied license to practice the asserted patents, and because Appellees do not have an express license, we *vacate* and *remand*.

BACKGROUND

Endo sells Opana® ER, which are branded extended-release tablets containing a painkiller called oxymorphone. The asserted patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) entry for Opana® ER. Two of the asserted patents, U.S. Patent Nos. 8,309,122 (the '122 patent) and 8,329,216 (the '216 patent), are each continuations of the same parent application and are directed to extended-release oxymorphone compositions and methods of treating pain using those compositions. The third patent-in-suit, U.S. Patent No. 7,851,482 (the '482 patent), is not related to the other two patents. It recites purified oxymorphone compositions and methods of making those compositions. The '122 and '216 patents are at issue in both appeals, and the '482 patent is at issue only in the Actavis appeal.

Prior to this litigation, Endo sued Appellees for patent infringement under 35 U.S.C. § 271(e)(2)(A) based on their Abbreviated New Drug Applications (ANDAs) to market generic versions of Opana® ER—the same products as those at issue in these appeals. The first set of lawsuits settled after Endo granted to Appellees a license and a covenant not to sue. The settlement and license agreement between Endo and Roxane (Roxane Agreement) defines "Licensed Patents" as follows:

> (a) any [U.S.] patents that are *both* (i) *now owned* by Endo . . . and (ii) *issued as of the Effective Date of this Agreement*, including the Opana® ER Patents,

> (b) *any [U.S.] patent applications that claim priority to the Opana® ER Patents, including any continuation*, continuation-in-part and divisional *patent applications that claim priority to Opana® ER Patents*, and
>
> (c) any patents resulting from the reissue or reexamination of patents or patent application of patents or patent applications comprised within clauses (a) and (b) . . .

J.A. in appeal no. 2013-1662 (Roxane J.A.), at 4973 § 1.16 (emphases added). The Roxane Agreement defines "Opana® ER Patents" as U.S. Patent Nos. 5,662,933, 5,958,456, and 7,276,250. *Id.* § 1.20.

Pursuant to the agreement, Endo granted Roxane a covenant that it would not assert that Roxane's generic versions of Opana® ER "infringe[] the *Licensed Patents*" and a license "*under the Licensed Patents* . . . to make, use, have made, sell, offer to sell, import and use" those generic products. Roxane J.A. 4978 §§ 4.1(a),(b) (emphases added); *see also* Roxane J.A. 4974 §§ 1.28, 1.29. Finally, the Roxane Agreement includes a "No Implied Rights" provision stating that Endo does not grant to Roxane any license or right "whether by implication, estoppel or otherwise, other than as expressly granted herein." Roxane J.A. 4949 § 4.4. The settlement and license agreement between Endo and Actavis (Actavis Agreement) is similar. The Actavis Agreement includes a grant of a license, a covenant not to sue, and a "No Implied Rights" provision, but covers one additional patent not included in the Roxane Agreement and not relevant to this appeal. J.A. in appeal no. 2013-1658 (Actavis J.A.), at 4893–908.

The patents that are the subject of this litigation issued after Endo's agreements with Appellees. The '122 and '216 patents issued to Endo and the '482 patent was acquired by Endo. Endo again sued Appellees for patent

infringement under 35 U.S.C. § 271(e)(2)(A) and moved for a preliminary injunction to prevent the marketing and sales of their generic oxymorphone formulations. Appellees opposed on the theories of express license and implied license by reason of legal estoppel. With regard to the latter, Appellees argued that Endo attempted to deprive them "of the benefit of [the] earlier bargain." Roxane J.A. 4823; *see also* Actavis J.A. 2717.

At a joint hearing, the district court commented that "this is a highly unfair and unjust situation if . . . infringement of the new patents would stop the marketing and permitting process that was going on by Actavis and Roxane." Actavis J.A. 6411. The court held that "as a matter of law . . . Endo is estopped from claiming that the activity of Actavis and Roxane, which has gone on for a substantial period of time, is now suddenly barred because of these new patents." *Id.* The court therefore denied Endo's motions. *Endo Pharm., Inc. v. Actavis Inc.*, C.A. No. 12-cv-8985-TPG (S.D.N.Y. Sept. 18, 2013), ECF No. 35.

Endo appeals. We have jurisdiction under 28 U.S.C. § 1292(a)(1).

DISCUSSION

We review decisions to grant or deny a preliminary injunction for an abuse of discretion, which may be established when a district court based its decision on an error of law. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006). "To the extent the court's decision is based upon an issue of law, we review that issue *de novo*." *Id.* Whether legal estoppel has been created and whether an implied license exists are questions of law. *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1578, 1580 (Fed. Cir. 1997). "The interpretation of a Settlement Agreement, *i.e.*, a contract, is a question of law that we [also] review *de novo*." *Augustine Med., Inc. v. Progressive Dynamics, Inc.*, 194 F.3d 1367, 1370 (Fed.

