

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

ALLERGAN, INC.,
Plaintiff-Appellant

DUKE UNIVERSITY,
Plaintiff

v.

**SANDOZ, INC., AKORN, INC., HI-TECH
PHARMACAL CO., INC., APOTEX, INC., APOTEX
CORP.,**
Defendants-Appellees

2016-1085, 2016-1160

Appeals from the United States District Court for the Middle District of North Carolina in Nos. 1:14-cv-01028-CCE-LPA, 1:14-cv-01034-CCE-LPA, Judge Catherine C. Eagles.

Decided: March 17, 2017

CRAIG E. COUNTRYMAN, Fish & Richardson P.C., San Diego, CA, argued for plaintiff-appellant. Also represented by JONATHAN ELLIOT SINGER; ELIZABETH M. FLANAGAN,

Wilmington, DE; DEANNA JEAN REICHEL, Minneapolis, MN.

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Before REYNA, WALLACH, and CHEN, *Circuit Judges*.

WALLACH, *Circuit Judge*.

Appellant Allergan, Inc. (“Allergan”) appeals the final decision of the U.S. District Court for the Middle District of North Carolina (“District Court”) dismissing its patent infringement case against Sandoz, Inc. et al. (“Sandoz”) with prejudice based on collateral estoppel and declaring several claims of Allergan’s patent invalid as obvious. We affirm-in-part and reverse-in-part.

BACKGROUND

This case comes to our court with a lengthy procedural history involving both parties and six related patents: U.S. Patent Nos. 7,388,029 (“the ’029 patent”), 7,351,404 (“the ’404 patent”), 8,263,054 (“the ’054 patent”), 8,038,988 (“the ’988 patent”), 8,101,161 (“the ’161 pa-

tent”), and 8,926,953 (“the ’953 patent”).¹ All of the patents generally recite a topical solution to treat hair loss or reduction with the compound bimatoprost, a molecular substance that can affect cell growth and functionality. See ’029 patent, Abstract; ’404 patent, Abstract; ’054 patent, Abstract; ’988 patent, Abstract; ’161 patent, Abstract; ’953 patent, Abstract. Allergan sued Sandoz for infringement of, inter alia, the ’029 patent and the ’404 patent, and Sandoz countersued, arguing that the patents were invalid for various reasons. See *Allergan, Inc. v. Apotex, Inc. (Allergan I)*, Nos. 1:10-cv-681, 1:11-cv-298, 1:11-cv-650, 2013 WL 286251, at *1 (M.D.N.C. Jan. 24, 2013); J.A. 2988, 3998 (complaints against Apotex and Sandoz). The District Court found in favor of Allergan. *Allergan I*, 2013 WL 286251, at *13. Sandoz appealed, and we reversed the District Court’s invalidity findings based on obviousness for the ’404 and ’029 patents and vacated the District Court’s injunction. See *Allergan, Inc. v. Apotex, Inc. (Allergan II)*, 754 F.3d 952, 970 & n.13 (Fed. Cir. 2014).

While *Allergan I* was pending, Allergan filed a second suit alleging that Sandoz infringed the ’054 patent, the ’988 patent, and the ’161 patent. See J.A. 223, 236. The case was stayed pending the appeal and resolution of

¹ The ’029, ’054, ’988, ’161, and ’953 patents are continuations of the ’404 patent. A continuation patent application is “an application filed subsequently to another application, while the prior application is pending, disclosing all or a substantial part of the subject matter of the prior application and containing claims to subject-matter common to both applications, both applications being filed by the same inventor or his legal representative.” *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1348 n.1 (Fed. Cir. 2016) (internal quotation marks and citation omitted).

Allergan I. J.A. 3919–20. Following *Allergan II*, Apotex, Inc. (“Apotex”), the primary named defendant in the second suit, filed a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), which the District Court granted. *Allergan, Inc. v. Apotex, Inc. (Allergan III)*, Nos. 1:12-cv-247, 1:13-cv-16 (M.D.N.C. Jan. 14, 2015) (J.A. 2984–86). Allergan then moved to voluntarily dismiss its claims against the other defendants pursuant to Federal Rule of Civil Procedure 41(a)(2), which the District Court granted. J.A. 2987.

