United States Court of Appeals for the Federal Circuit

ALCON RESEARCH LTD.,
Plaintiff-Appellant,

v.

BARR LABORATORIES, INC.,
Defendant-Cross-Appellant.

2012-1340, -1341

Appeals from the United States District Court for the District of Delaware in No. 09-CV-0318, Judge Legrome D. Davis.

Decided: March 18, 2014

ADAM L. PERLMAN, Williams & Connolly LLP, of Washington, DC, argued for plaintiff-appellant. With him on the brief were GLENN J. PFADENHAUER, KEVIN HARDY, and DAVID M. KRINSKY. Of counsel was KANNON K. SHANMUGAM.

WILLIAM P. FERRANTI, Winston & Strawn LLP, of Chicago, Illinois, argued for defendant-cross appellant. With him on the brief was GEORGE C. LOMBARDI. Of counsel on the brief was BRADLEY C. GRAVELINE, Sheppard Mullin Richter & Hampton, LLP, of Chicago, Illinois.

Before NEWMAN, LOURIE, and BRYSON, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Alcon Research Ltd. ("Alcon") appeals from the final judgments of the United States District Court for the District of Delaware finding that Barr Laboratories, Inc. ("Barr") does not infringe claim 12 of Alcon's U.S. Patent 5,631,287 (the "'287 patent") and claim 19 of Alcon's U.S. Patent 6,011,062 (the "'062 patent") and holding those claims invalid for lack of enablement and lack of an adequate written description under 35 U.S.C. § 112, ¶ 1.[1] *Alcon Research Ltd. v. Barr Labs. Inc.*, 837 F. Supp. 2d 364 (D. Del. 2011). Barr cross-appeals from the district court's denial of Barr's post-judgment motion pursuant to Federal Rule of Civil Procedure 59(e) to amend the district court's judgment and enter judgment as a matter of law ("JMOL") of noninfringement as to Alcon's U.S. Patents 5,510,383 (the "'383 patent") and 5,889,052 (the "'052 patent"). *Alcon Research Ltd. v. Barr Labs. Inc.*, No. 09-0318, 2012 WL 928189 (D. Del. Mar. 16, 2012).

We conclude that the district court was not clearly erroneous in finding that Barr's product would not infringe the asserted claims of the '287 and '062 patents and that the court did not abuse its discretion in denying Barr's motion to amend for JMOL of noninfringement of the '383 and '052 patents. However, we conclude that the district

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[1] Paragraph 1 of 35 U.S.C. § 112 was replaced with newly designated § 112(a) by § 4(c) of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, and AIA § 4(e) makes those changes applicable "to any patent application that is filed on or after" September 16, 2012. Because the applications resulting in the patents at issue in this case were filed before that date, we will refer to the pre-AIA version of § 112.

court's invalidity determinations as to the asserted claims of the '287 and '062 patents were not in accordance with law. Accordingly, we affirm in part and reverse in part.

BACKGROUND

Alcon owns the '287 and '062 patents, which are directed to methods for enhancing the stability of prostaglandin compositions, including Alcon's glaucoma and ocular hypertension drug Travatan Z®, which contains travoprost, the synthetic prostaglandin fluprostenol isopropyl ester. Claim 12 of the '287 patent depends from claim 1 of that patent and reads as follows:

> 1. A method of enhancing the chemical stability of an aqueous composition comprising a therapeutically-effective amount of a prostaglandin, wherein the method comprises adding a chemically-stabilizing amount of a polyethoxylated castor oil [("PECO")] to the composition.
>
> 12. The method of claim 1 wherein the composition is a topically administrable ophthalmic composition.

'287 patent col. 8 ll. 57–61, col. 10 ll. 53–54. The '062 patent is a continuation in part of the '287 patent. '062 patent col. 1 ll. 1–10. Claim 19 of the '062 patent, which depends from claim 12 of that patent, is identical to claim 12 of the '287 patent except that it limits the requisite PECO to one "selected from the group of PEG-5 to PEG-200 hydrogenated castor oils." *Id.* col. 11 l. 65–col. 12 l. 3, col. 14 ll. 15–16.