Cir. 1999). "The burden of proving that an implied license exists is on the party asserting an implied license as a defense to infringement." *Id*.

I. Express License

Endo argues that the district court abused its discretion in denying Endo's motions for a preliminary injunction. Endo contends that the plain language of the agreements, which limit "Licensed Patents" to several enumerated patents and applications claiming priority to them, does not grant Appellees an express license to practice the asserted patents. It argues that the "No Implied Rights" provision further makes clear that the agreements do not cover the asserted patents. In the district court, both Actavis and Roxane argued that they have an express license to practice these newly issued patents. In this appeal, Actavis no longer presents this argument, although Roxane continues to do so. The district court did not decide the question of express license, stating that "I do not feel, for the purposes of a preliminary injunction motion, that I am able to make any findings on the issues that I have just described." Actavis J.A. 6438.

Roxane responds that the express terms of the settlement and license agreement grant it a license to practice the asserted patents because the previously licensed U.S. Patent No. 7,276,250 ('250 patent) claims priority to U.S. Provisional Application No. 60/303,357 ('357 application), and the '122 and '216 patents also claim priority to that provisional application. It contends that the word "including" in § 1.16(b) of the Roxane Agreement shows that the agreement covers more than just continuation, continuation-in-part, and divisional applications that claim priority to the Opana® ER Patents. Roxane argues that this section "necessarily embraces any patent applications that claim priority to any applications and provisional applications" to which the licensed patents likewise claim

priority. Roxane Br. 29. It contends that Endo's interpretation reads out the word "including" and other license terms, and argues that the common provisional application teaches subject matter that "binds" the '250 patent to the asserted '122 and '216 patents.

Roxane's express license arguments are meritless. Section 1.16(b) of the Roxane Agreement covers U.S. patent applications that "claim priority to the Opana® ER Patents [*e.g.*, any of the licensed patents], including any continuation, continuation-in-part and divisional patent applications that claim priority to Opana® ER Patents." Roxane J.A. 4973 § 1.16(b). There can be no dispute that the '122 and '216 patents are not continuations of any of the licensed patents.[1] Likewise, there is no reasonable

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[1] We note that counsel for Actavis repeatedly argued to the district court that the '122 and '216 patents are continuations of the '250 patent and are therefore expressly licensed. *See, e.g.*, Actavis J.A. 2716 ("Endo's '122 patent and '216 patent are continuations of a patent called out by number as licensed in the 2009 settlement and license agreement."). This is flatly wrong, and it is difficult to believe that this argument was made given what is required for an application to be a continuation. For example, to be called a "continuation" of a prior patent, a patent must make an express cross-reference to the nonprovisional application from which the prior patent issued. The continuation must also have the same disclosure as the prior patent. *See* Manual of Patent Examining Procedure (MPEP) § 201.07 (8th ed. Rev. 9, Oct. 2012). The '122 and '216 patents do not have the same disclosure as the '250 patent, nor do they claim priority to the application that issued as the '250 patent. To be continuations of the '250 patent, the '122 and '216 patents would have to, on their face, expressly indicate

argument that the '122 and '216 patents claim priority to any of the licensed patents. An application that claims priority to another patent must contain an express cross-reference to "a prior-filed nonprovisional application from which the patent issued." 37 C.F.R. § 1.78(d)(2) (2013); *see* 35 U.S.C. § 120 (2012); *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1351 (Fed. Cir. 2010). The '216 and '122 patents, however, do not cross-reference the applications that issued as any of the licensed patents. *See* '122 patent col. 1 ll. 6–7; '216 patent col. 1 ll. 6–7. Therefore, it is quite clear that the '122 and '216 patents do not "claim priority to" any of the licensed patents.

Roxane's argument that the word "including" somehow broadens what it means "to claim priority to" another patent is unpersuasive. The Roxane Agreement covers "any applications that claim priority to the ['250 patent], including any continuation, continuation-in-part and divisional" patent applications. Roxane J.A. 4973. Claiming priority to a licensed patent is a prerequisite for the license, and "including" by no means eviscerates that requirement. There is no reading of this language that extends coverage to patents that merely have a provisional application in common with the licensed patents. The figure reproduced below, which is part of the record, shows this clearly. *See* Roxane J.A. 5232. The '122 and '216 patents claim priority to the '357 provisional application, and the '250 patent claims priority to the '357 application as well. The '122 and '216 patents *do not* claim priority to the '250 patent. Although the language is clear on its face, the fact that Endo and Roxane considered including in their agreement a grant of a license to "any application *claiming a common priority date as* the li-