During the pendency of the two suits, Allergan’s application for the ’953 patent was pending before an examiner at the U.S. Patent and Trademark Office (“USPTO”). While the application for the ’953 patent was pending and after the ’404 patent had been invalidated as obvious by this court in *Allergan II*, Allergan submitted ex parte declarations to the Examiner related to two prior art references used to invalidate the ’404 patent. J.A. 1965–66; see J.A. 1967–76 (ex parte declarations). The testimony was intended to show that one of the inventors of both the ’404 patent and the then-pending application for the ’953 patent, Dr. Amanda VanDenburgh, was an author of the prior art references, such that the references were no longer prior art under 35 U.S.C. § 102(a) (2012).²

² Section 102(a) states, in relevant part: “A person shall be entitled to a patent unless—the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a)(1). This has been interpreted by our predecessor court to mean that “one’s own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner or form which otherwise would fall under § 102(a).” *In re Katz*, 687 F.2d 450, 454 (CCPA 1982). Congress amended § 102(a) when it passed the

J.A. 1965–76. The USPTO issued the '953 patent and Allergan filed two complaints asserting claims 1–26 of the '953 patent against Sandoz. J.A. 363–80 (First Amended Complaint against Apotex), 1500–52 (First Amended Complaint against remaining defendants).³ These complaints form the basis for this appeal. However, Allergan was given leave to file second amended complaints, which reduced the disputed claims to claims 8, 23, and 26 of the '953 patent (“the Asserted Claims”). See J.A. 944–56 (Second Amended Complaint against Apotex), 1875–98 (Second Amended Complaint against remaining defendants).

Sandoz filed a motion to dismiss the subject suit pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief could be granted based on collateral estoppel, J.A. 957–62, 1918–21, which the District Court granted, *Allergan, Inc. v. Sandoz, Inc.* (*Allergan IV*), Nos. 1:14-cv-1028, 1:14-cv-1034 (M.D.N.C. Aug. 31, 2015) (J.A. 1–13). The District Court stated that “[t]he '953 patent at issue in this case claims . . . substantially the same subject matter as[] invalid '404 patent claim 14 and the relevant claims of the

Leahy-Smith America Invents Act (“AIA”). Pub. L. No. 112-29, § 3(b)(1), 125 Stat. 284, 285 (2011). Because the application that led to the '953 patent contained claims having an effective filing date on or after March 16, 2013 (the effective date of the statutory changes enacted in 2011), the AIA’s § 102(a) would apply to a substantive review of the '953 patent. See *id.* § 3(n)(1), 125 Stat. at 293. This court has not determined whether the *Katz* standard applies to reviews of prior art under the AIA’s § 102, nor does either party ask us to do so here. See *generally* Appellant’s Br.; Appellee’s Br.

³ The original complaints did not assert the '953 patent. See J.A. 300–62, 3650–732.

'054, '161, and '988 patents.” J.A. 5. The District Court did not consider the ex parte testimony that Allergan submitted to the Examiner during the '953 patent prosecution. See J.A. 1–13. The District Court entered judgment for Sandoz, holding that “[t]he '953 patent is hereby declared and adjudged invalid as obvious” J.A. 9.⁴

Allergan appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2012).

DISCUSSION

I. Choice of Law and Standard of Review

Because the criteria of collateral estoppel are not unique to patent issues, “[w]e apply the law of the regional circuit to the general procedural question of whether issue preclusion applies,” here, the Fourth Circuit. *Sovereign Software LLC v. Victoria’s Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1314 (Fed. Cir. 2015) (citation omitted). The Fourth Circuit reviews de novo the application of collateral estoppel. See *Tuttle v. Arlington Cty. Sch. Bd.*, 195 F.3d 698, 703 (4th Cir. 1999). “However, for any aspects that may have special or unique application to patent cases, Federal Circuit precedent is applicable.” *Aspex Eyewear, Inc. v. Zenni Optical Inc.*, 713 F.3d 1377, 1380 (Fed. Cir. 2013). For example, “the question whether a particular claim in a patent case is the same as or separate from another claim has special application to patent cases, and we therefore apply our own law to that issue.” *Id.* (internal quotation marks and citation omitted).