Barr submitted Abbreviated New Drug Application ("ANDA") 91-411 to the U.S. Food and Drug Administration (the "FDA"), seeking approval to manufacture, use, and sell an ophthalmic travoprost solution as a generic version of Travatan Z®. Barr's ANDA filing was second to that of Par Pharmaceuticals, Inc. *Alcon*, 837 F. Supp. 2d at 368. Although the '287 and '062 patents are not listed

as referenced to Travatan Z® in the *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (commonly known as the "Orange Book") maintained by the FDA, Alcon initiated suit, asserting that Barr's ANDA submission constituted an act of infringement of claim 12 of the '287 patent, claim 19 of the '062 patent, and claims from four other patents, including its Orange Book-listed '383 and '052 patents. However, Alcon did not assert its '383 and '052 patents at trial and neither party adduced any evidence that specifically related to those patents. Barr stipulated that its generic product infringed the remaining two patents that Alcon had asserted, *viz.*, U.S. Patents 6,503,497 and 6,849,253, and that those patents were not invalid. *Id.*[2]

Following a *Markman* hearing, the district court construed the claimed phrase "enhancing the chemical stability" to mean "to increase or increasing the ability of the prostaglandin to resist chemical change (as distinguished from merely increasing the physical stability of the prostaglandin or composition)," *i.e.*, "reducing or decreasing [travoprost] degradation." *Id.* at 369; *see also Alcon Research Ltd. v. Barr Labs. Inc.*, No. 09-0318, 2011 WL 3901878, at *15–16 (D. Del. Sept. 6, 2011). The court distinguished physical stability as referring to physical phenomena such as absorption, adsorption, and precipitation. *Id.*

The court also construed the claim term "prostaglandin" to correspond to the disclosure in the written description of the patents regarding the prostaglandins that may be used with the invention. *Alcon*, 2011 WL 3901878, at *13–14. The court thus determined the term "prostaglan-

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[2] Neither party raises or challenges the propriety of asserting patents that were not listed in the Orange Book against a generic manufacturer based on the filing of an ANDA, and we accordingly do not reach that issue.

din" to mean "the natural compounds PGE_1, PGE_2, PGE_3, $PGF_{1\alpha}$, $PGF_{2\alpha}$, $PGF_{3\alpha}$, PGD_2, and PGI_2 (prostacyclin), as well as analogues and derivatives of such natural compounds (including the pharmaceutically acceptable esters and salts of such natural compounds and their analogues and derivatives), which have similar biological activities of either greater or lesser potencies." *Id.* at *15. Travoprost is a type $PGF_{2\alpha}$ prostaglandin analog.

After a bench trial, the court found that Barr's ANDA product did not infringe either claim 12 of the '287 patent or claim 19 of the '062 patent because Alcon failed to prove by a preponderance of the evidence that Barr manufactured its generic Travatan Z® product by a method that comprised adding a chemically-stabilizing amount of PECO to its composition. *Alcon*, 837 F. Supp. 2d at 369. The court noted that Alcon did not test Barr's product and determined that Alcon's only evidence was an accelerated stability study conducted by Alcon during its development work that compared several travoprost compositions with different amounts of PECO. *Id.* at 373–80.

The court found that Table 7 of Alcon's development study recorded data showing that some amount of travoprost was lost over an eight week test period, but the parties disputed the reason for that loss, *viz.*, physical instability versus chemical instability. *Id.* at 374–80. The court nevertheless found that the results "could be attributed to a number of factors other than PECO enhancing the chemical stability of the Travoprost, e.g., experimental error or uncertainty, adsorption, precipitation, or other physical loss" and that, in any event, "the tested formulations differ[ed] significantly from Barr's ANDA product." *Id.* at 376. Accordingly, in finding noninfringement, the court ultimately concluded that because "variables such as pH, buffer, buffer concentration, preservatives, chelating agents, and other excipients can affect the chemical stability of prostaglandins in opthalmic formulations," as Alcon conceded, "the composi-

tional differences between [Alcon's] Solubility Study formulations and Barr's ANDA product preclude[d] . . . relying on the Solubility Study data to draw any reliable inferences with respect to the stability of Barr's ANDA product." *Id.* at 376–77.