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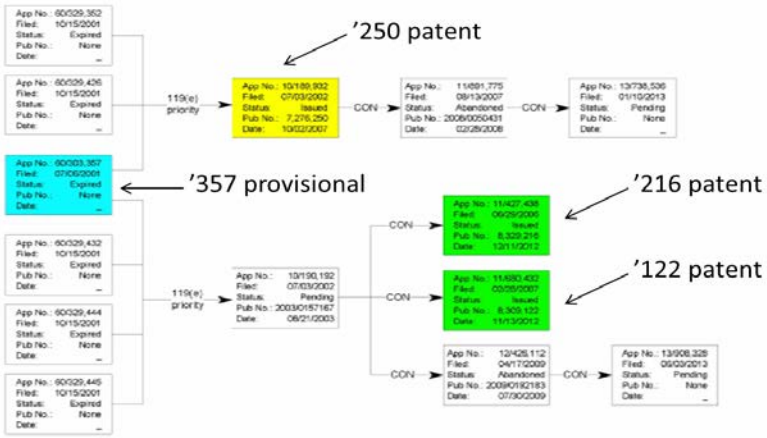
that they are continuations of the application that issued as the '250 patent—unequivocally, they do not.

censed patents" reinforces this conclusion. Roxane J.A. 4864–65 (emphasis added). Because the '122 and '216 patents have a provisional application in common with the '250 patent, the "common priority date" language would have expressly covered the '122 and '216 patents. *See* 35 U.S.C. § 119(e)(1) (2012). But that language does not appear in the final version of the Roxane Agreement.



The Actavis Agreement likewise does not cover the '122, '216, and '482 patents at issue in the Actavis appeal. It contains the same "continuations, continuations-in-part or divisionals" language as the Roxane Agreement. *See* Actavis J.A. 4893, 4895, 4898. For the reasons discussed above, the asserted patents are not continuations, continuations-in-part, or divisionals of the licensed patents. *See* MPEP §§ 201.06–.08. Finally, the '482 patent is completely unrelated to any of the previously licensed patents, and is likewise not covered by the agreement. We hold that Appellees do not have an express license to practice any of

the patents asserted in this litigation.

II. Implied License

Endo argues that the district court legally erred in concluding that Appellees are impliedly licensed to practice the asserted patents due to legal estoppel. It contends that the court's recognition of an implied license defense is incorrect. It argues that the specifications of the asserted patents are different from those of the previously licensed patents, and that the claims cover different subject matter. Endo points out that the previously licensed patent (the '250 patent) that claims priority to the same provisional application as the '122 and '216 patents was not even asserted in the previous litigation, and only added to the final settlement and license agreements because Endo realized that Appellees did not infringe it. Endo argues that, in contrast, the '122 and '216 patents—and the unrelated '482 patent—cover the accused generic tablets. Endo argues that the cases relied upon by Appellees regarding estoppel are distinguishable because they involved continuations and because the licenses in those cases included products as well as patents. Endo argues that, by ignoring the language of the agreements and the parties' intent, the district court's approach violates the sanctity of contract and thus implicates serious public policy concerns.

Appellees respond that they have an implied license to practice the asserted patents based on the principle that equity does not permit the licensor to detract from its grant of a property right. Appellees contend that Endo granted them a license to market their accused generic products for valuable consideration, that they relied on the license in going forward with the Food and Drug Administration approval of the ANDAs, and that Endo's later-obtained patents "eviscerated" the benefit of the licenses. Appellees argue that the "No Implied Rights" language in the agreements is not dispositive because

estoppel "must override any such provision." Roxane Br. 22; *see* Actavis Br. 29–30.

Appellees contend that the facts here are analogous to those in *TransCore, LP v. Electronic Transaction Consultants Corp.*, where we held that the patentee was legally estopped from bringing a second infringement action even though the earlier settlement agreement stated that it "shall not apply to any other patents." 563 F.3d 1271, 1279 (Fed. Cir. 2009). They argue that *TransCore* and related cases dictate that Endo cannot deprive Appellees of the benefit of the earlier bargain, and that nothing in the reasoning of *TransCore* limits its holding to continuations or even related applications. Appellees contend that the settlement and license agreements should be deemed as allowing them to make, use, and sell their generic tablets without threat of further lawsuits by Endo.