⁴ Separate amended final judgments were issued for all appellees except Sandoz, Inc. declaring that only the Asserted Claims of the '953 patent were invalid as obvious. J.A. 7, 12–13 (Final Judgments); see J.A. 195 (describing the initial judgment), 204–05 (describing amended judgments).

II. The District Court Properly Dismissed the Case Based on Collateral Estoppel

A. Legal Standards

The doctrine of “[c]ollateral estoppel forecloses the re-litigation of issues of fact or law that are identical to issues which have been actually determined and necessarily decided in prior litigation in which the party against whom issue preclusion is asserted had a full and fair opportunity to litigate.” *Sedlack v. Braswell Servs. Grp., Inc.*, 134 F.3d 219, 224 (4th Cir. 1998) (internal quotation marks, brackets, and citation omitted). In the Fourth Circuit, collateral estoppel bars subsequent litigation of an issue of law or fact when: (1) “the issue sought to be precluded is identical to one previously litigated”; (2) “the issue was actually determined in the prior proceeding”; (3) “the issue’s determination was a critical and necessary part of the decision in the prior proceeding”; (4) “the prior judgment is final and valid”; and (5) “the party against whom collateral estoppel is asserted had a full and fair opportunity to litigate the issue in the previous forum.” *Collins v. Pond Creek Mining Co.*, 468 F.3d 213, 217–18 (4th Cir. 2006) (internal quotation marks and citation omitted).

Allergan alleges that collateral estoppel should not apply in this case because elements (1), (2), and (5) are not met. Appellant’s Br. 14. We review these elements in turn.

1. Identity of the Issues

“Complete identity of claims is not required to satisfy the identity-of-issues requirement for claim preclusion.” *Soverain Software*, 778 F.3d at 1319 (citations omitted). “If the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies.” *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d

1333, 1342 (Fed. Cir. 2013) (citation omitted). For example, in *Ohio Willow Wood*, this court found that issue preclusion applied where a different claim in another patent had previously been invalidated because “the[] patents use[d] slightly different language to describe substantially the same invention.” *Id.*

Allergan argues that the Asserted Claims of the ’953 patent present new issues that were not decided in *Allergan I*, *Allergan II*, or *Allergan III* because “prior cases addressed whether it would have been obvious to use bimatoprost to increase eyelash growth, not eyelash darkness” as recited in the Asserted Claims. Appellant’s Br. 15, *see id.* at 15–22. In addition, Allergan argues that the prior art references do not teach increasing eyelash darkness, *id.* at 17–19, and that the District Court in *Allergan IV* improperly looked to the specification of the ’953 patent, rather than only the Asserted Claims, in reaching its conclusion that collateral estoppel applied, *id.* at 19–20.

The District Court held that the issues related to the Asserted Claims were identical to those addressed in all prior litigations against invalidated claims of the ’404, ’054, ’161, and ’988 patents because “[t]he ’953 patent is not limited to darkness,” citing its “repeated[] references [to] ‘enhancing the growth’ of eyelashes by increasing length, thickness[,] and darkness.” J.A. 4. These enhancements, it found, were also at issue in *Allergan I*, *Allergan II*, and *Allergan III*. J.A. 4–5. It also found that the ’404 patent trial determined issues of eyelash darkness, as found in the District Court’s claim construction of the term “a method for stimulating hair growth” to mean “a method of converting vellus intermediate hair to growth as terminal hair,” where the patent defined vellus hairs as “fine” and “thin” and defined terminal hairs as “coarse” and “pigmented.” J.A. 4–5 (internal quotation marks omitted).