The court also held claim 12 of the '287 patent and claim 19 of the '062 patent invalid under 35 U.S.C. § 112, ¶ 1, for lack of enablement and lack of an adequate written description. *Id.* at 370, 380–84. The court concluded that Barr proved by clear and convincing evidence that one skilled in the art could neither carry out the full scope of the asserted claims without undue experimentation nor would have recognized that the inventors were in possession of the claimed invention at the time the patent applications were filed because: (i) the claims were too broad; (ii) the patent disclosure was too limited; and (iii) the art of chemically stabilizing prostaglandins was too unpredictable. *Id.* However, the court rejected Barr's asserted defenses that Alcon's claims were invalid for anticipation, obviousness, and indefiniteness. *Id.* at 370–71, 384–92.

Barr then moved for JMOL of noninfringement of Alcon's '383 and '052 patents, which the court denied, "declin[ing] to make any findings or draw any conclusions about the infringement or validity of [those] patents" because "neither party presented any evidence" on them and thus they "were not actually litigated and adjudicated" or fairly placed at issue during trial. *Id.* at 371, 392. Barr subsequently filed a post-judgment motion pursuant to Federal Rule of Civil Procedure 59(e) to amend the district court's judgment and to enter JMOL of noninfringement of those two patents on the ground that the court's resolution of the matter in the first instance constituted a clear error of law that required correction in order "to prevent manifest injustice." *Alcon*, 2012 WL 928189, at *8.

The court again denied Barr's motion. *Id.* at *7–12. The court reasoned that, because Barr had never filed a counterclaim, Barr had no basis to assert that it was entitled to a declaratory judgment of noninfringement given that Alcon lacked fair notice of the risk of such an adverse determination. *Id.* at *7, *11. The court held that "the parties' joint pretrial submissions reflected the parties' understanding that the unasserted claims were no longer a part of the case." *Id.* at *10. Accordingly, the court concluded that the pleadings should "be conformed to the judgment, not *vice versa*." *Id.* at *9 (quoting *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. G.m.b.H.*, 945 F.2d 1546, 1554–55 (Fed. Cir. 1991)).

Alcon timely appealed and Barr timely cross-appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

Infringement is a question of fact that we review for clear error. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1339 (Fed. Cir. 2003). A factual finding is clearly erroneous when, despite some supporting evidence, we are left with a definite and firm conviction that the district court was in error. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006).

Alcon argues that the district court erred in finding that Barr's ANDA product did not infringe the asserted claims of Alcon's '287 and '062 patents because its testing of travoprost formulations containing the same PECO in the same concentration as Barr's proposed generic product demonstrated that the PECO added to Barr's composition enhances the stability of the prostaglandin. Alcon contends that the district court's findings are undermined by its purportedly improper credibility determinations regarding Alcon's experts and its consequent rejection of

their testimony. Barr responds that it does not infringe because Alcon presented no evidence directly relating to whether Barr's ANDA product infringed the '287 and '062 patents and no evidence directly relating to whether PECO enhances the chemical stability of any prostaglandin.

We agree with Barr that Alcon failed to present evidence of infringement. Unlike a classic patent infringement case in which infringement exists if at least one claim of an asserted patent reads on a product or process that the accused infringer has introduced into the U.S. marketplace, an infringement inquiry provoked by an ANDA filing under the Hatch-Waxman system pursuant to 35 U.S.C. § 271(e)(2)(A) is focused on a comparison of the asserted patent against "the product that is likely to be sold following ANDA approval." *Abbott Labs. v. Tor-Pharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). That determination is based on consideration of all of the relevant evidence and, "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." *Id.*; *see also Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1279–80 (Fed. Cir. 2013); *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248–50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569–70 (Fed. Cir. 1997).