We hold that Appellees' broad reading of *TransCore* is incorrect and agree with Endo that the district court erred as a matter of law in finding legal estoppel in favor of Actavis and Roxane. We begin with the well-established proposition, recognized in *TransCore*, that a patent license does not convey to the licensee "an absolute right" to make, use, or sell a product "because not even the patentee . . . is given that right." *Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Maschinefabrik Aktiengesellschaft*, 829 F.2d 1075, 1081 (Fed. Cir. 1987) (quoted in *TransCore*, 563 F.3d at 1275–76). The patentee's right "is merely one to exclude others from making, using or selling [the product covered by the licensed patent], 35 U.S.C. § 154" and "the patentee . . . and his licensee, when making, using, or selling [the product], can be subject to suit under other patents" when practicing the patented invention. *Id.*

The doctrine of legal estoppel does not nullify these general principles. Instead, it "refers to a *narrow category of conduct* encompassing scenarios where a patentee has

licensed or assigned a right, received consideration, and then sought to derogate from the right granted." *TransCore*, 563 F.3d at 1279 (alteration omitted) (emphasis added). In *TransCore*, the patentee asserted a continuation patent that "was broader than, and necessary to practice" one of the patents included in a prior settlement agreement. *Id.* We observed that the fact that the patentee "adopted its [licensed] patent infringement contentions as its contentions related to the [asserted] patent," *id.*, provided undisputed evidence that the patentee "sought to enforce the [asserted] patent in derogation of the rights it granted" under the prior agreement, *id.* at 1279 n.4. Even though the agreement stated that it "shall not apply to other patents . . . to be issued in the future," we concluded that the patentee was legally estopped from asserting a patent whose claim scope fully encompassed that of the claims of one of the licensed patents. *Id.* at 1279. We thus recognized that the asserted patent claims were broader than the licensed claims. To avoid a windfall to the licensee, we expressly limited the implied license to the scope of the licensed claims. *Id.* ("[T]o obtain the benefit of its bargain with [the licensor], [the licensee] must be permitted to practice the [asserted patent] to the same extent it may practice the [licensed patents]."); *id.* at 1279–80 ("[Licensee's] rights under its implied license to the [asserted patent] are necessarily coextensive with the rights it received in the . . . license agreement.").

Our subsequent cases confirm the limited scope of *TransCore*. In *General Protecht Group, Inc. v. Leviton Manufacturing Co., Inc.*, we found an implied license where the asserted patents had "[t]he same inventive subject matter [as that] disclosed in the licensed patents" and "[t]he same products were accused." 651 F.3d 1355, 1361 (Fed. Cir. 2011). As in *TransCore*, the patents at issue in *General Protecht* were *continuations* of the licensed patents. *See id.* at 1360 (quoting *TransCore*, 563

F.3d at 1279–80). We observed that "the newly asserted continuations are based on the same disclosure as the previously licensed patents and that, by definition, the continuations can claim no new inventions not already supported in the earlier issued patents." *Id.* at 1361. After explaining that *TransCore* "prohibits a patent licensor from derogating from rights granted under the license," we held that "where . . . *continuations issue from parent patents that previously have been licensed as to certain products*, it may be presumed that, absent a clear indication of mutual intent to the contrary, those products are impliedly licensed under the continuations as well." *Id.* (emphasis added). In *Intel Corp. v. Negotiated Data Solutions, Inc.*, we explained that *TransCore* and *General Protecht* "analyzed a licensee's rights when the patent holder received a *continuation patent*" and "recognized that allowing the patent holder to sue on subsequent patents, when those later patents contain *the same inventive subject matter that was licensed*, risks derogating rights for which the licensee paid consideration." 703 F.3d 1360, 1366 (Fed. Cir. 2012) (emphases added). Taken together, these cases stand for the rule that a license or a covenant not to sue enumerating specific patents may legally estop the patentee from asserting *continuations* of the licensed patents in the absence of mutual intent to the contrary. *See Gen. Protecht*, 651 F.3d at 1361; *TransCore*, 563 F.3d at 1279. We reject Appellees' invitation to expand the implied license doctrine. You get what you bargain for. And we will not use the implied license doctrine to insert ourselves into that bargain and rewrite the contract.

Endo is not estopped from asserting the patents at issue in these appeals because none of the asserted patents is a continuation of any of the licensed patents. The only familial relationship between the asserted and licensed patents is that the '122 and '216 patents claim priority to the same provisional application as the '250 patent. That,

however, does not make these patents continuations of the '250 patent. *See* MPEP § 201.07. The '482 patent is not related to any of the licensed patents. The lack of a continuation relationship between any of the asserted and licensed patents and explicit disclaimer of any other licenses not within the literal terms of the contract are dispositive.