We agree with the District Court that the Asserted Claims are substantially similar to the invalidated claims of the '404, '054, '161, and '988 patents, and that any differences between the claims do not materially alter the question of invalidity. With respect to the darkness limitation claimed in the Asserted Claims of the '953 patent, that limitation was also disputed in all three prior litigations as one of many attributes flowing from the use of the claimed bimatoprost solution. During the '404 patent's claim construction, Allergan offered, and the District Court accepted, J.A. 3073, a construction for "a method for stimulating hair growth" to include "a method of converting vellus or intermediate hair to growth as terminal hair," which would "increas[e] the . . . thickness of hair," J.A. 3072. The '404 patent's specification defined vellus hairs as "fine" and "thin" and terminal hairs as "coarse" and "pigmented." J.A. 4–5. The '404 patent's specification recites the change from "coarse, pigmented, long hairs" to "fine, thin, non-pigmented short hairs," the type of hair loss that the patented invention seeks to remedy. '404 patent col. 1 ll. 36–39. Thus, the parties' original claim construction dispute included darkness.

The previously litigated patents include several additional statements that demonstrate that increasing eyelash darkness was one attribute of their inventions. For example, the '404 patent's specification describes "increased pigmentation of the lashes" as an example of more robust hair growth, *id.* col. 7 l. 51, and describes lashes treated with the solution as "longer, thicker[,] and fuller," *id.* col. 7 ll. 1–6. Indeed, the '404 patent claims a method that enhances hair growth *and* increases "one or more" of the following traits: "luster, sheen, brilliance, gloss, glow, shine or patina." *Id.* col. 16 ll. 13–15 (claim 9). The '054 patent, estopped in *Allergan III*, goes even further, making increased eyelash darkness a requirement of claim 1. *See* '054 patent col. 14 ll. 3–6 ("A method of increasing eyelash growth in a human including length,

thickness *and darkness* of the eyelashes, the method comprising administering bimatoprost to an eyelid margin of the human.” (emphasis added)).

Both the current litigation and prior litigation concern eyelash darkness as well as broader qualities associated with hair growth. The patent claims “use slightly different language to describe substantially the same invention” and, thus, satisfy the identity of issues requirement for finding collateral estoppel. *Ohio Willow Wood*, 735 F.3d at 1342.⁵

2. The Issue Was Actually Determined in the Prior Litigation

The requirement that an issue have been actually decided is generally satisfied if the issue “was actually litigated and decided in an earlier proceeding.” *Combs v. Richardson*, 838 F.2d 112, 114 (4th Cir. 1988); Restatement (Second) of Judgments § 27(d) (1982) (an issue is actually litigated if it “is properly raised, by the pleadings

⁵ Allergan argues in the alternative that the identity-of-issues requirement is not met because “[n]either [prior art] references . . . disclose a method of using a bimatoprost composition to increase eyelash darkness, as required by the [A]sserted [C]laims of the ’953 patent.” Appellant’s Br. 17. But “any need or problem known in the field . . . and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 420 (2007). We previously found in *Allergan II* that it would have been obvious to use a topical application of a bimatoprost composition to grow eyelashes. Solving the problem of growing eyelashes would have provided a motivation to combine the same prior art in the same manner that is claimed by the ’953 patent to achieve increased eyelash darkness.

or otherwise, and is submitted for determination, and is determined”). Allergan contends that “the parties never briefed ‘darkness,’” and “the [D]istrict [C]ourt’s opinion never discussed it,” such that the issue was never actually determined. Appellant’s Br. 22; *see id.* at 19–22.

However, we find evidence in the record sufficient to hold that the issue was actually determined in *Allergan I* and *Allergan II*. Unlike cases where we have found this element was not met because “[n]either party requested that any terms of the . . . method claims . . . be construed” or “move[d] for a determination of summary judgment,” *Brain Life, LLC v. Elekta, Inc.*, 746 F.3d 1045, 1055 (Fed. Cir. 2014), the issue of darkness was discussed in the claim construction proceedings for the ’404 patent, *see* J.A. 3069, 3071–73. Moreover, the claims of the ’404 patent, as construed to include the language covering increased pigmentation, were litigated by the parties at a bench trial. *See Allergan I*, 2013 WL 286251, at *1, *7–8. The trial record further demonstrates that the parties debated the language “converting vellus or intermediate hair to growth as terminal hair” which, as discussed above, describes a process of increasing eyelash darkness. *Id.* at *13 (internal quotation marks and brackets omitted) (reviewing Sandoz’s arguments with respect to the phrase); *see* J.A. 3247–48 (Allergan’s proposed findings of fact in the ’404 patent litigation stating that “Latisse®,” a “commercial embodiment of claim 14 of the ’404 patent,” “increas[es] . . . eyelash darkness”), 3248 (Allergan stating that the use of Latisse® results in “darker eyelash hair”), 3253–54 (Allergan alleging infringement of its ’404 patent for reasons marked as confidential). We find this sufficient to meet the “actually litigated” prong of the collateral estoppel test.