In its attempt to prove that the addition of PECO in Barr's proposed generic product would chemically stabilize the prostaglandin travoprost and thus infringe the asserted claims of the '287 and '062 patents, Alcon relied solely on a theory that the data reported in Table 7 of a stability study that Alcon conducted during its development work could be extrapolated to infer that the addition of PECO would chemically stabilize travoprost in Barr's

ANDA composition. The data in Table 7 of Alcon's report, which was styled as a "Soaking Study to Evaluate the Compatibility of Travoprost with Polypropylene Packaging Materials," were generated by subjecting travoprost compositions to elevated temperatures and then analyzing them at regular intervals to measure the amount of travoprost remaining in the composition. J.A. 6984. At trial, both parties agreed that the data showed that travoprost was lost over time—that is, less travoprost was present in the tested compositions at the end of eight weeks than had been present when the test began—and that more travoprost remained in the compositions with 0.5% PECO at the end of eight weeks than in the composition that did not contain any PECO. J.A. 5619–25, 6066.

Critically, however, the district court found, and the parties do not dispute on appeal, that the composition of the generic product proposed in Barr's ANDA is significantly different from the compositions tested in Alcon's study. *Alcon*, 837 F. Supp. 2d at 376; J.A. 6984, 6991. The test formulations used by Alcon to compile the data in Table 7 were maintained at pH 6.0–6.1 and contained, *inter alia*, 0.005% weight by volume of travoprost, varying concentrations of PECO, the antimicrobial preservative benzalkonium chloride, and a buffer solution comprising tromethamine, boric acid, and mannitol. *Id.* In contrast, the generic product proposed in Barr's ANDA is maintained at a different pH, is composed of 0.004% weight by volume of travoprost and a buffered preservative system comprising propylene glycol, sorbitol, and zinc chloride, but does not contain benzalkonium chloride or a tromethamine/boric acid/mannitol buffer solution. *Id.* Alcon itself admitted that variation in parameters including pH, preservatives, and buffers can have a substantial impact on the chemical stability of a prostaglandin in an ophthalmic formulation. *Id.* at 376–77; Appellant Br. 39; J.A. 5539–40, 5985. The data in Table 7 therefore were not

evidence that Barr's product, if and when approved, would infringe the asserted claims.

We thus conclude that the district court did not clearly err in finding that the data in Alcon's Table 7 had no bearing on whether Barr's proposed generic product infringed Alcon's patents. The formulations tested in Alcon's stability study were meaningfully different from the product described in Barr's ANDA and thus provided no basis from which to draw any reliable inferences regarding whether the PECO in Barr's composition would chemically stabilize the prostaglandin. *See Lucent Tech., Inc. v. Gateway, Inc.*, 543 F.3d 710, 722–24 (Fed. Cir. 2008) (recognizing that overly speculative circumstantial evidence will not suffice to prove infringement).

We have considered Alcon's remaining arguments regarding the district court's infringement analysis and find them unpersuasive. Accordingly, we affirm the district court's holding that Alcon failed to prove by a preponderance of the evidence that the generic product described in Barr's ANDA infringes either claim 12 of Alcon's '287 patent or claim 19 of Alcon's '062 patent.

II

Section 112 of the patent statute describes what must be contained in a patent specification. Among other requirements, it must contain "a written description of the invention, and of the manner and process of making and using it . . . [such] as to enable any person skilled in the art to which it pertains, . . . to make and use the same . . . ." 35 U.S.C. § 112, ¶ 1 (2006). Thus, this statutory language mandates satisfaction of two separate and independent requirements: an applicant must both describe the claimed invention adequately and enable its production and use. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991).

Furthermore, patents are presumed to be valid and overcoming this presumption requires clear and convincing evidence. 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2242 (2011); *Ariad*, 598 F.3d at 1354.

A

Whether a claim satisfies the enablement requirement of 35 U.S.C. § 112 is a question of law that we review without deference, although the determination may be based on underlying factual findings, which we review for clear error. *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).