Appellees rely heavily on the general rule that "[t]he grantor is estopped from taking back in any extent that for which he has already received consideration." Actavis Br. 27 (quoting *TransCore*, 563 F.3d at 1279 (quoting *AMP Inc. v. United States*, 389 F.2d 448, 452 (Ct. Cl. 1967))); *see also* Roxane Br. 20–21. But this rule does not apply to the cases before us because, unlike accused infringers in *TransCore* and *General Protecht*, Appellees seek to capture via implied license subject matter *in addition to that* for which they bargained. *AMP* is not to the contrary because the agreement at issue in that case gave the Government the license "to practice, and cause to be practiced . . . throughout the world, each *Subject Invention*"—rather than any specific patents. 389 F.2d at 450, 454 (emphasis added). *AMP* made clear that "[t]he facet of this licensing agreement which is of crucial importance . . . is that it licenses the Government to use an *idea* and not just the Byrem Patent itself." *Id.* at 454 (emphasis in original). By asserting a newly acquired patent covering the licensed invention, AMP derogated from its grant, and the Court of Claims concluded that AMP's patent infringement suit was barred by legal estoppel "in order to protect the specific rights granted to the Government by contract." *Id.* at 454.

Here, rather than grant a license to an "idea," Endo has granted to Appellees a license and covenant not to sue limited to specific patents and patent applications. If Appellees wanted to market and sell their accused generic products free from any threat of being sued by Endo for patent infringement, they could have negotiated for the

appropriate language in the settlement and license agreements. As we observed in *Spindelfabrik*, "patent license agreements can be written to convey different scopes of promises not to sue, *e.g.*, a promise not to sue under a specific patent or, more broadly, a promise not to sue under any patent the licensor now has or may acquire in the future." 829 F.2d at 1081 (quoted in *TransCore*, 563 F.3d at 1276). Having agreed to licenses that do not cover the patents at issue in these appeals, Appellees will not now be heard to complain.

CONCLUSION

We have considered the parties' remaining arguments and do not find them to be persuasive. We *vacate* the district court's denials of a preliminary injunction in both cases and *remand* for further proceedings.

VACATED AND REMANDED

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2013-1662

Appeal from the United States District Court for the Southern District of New York in No. 13-CV-3288, Senior Judge Thomas P. Griesa.

DYK, *Circuit Judge*, dissenting in part.

I agree with the majority that Roxane did not have an express or implied license to practice the '122 and '216 patents. Roxane was aware of Endo's applications for those patents at the time of the settlement with Endo, and the parties agreed not to include them in the settlement agreement. This, it seems to me, is inconsistent with an implied license. I also agree that Actavis does not have an implied license to the '482 patent, which Endo did not own at the time of the Actavis settlement agreement.

I part company with the majority on the question of whether Actavis has an implied license to the '122 and '216 patents. At the time of their settlement agreement, Endo owned those patent applications, which claimed priority to the same provisional application that provided priority to a patent covered by the settlement agreement (the '250 patent). During the settlement negotiations, Endo did not disclose the '122 and '216 patent applications, but rather licensed Actavis to produce the product at issue here. Furthermore, there are material differences between the Actavis and Roxane agreements and negotiations. Under these circumstances, I conclude that Actavis has an implied license to practice the '122 and '216 patents with respect to the product covered by the ANDA that was the subject of the settlement agreement. I respectfully dissent from the majority's contrary conclusion.

I

Under the Hatch-Waxman Act, pharmaceutical manufacturers filing a New Drug Application (NDA) must list patents in the FDA's Orange Book that "could reasonably be asserted" against a competing generic producer. 21

U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(c)(2)(ii). Endo filed an NDA for a pain relief medication called Opana® ER on June 22, 2006 (NDA No. 21-610). Endo listed four patents covering the NDA product—the '250, '933, '456, and '143 patents—in the Orange Book. The FDA approved Endo's NDA.

On February 14, 2008, Actavis sent Endo notice that it had filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to market a generic version of Opana® ER, as did Roxane on December 21, 2009. After receiving these notices, Endo sued Actavis and Roxane (which had also filed a similar ANDA) in the United States District Court for the District of New Jersey, claiming that Actavis and Roxane's ANDA filings constituted an act of infringement. *See* 35 U.S.C. § 271(e)(2)(A). Endo asserted only the '456 patent in the complaint.