3. Allergan Had a Full and Fair Opportunity to Litigate the Issues in the Prior Litigation

A judgment will not have a preclusive effect if a patentee can demonstrate that it did not have a full and fair opportunity to litigate the issue. *Va. Hosp. Ass'n v. Baliles*, 830 F.2d 1308, 1311 (4th Cir. 1987). “Determining whether a patentee has had a full and fair chance to litigate the validity of [the] patent . . . is . . . not a simple matter.” *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 333 (1971). However, most of the grounds relevant to this test—e.g., incentive to litigate, choice of forum, or comprehension of the technical subject matter—are inapplicable here. *See id.* at 332–34. Allergan’s full and fair opportunity argument hinges on the ex parte testimony submitted to the Examiner during the prosecution of the application leading to the ’953 patent.

Allergan alleges that it did not have the opportunity to present certain ex parte evidence in *Allergan I* or *Allergan II* because this court changed the legal standard to prove that one’s own work is not prior art under § 102(a) by adding a requirement that the inventor be “responsible for directing the production of the publication’s content.” Appellant’s Br. 23 (internal quotation marks omitted). In support of the purported change in law, Allergan cites our statement in *Allergan II* that “Appellees have not produced evidence that shows [Dr. VanDenburgh] was *responsible for directing the production* of either article’s content.” *Id.* at 24 (quoting *Allergan II*, 754 F.3d at 969) (emphasis added); *see id.* at 22–26.

Allergan’s arguments are not persuasive. First, Allergan offers no explanation for why such additional evidence could not have been submitted to the District Court in *Allergan III*. *See generally id.* Second, *Allergan II* did not change the applicable legal standard for showing an inventor’s work on a publication removes the

material from § 102(a) prior art. Instead, we repeated the applicable standard articulated in *Katz* and analyzed the evidence against that standard. *See Allergan II*, 754 F.3d at 969 (stating the relevant inquiry was whether the references “were solely Dr. VanDenburgh’s work and hers alone” (citation omitted)). In reaching our conclusion, we looked to authorship of the reference in question and of internal pre-publication reports, supervision of clinical trials, and involvement in the trials and results-assessment. *Id.* The language Allergan cites is a descriptive part of the comprehensive, fact-based evidentiary test in *Katz*. We quoted *Katz* in our conclusion, holding that there was no evidence that Allergan’s explanation of the prior art references were “in any way consistent with the content of the articles and the nature of the publications.” *Id.* (citation omitted); *see Katz*, 687 F.2d at 455 (stating that, in addition to authorship, “[t]he content and nature of the printed publication” must be considered). Allergan had a full and fair opportunity to litigate its position, and all elements of the test for collateral estoppel have been met.

III. The District Court Erred in Invalidating the Entire ’953 Patent

Finally, notwithstanding collateral estoppel, Allergan alleges that the District Court “erroneously invalidated unasserted claims of the ’953 patent” in its final judgment with respect to Sandoz, Inc. Appellant’s Br. 26 (capitalization omitted). Because Allergan narrowed its assertion of infringement in its Second Amended Complaint to the three Asserted Claims, it contends that “[t]he [D]istrict [C]ourt . . . had no subject matter jurisdiction over any of the other claims of the ’953 patent and [had] no power to invalidate them.” *Id.* We agree.