Alcon argues that the district court erred in holding the asserted claims of the '287 and '062 patents invalid for lack of enablement because it only weighed the breadth of the claims against the detail of the patent disclosures. Alcon contends that Barr presented no evidence that any experimentation would be required for a person of ordinary skill in the art to practice the invention as claimed.

Barr responds that the patents provide very little guidance to one skilled in the art in the form of only three working examples and do not disclose any data for chemical stability. Barr contends that the reported data relate only to physical stability, not prostaglandin degradation, and that the patents do not disclose how PECOs work to chemically stabilize prostaglandins. Barr further asserts that the technology at issue is highly unpredictable, particularly with regard to choice of pH, buffer, buffer concentration, preservatives, chelating agents, and other excipients.

We agree with Alcon that the district court erred in its enablement analysis. To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without "undue experimentation." *In re Wands*, 858 F.2d

731, 736–37 (Fed. Cir. 1988); *see also Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998) ("[I]t is imperative when attempting to prove lack of enablement to show that one of ordinary skill in the art would be unable to [practice] the claimed invention without undue experimentation.") (emphasis omitted). After the challenger has put forward evidence that some experimentation is needed to practice the patented claim, the factors set forth in *Wands* then provide the factual considerations that a court may consider when determining whether the amount of that experimentation is either "undue" or sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out. *Wands*, 858 F.2d at 737.

The district court erred here because its enablement analysis did not address that determinative question: Barr failed to make the threshold showing that any experimentation is necessary to practice the claimed methods, *i.e.*, to use PECO to enhance the stability of a prostaglandin given the disclosures of Alcon's '287 and '062 patents. Instead, the district court's holding rested on its finding that the full scope of the claims was not enabled after applying the *Wands* factors as if they were a generalized test for deciding whether a patent disclosure is sufficiently detailed to support a broad claim. *Alcon*, 837 F. Supp. 2d at 370, 380–83.

The claimed methods comprise only a single step—adding a chemically-stabilizing amount of PECO to the prostaglandin composition—that Barr's own expert testified was "routine." J.A. 6069. The claims as a whole merely require that the addition of PECO to the composition provide some increase in chemical stability, but do not require a particular level of stability or a particular magnitude of increase. Moreover, the patents disclose exemplary compositions within the scope of the claims, detail how those example compositions are prepared from commercially-available ingredients, and provide step-by-

step procedures for adding PECO to a prostaglandin composition in a way that embodies the claimed invention. '287 patent col. 7 l. 26–col. 8 l. 46; '062 patent col. 7 l. 63–col. 9 l. 42. The patents also identify the various prostaglandins and PECOs that can be used and a range of suitable concentrations for both components, including narrow preferred embodiments. '287 patent col. 2 l. 7–col. 6 l. 37; '062 patent col. 2 l. 16–col. 7 l. 1.

In light of those disclosures, the district court's nonenablement ruling was premised on testimony that many "variables" including the number of prostaglandins and the range of PECOs encompassed by the claims, as well as "[v]arious parameters including pH, buffer, buffer concentration, preservatives, chelating agents, and other excipients *may* affect the chemical stability of prostaglandins in ophthalmic formulations." *Alcon*, 837 F. Supp. 2d at 382–83 (emphasis added). Indeed, Barr's expert observed that "when 'you have a lot of variables on top of one another, the experimentation gets out of control quickly.'" *Id.* at 383 (citing J.A. 6009). But such an unsubstantiated conclusory statement is not sufficient. *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1339 (Fed. Cir. 2013). Barr adduced no evidence at trial that changing any of the "variables" or "[v]arious parameters" identified by the district court would render Alcon's claimed invention inoperable, nor was there any evidence that experimenting with those variables was required for an ordinarily skilled artisan to be capable of increasing the chemical stability of a prostaglandin by adding PECO. Adjusting variables may be relevant to *optimizing* the stability of a given prostaglandin composition, but Barr proffered no evidence that any experimentation, let alone undue experimentation, with those variables would be necessary in order to *practice* the claimed invention. Without that evidence, there is no foundation for the district court's nonenablement ruling.