Before the litigation could proceed to trial, Endo entered into separate settlement and license agreements with Actavis in 2009 and Roxane in 2011, permitting these companies to sell generic versions of Opana® ER pursuant to their ANDA filings. Sections 4.1(a) and (b) of Actavis's agreement with Endo granted Actavis a license to produce and sell generic versions of Opana® ER under the '456 patent and specified that "Endo . . . covenant[s] not to sue [*i.e.*, licenses] Actavis . . . for infringement of . . . the Opana® ER Patents [*i.e.*, the '250, '933, and '143 patents] based on the manufacture, use, import, sale or offer for sale of any Opana® ER Generic Products . . . ." Actavis J.A. 3305. The Actavis agreement defined "Opana® ER Generic Product" as "any product that is . . . sold under the Actavis ANDA." Actavis J.A. 3302. Sections 4.1(a) and (b) of Roxane's settlement agreement with

Endo were similar.[1] Both agreements also contained clauses stating: "Endo . . . do[es] not grant to Actavis [or Roxane] . . . any license, right or immunity, whether by implication, estoppel or otherwise, other than as expressly granted herein." Actavis J.A. 3306; Roxane J.A. 4569. However, as I later discuss, Roxane's negotiation history and resulting agreement differed significantly in other respects from that of Actavis.

The FDA approved both Actavis's and Roxane's ANDAs, and those companies have been selling generic versions of Opana® ER under their ANDAs since 2011.

At the time of the settlement agreements, Endo had pending patent applications for the '122 and '216 patents. This was disclosed to Roxane but not to Actavis. After Actavis and Roxane began to sell their generic versions of Opana® ER pursuant to their settlement agreements, the PTO issued the '122 and '216 patents to Endo in November and December 2012, respectively. These patents cover Opana® ER's active ingredient as well as its slow release method. *See* U.S. Patent No. 8,309,122; U.S. Patent No. 8,329,216. Endo has now listed these new patents in the Orange Book as related to Opana® ER. The '122 and '216 patents claim priority to the same 2001 provisional application that gave priority to the '250 patent licensed under the settlement agreements.

In this case, Endo has sought to enjoin Actavis and Roxane's production of Opana® ER generic products on the ground that such sales infringe the '122 and '216 patents. Thus, the question is whether, as the district court held, these companies have implied licenses to

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[1] The Roxane agreement defined "Opana® ER Patents" as only the '250, '456, and '933 patents because the '143 patent expired in 2008.

produce the disputed products under their settlement agreements with Endo.

II

In my view, the majority's holding that Actavis has no right to an implied license is inconsistent with our prior decisions in *TransCore, LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009) and *General Protecht Group, Inc. v. Leviton Manufacturing Co., Inc.*, 651 F.3d 1355 (Fed. Cir. 2011). The majority reads these cases as standing for the proposition "that a license or a covenant not to sue enumerating specific patents may legally estop the patentee from asserting *continuations* of the licensed patents in the absence of mutual intent to the contrary." Majority Op. at 13. I think there is no meaningful distinction between the provisional patent relationship at issue in this appeal and the continuation patent relationships at issue in our earlier decisions.

The logic driving *TransCore* and *General Protecht* is rooted in a decision of our predecessor court, *AMP Inc. v. United States*, 389 F.2d 448 (Ct. Cl. 1968). Our predecessor court's decision in *AMP* recognized that a patentee may convey rights to future patents on that invention in licensing agreements even when the licensing agreement does not explicitly cover future patents on the same invention. *Id.* at 454-56. *TransCore* applied *AMP*'s holding to a situation similar to the present appeals. *TransCore* held that a patentee cannot license existing patents to another party for the production of a specific product and then assert a newly acquired patent against that party to prevent it from producing the same product. *TransCore*, 563 F.3d at 1278-79. As the majority accurately summarizes, the patentee in *TransCore*, after agreeing to license the product under existing patents, "asserted a continuation patent that 'was . . . necessary to practice' one of the patents included in a prior settlement agreement." Major-

ity Op. at 12 (quoting *TransCore*, 563 F.3d at 1279). Although the *TransCore* settlement agreement, similar to the settlement agreements at issue here, provided that "'[t]his Covenant Not To Sue shall not apply to any other patents . . . to be issued in the future,'" 563 F.3d at 1273, we held that "in order for [the licensee] to obtain the benefit of its bargain with TransCore, it must be permitted to practice the [new patent] to the same extent it may practice the [licensed] patents." *Id.* at 1279. We further explained that "[t]his language may protect TransCore against broad claims that future patents generally are impliedly licensed, but it does not permit TransCore to derogate from the rights it has expressly granted and thus does not preclude a finding of estoppel." *Id.* Thus, *TransCore* clarified that an explicit disclaimer of any other license not within the literal terms of the contract does not protect the patentee from an implied license when such a license is necessary to ensure the licensee obtains "the benefit of its bargain." *Id.*