We may consider the scope of the judgment where it relates to a question of subject matter jurisdiction, an issue we review de novo. *See Metabolite Labs., Inc. v.*

Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1369 (Fed. Cir. 2004); *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1485–86 (Fed. Cir. 1998). Article III courts have subject matter jurisdiction in a suit where there is an actual case or controversy. See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128–29 (2007). For declaratory actions in patent infringement suits, we have clarified that where only certain claims of a patent are raised in a complaint and additional claims are not asserted or litigated, additional claims can be included in a final judgment only where there is a case or controversy for the court to adjudicate. See *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1581 n.8 (Fed. Cir. 1993); see also *MedImmune*, 549 U.S. at 127 (stating that there is no bright line rule for determining whether the case or controversy requirement is satisfied and asking courts to look at whether the dispute is “definite and concrete, touching the legal relations of parties having adverse legal interests,” and is “real and substantial” (internal quotation marks omitted)). “[C]ourts must look at all the circumstances to determine whether a declaratory judgment plaintiff has shown a case or controversy between the parties.” *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1282 (Fed. Cir. 2012) (internal quotation marks omitted).

Allergan’s Second Amended Complaint only asserted three claims of the ’953 patent.⁶ Sandoz, Inc. has not

⁶ Allergan’s Second Amended Complaint is the operative pleading document here. The Magistrate Judge entered an order granting leave to file an amended complaint, which was allowed as a matter of course for non-dispositive motions and was not contested or appealed by Sandoz. J.A. 1870–74; see *Aluminum Co. of Am. v. EPA*, 663 F.2d 499, 501 (4th Cir. 1981) (“[E]xceptions [in 28 U.S.C. § 636(b)(1)(a)] are motions which Congress consid-

shown a continuing case or controversy with respect to the withdrawn claims. As in prior cases in which we have found unasserted claims not invalidated, here, “the patentee narrowed the scope of its claims . . . before any dispositive rulings by the court,” and Sandoz, Inc.’s response “was limited to the ‘asserted claims.’” *Id.* at 1283, 1284; *see* J.A. 1918, 1919 (Sandoz, Inc.’s Rule 12(b)(6) motion requesting the court dismiss “Allergan’s claims in its Second Amended Complaint” and “declare that the claims” are invalid). Moreover, Sandoz, Inc. “did not present evidence or argument of how the prior [patents] suggested the additional limitations present in” the unasserted claims. *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1356 (Fed. Cir. 2001); *see* J.A. 1978–93 (Sandoz, Inc.’s expert declaration filed with its motion to dismiss reviewing only the Asserted Claims and claims referenced therein).

All claims are “presumed valid independently of the validity of the other claims.” 35 U.S.C. § 282. Considering all of the circumstances before the District Court, we find that “[t]here was no case or controversy with respect to the unasserted claims at the time of the [Rule 12(b)(6)] motions; therefore the [D]istrict [C]ourt did not have jurisdiction over the unasserted claims.” *Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1308 (Fed. Cir. 2012) (citation omitted). Because we find that the District Court erred in

ered to be ‘dispositive.’”); 28 U.S.C. § 636(b)(1)(a)–(c) (omitting motion to amend complaint from list of actions on which a magistrate judge can only issue a recommendation or cannot otherwise rule); Fed. R. Civ. Proc. 72(a) (instructing magistrate judges to “issue a written order stating the decision” when appropriate for non-dispositive matters); J.A. 1918 (Sandoz, Inc.’s Rule 12(b)(6) motion to dismiss “Allergan’s claims in its Second Amended Complaint”).

invalidating the unasserted claims in the '953 patent, we reverse the District Court's order granting collateral estoppel and finding invalidity of Allergan's '953 patent with respect to Sandoz, Inc. for claims 1-7, 9-22, and 24-25 of the '953 patent.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. We affirm the District Court's judgments with respect to Akorn, Inc., Hi-Tech Pharmacal Co., Inc., Apotex Inc., Apotex Corp., and claims 8, 23, and 26 of the '953 patent as applied to Sandoz, Inc. We reverse the District Court's judgment for Sandoz, Inc. with respect to claims 1-7, 9-22, and 24-25 of the '953 patent. For these reasons, the final decision of the U.S. District Court for the Middle District of North Carolina is

AFFIRMED-IN-PART, REVERSED-IN-PART

COSTS

Each party shall bear its own costs.