Furthermore, a patent does not need to guarantee that the invention works for a claim to be enabled. It is well settled that an invention may be patented before it is actually reduced to practice. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 61 (1998). Similarly, a patentee is not required to provide actual working examples; we have rejected enablement challenges based on the theory that there can be no guarantee that prophetic examples actually work, as "[t]he burden is on one challenging validity to show by clear and convincing evidence that the prophetic examples together with other parts of the specification are not enabling." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984). Nor is it "a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." *Newman v. Quigg*, 877 F.2d 1575, 1581–82 (Fed. Cir. 1989) (citing *Diamond Rubber Co. v. Consol. Rubber Tire Co.*, 220 U.S. 428, 435–36 (1911)). Thus, it is likewise irrelevant here, as a legal matter, whether the '287 and '062 patents contain data proving that PECOs enhance the chemical stability of prostaglandins.

Accordingly, because Barr did not show that any claimed embodiments would be inoperable and that a person of ordinary skill in the art would have been unable to practice the asserted claims without resorting to any experimentation, let alone undue experimentation, we conclude that the district court erred as a matter of law in holding that Barr proved its invalidity case based on nonenablement by clear and convincing evidence. Barr had the burden of proof to show that Alcon's patents lacked enabling disclosures, but failed to carry that burden. We therefore reverse the district court's judgment that claim 12 of the '287 patent and claim 19 of the '062 patent are invalid for lack of enablement.

B

Whether a claim satisfies the written description requirement is a question of fact that, on appeal from a bench trial, we review for clear error. *Ariad*, 598 F.3d at 1351. However, the district court's interpretation of precedent regarding the written description requirement is reviewed without deference. *Amgen*, 314 F.3d at 1338.

Alcon argues that the district court erred in holding the asserted claims of the '287 and '062 patents invalid for lack of an adequate written description because the patent specifications sufficiently describe the invention and a variety of the embodiments that the inventor envisaged. Alcon contends that there was no evidence that a person of ordinary skill in the art would not have recognized or understood that the inventor possessed the claimed invention.

Barr responds that the claims "flunk the written description requirement" because they encompass "a method for enhancing the chemical stability of innumerable prostaglandins by adding to them PECO in an endless number of combinations and concentrations" and therefore are not precise and "overreach" the scope of the patent disclosures. Appellant Br. 49–50. Barr contends that the specifications only disclose physical data from one compound to support the proposition that PECO enhances the chemical stability of all prostaglandins, but that they do not disclose any data on chemical stability, prostaglandin degradation products, or prostaglandin degradation pathways.

We agree with Alcon that the specifications provide an adequate written description of the claimed invention. "[T]he hallmark of written description is disclosure." *Ariad*, 598 F.3d at 1351. The standard for satisfying the written description requirement is whether the disclosure "allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described."

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 968 (Fed. Cir. 2002). There is no requirement that the disclosure contain "either examples or an actual reduction to practice"; rather, the critical inquiry is whether the patentee has provided a description that "in a definite way identifies the claimed invention" in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing. *Ariad*, 598 F.3d at 1350, 1352; *Koito Mfg. Co. v. Turn-Key-Tech., LLC*, 381 F.3d 1142, 1154 (Fed. Cir. 2004). That assessment "requires an objective inquiry into the four corners of the specification." *Ariad*, 598 F.3d at 1351.

The '287 patent details the claimed invention and provides a step-by-step description of how a person of ordinary skill in the art may use it. It discloses the "unexpected[] discover[y] that the use of . . . polyethoxylated castor oils in [pharmaceutical] compositions," especially those "topically applied to the eye," "enhances the chemical stability of prostaglandins." '287 patent col. 1 ll. 46–51; col. 6 l. 16–col. 7 l. 25. It provides exemplary formulations that embody the claimed invention, reciting concentrations of every ingredient. *Id.* col. 7 ll. 26–46. It also discloses data generated by the inventor from accelerated stability testing showing the effect of PECO and prostaglandin concentration on stability and comparing the effect of PECO to that of a more commonly used surfactant, polysorbate 80. *Id.* figs. 2 & 3, col. 1 ll. 59–62, col. 8 ll. 32–39. The patent also describes various classes of prostaglandins to which the invention was understood to relate, which are covered by the term "prostaglandin" under the district court's construction of that term, as well as preferred concentrations and thirty-two specifically preferred examples of those prostaglandins. *Id.* col. 2 l. 23–col. 6 l. 15. It describes various types of PECOs that may be used in the invention, again with preferred types and concentrations. *Id.* col. 2 ll. 7–21. And the patent describes the various formulation parameters, including