Similarly, in *General Protecht*, the patentee sued General Protecht for infringement of two patents, reached a license and settlement agreement with General Protecht allowing it to produce a defined product under the existing patents, and then, three years later, sued General Protecht again, alleging infringement of two new patents that issued after the settlement agreement. *Gen. Protecht*, 651 F.3d at 1357-58. The patentee argued that *TransCore* "d[id] not control" its appeal because *TransCore* "is limited to cases where the claims of the continuation are broader than and therefore necessary to practice the claims of the expressly licensed patents." *Id.* at 1361. In response, this court reasoned that

> [the patentee] cannot deny . . . that the newly asserted continuations are based on the same disclosure as the previously licensed patents and that, by definition, the continuations can claim no new invention not already supported in the earlier is-

> sued patents. Moreover, the same products accused in the earlier suit are accused here. *TransCore* prohibits a patent licensor from derogating from rights granted under the license by taking back in any extent that for which it has already received consideration. In this case, [the patentee's] actions have unquestionably derogated from [General Protecht]'s rights under the Settlement Agreement. *The same products were accused. The same inventive subject matter was disclosed in the licensed patents. If [the patentee] did not intend its license of these products to extend to claims presented in continuation patents, it had an obligation to make that clear.*

Id. (emphasis added) (internal quotation marks and citation omitted) (alteration in original omitted).

Here too, if Endo succeeds on its infringement allegations, Actavis will not be able to sell the very product for which it secured licenses in its settlement agreement. Although the '122 and '216 patents are not continuations of the licensed patents, as was the case in *TransCore* and *General Protecht*, the logic of those cases applies equally here. Under 35 U.S.C. § 119(e)(1), a patent that claims priority to a provisional application must "have the same effect, as to such invention [the provisional invention], as though filed on the date of the provisional application." 35 U.S.C. § 119(e)(1). Thus, as we have explained in the past, "'[w]hat is claimed by the patent application [claiming priority to a provisional application] must be the same as what is disclosed in the [provisional] specification.'" *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1296 (Fed. Cir. 2002) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002)) (citing *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)); *see also Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1342 (Fed. Cir. 2010). That is to say, a patent claiming priority to a provisional application must

cover the same inventive subject matter as the provisional application.

Since the '250 patent (covered by the license agreements) and the '122 and '216 patent applications (subsequently issued) claim priority to the same provisional application and, thus, must cover the same inventive subject matter, the agreements confer an implied license to the two new patents absent contrary evidence. In other words, under our decisions in *TransCore* and *General Protecht*, the settlement agreements here created a presumption that the '122 and '216 patents were impliedly licensed to Actavis and Roxane, even though the only licenses explicitly mentioned in the settlement agreements were to the '250, '456, and '933 patents.

III

Nevertheless, I also think that the parties can agree to eliminate the presumption of implied licenses. Under our prior decisions, this cannot be accomplished simply by stating that the agreement does not extend to any patents beyond those listed in the agreement. *TransCore* and *General Protecht* rejected this very contention. *See Gen. Protecht*, 651 F.3d at 1362-63; *TransCore*, 563 F.3d at 1279. Here, as to Roxane there is more. In the course of its negotiations with Endo, Roxane became aware of the '122 and '216 patent applications, sought to have these pending patents included in the agreement, and ultimately failed to secure a license to them. That history, it seems to me, is sufficient to negate an implied license. But the Actavis negotiations were different, having occurred two years before the Roxane agreement. The record contains no indication that the '122 and '216 patent applications were discussed during Actavis-Endo negotiations or that Actavis was even aware of Endo's applications for the '122 and '216 patents.

While the majority states that the language of the Actavis and Roxane agreements is "similar," Majority Op. at

4, there are, in fact, important differences. *Compare* Actavis J.A. 3300, 3302, 3305 *with* Roxane J.A. 4563, 4568. While both agreements provide an explicit license to produce generic versions of Opana® ER covered by Actavis's and Roxane's ANDAs under the '250, '456, and '933 patents, clause (c) of the agreements is different. Clause (c) of the Actavis agreement reads:

> (c) For avoidance of doubt, and notwithstanding anything to the contrary in this Agreement, the License and Covenant Not to Sue do not grant to Actavis any rights or immunities with respect to any products *other than the Opana® ER Generic Products*, including any combination products.

Actavis J.A. 3305 (emphasis added). Critically, the agreement defines "Opana® ER Generic Products" as "*any product* that is marketed and/or sold under *the Actavis ANDA*." Actavis J.A. 3302 (emphases added). Actavis sells the allegedly infringing product under the Actavis ANDA.

In contrast, clause (c) of the Roxane license agreement reads:

> (c) . . . the License and Covenant Not to Sue does not grant to Roxane any rights or immunities with respect to any products other than the Roxane Products or *with respect to any patents other than the Licensed Patents*.

Roxane J.A. 4568 (emphasis added). The agreement defines "Licensed Patents" as

> (a) any United States patents that are both (i) *now owned* by Endo . . . and (ii) *issued as of the Effective Date of this Agreement*, including the Opana® ER Patents, (b) any United States patent applications that *claim priority to the Opana® ER Patents*, including any continuation, continuation-in-part and divisional patent applications that claim priority to the Opana® ER Patents, and (c)

> any patents resulting from the reissue or reexamination of patents or parent applications comprised within clauses (a) and (b) above, in each case that Endo . . . could assert would be infringing by the making, using, selling, offering to sell or importing of the Roxane Product.

Roxane J.A. 4563 (emphases added). Thus, while the Actavis license is only limited to "*any product* that is marketed and/or sold under the Actavis ANDA," Actavis J.A. 3302 (emphasis added), the Roxane license specifies that it neither extends to any other "products" *nor* "to any patents *other than the Licensed Patents*," Roxane J.A. 4568 (emphasis added), *i.e.*, the 250, '456, and '933 patents. Thus, in subsection (c), the Actavis agreement does not limit the license to specific patents as the Roxane agreement does. A comparison of the two license agreements and the different negotiation histories suggests that Actavis could reasonably conclude it had negotiated a right to sell all Opana® ER generic products despite the interim issuance of the '122 and '216 patents, not merely practice the patents expressly licensed.[2]

The majority concludes: "If Appellees wanted to market and sell their accused generic products free from any

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[2] With respect to the '482 patent, that patent does not claim priority to the provisional application, and the negotiating history does not suggest that Actavis could reasonably conclude that it had negotiated a license to all future patents that might be acquired by Endo relating to Opana® ER. Because the '482 patent issued to another company, Johnson Matthey, in 2010, was acquired by Endo in 2012, and does not claim priority to the provisional application, Actavis should not be treated as having an implied license to the '482 patent. Neither Endo nor Actavis could have known that Endo might later acquire this patent.

threat of being sued by Endo for patent infringement, they could have negotiated for the appropriate language in the settlement and license agreements." Majority Op. at 14-15. But under that theory, this court's precedent in *TransCore* and *General Protecht* would have been wrongly decided. An implied license is not foreclosed simply because the parties could have negotiated for an express license. Here, as in *General Protecht*, Actavis's agreement allowed it to produce and sell a defined product, and we should imply licenses to the new patents because "the same products accused in the earlier suit are accused here," *Gen. Protecht*, 651 F.3d at 1361, and the patents relate to the same inventive subject matter claimed in the provision application.

That the '122 and '216 patent applications were published at the time of the settlement negotiations should not affect this conclusion: in both *General Protecht* and *TransCore*, at least one of the new patents at issue was published as a pending application at the time of the settlement and licensing negotiations. *See Gen. Protecht*, 1357-58 (the patentee and General Protecht entered into a licensing agreement in 2007, and then the patentee sued General Protecht for infringement of two new patents—U.S. Patent Nos. 7,463,124 and 7,764,151—in 2010); U.S. Patent No. 7,463,124 (first published on March 24, 2005, and issued on December 9, 2008); *TransCore*, 563 F.3d at 1273-74.

There is nothing unfair in granting an implied license in Actavis's favor. Although Actavis could have researched pending patent applications at the time of the settlement, placing the burden of disclosure on the party with greater access to information (here, Endo) increases the efficiency of the bargaining process. *See generally* Bruce L. Hay, *Effort, Information, Settlement, Trial*, 24 J. Legal Stud. 29, 31, 55-56, 62 (1995); Lucian Arye Bebchuk, *Suing Solely To Extract a Settlement Offer*, 17 J. Legal Stud. 437, 448 (1988); Lucian Arye Bebchuk, *Litiga-*

tion and Settlement Under Imperfect Information, 15 RAND J. Econ. 404, 414 (1984). Assigning this burden to the party with inferior access to information creates an incentive for the more knowledgeable party to hide information: the more informed party will not face repercussions for failing to disclose information, and, indeed, will benefit from such information asymmetries. *See generally* Bebchuk, *Suing Solely*, *supra*, at 448; Bebchuk, *Litigation and Settlement*, *supra*, at 414 ("[L]egal rules and institutions that magnify the extent to which an informational asymmetry is present might well increase the likelihood of litigation."); Richard A. Posner, *An Economic Approach to Legal Procedure and Judicial Administration*, 2 J. Legal Stud. 339, 422-26 (1973). By creating incentives to hide and obscure important information in settlement negotiations, we undermine the purpose of the settlement process: the avoidance of further litigation.

I respectfully dissent.