osmolality and pH, that may be selected when practicing the invention. *Id.* col. 7 ll. 8–14.

The '062 patent, which is a continuation in part of the '287 patent, contains largely the same written description as the '287 patent but is focused on the use of hydrogenated PECOs. The '062 patent thus includes additional disclosures regarding the preferred types of hydrogenated PECOs that may be used with the claimed invention, two additional specifically preferred prostaglandins, and three additional exemplary formulations. *Id.* col. 2 ll. 16–33, col. 6 ll. 9–21, col. 9 ll. 20–42.

In summary, the '287 and '062 patent disclosures demonstrate that the inventors possessed the claimed invention: they conceived of and described their invention at the time the respective original patent applications were filed, including the idea that adding PECO would enhance the chemical stability of prostaglandins across a range of various formulation parameters as cited by the district court. *See Koito*, 381 F.3d at 1154–55. That is all that the written description requirement demands. *Id.*

Despite these disclosures, the district court concluded that the asserted claims were invalid for lack of an adequate written description "for essentially the same reasons that they fail the enablement requirement . . . ." *Alcon*, 837 F. Supp. 2d at 384. But written description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue. *See Ariad*, 598 F.3d at 1352. Barr's argument regarding the difference between physical and chemical stability, even if correct, is thus not relevant to the inquiry. Critically, Barr adduced no evidence, let alone clear and convincing evidence, that was probative of whether an ordinarily skilled artisan would not have understood from the dis-

closures of Alcon's '287 and '062 patents that the patentees invented, or possessed, the methods of the asserted claims. Without that evidence, there was no basis on which to find a lack of adequate written description.

Accordingly, we conclude that the district court erred in failing to apply the proper test for determining whether the patents recited an adequate written description and Barr again did not meet its burden of proving invalidity by clear and convincing evidence. We therefore reverse the district court's judgment that claim 12 of the '287 patent and claim 19 of the '062 patent are invalid for lack of an adequate written description.

III

Barr argues that its cross-appeal is subject to *de novo* review because it is an appeal from the denial of judgment as a matter of law. Appellee Br. 51. However, unlike a typical motion for judgment as a matter of law, the issues presented in this case are whether Alcon's infringement claims regarding its '383 and '052 patents were actually at issue during the trial below and whether the district court erred in denying Barr's Rule 59(e) post-judgment motion to amend. Those issues are thus limited to procedural matters not within our exclusive jurisdiction and we therefore apply the law of the circuit in which the district court sits, here the Third Circuit. *See Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1350 (Fed. Cir. 2000); *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 857–58 (Fed. Cir. 1991) ("[O]ur practice has been to defer to regional circuit law when the precise issue involves an interpretation of the Federal Rules of Civil Procedure or the local rules of the district court.").

In the Third Circuit, "a trial judge has broad discretion to determine which issues may be pursued at trial," *Price v. Inland Oil Co.*, 646 F.2d 90, 94 (3d Cir. 1981), and "[w]hen a district court rejects a motion to alter or amend a judgment, [the Third Circuit's] standard of review is

whether the district court abused its discretion," *Donivan v. Dallastown Borough*, 835 F.2d 486, 487 (3d Cir. 1987). Review is plenary, however, if the district court based its decision on an error of law. *Bushman v. Halm*, 798 F.2d 651, 656 n.9 (3d Cir. 1986).

Barr argues that it is entitled to an affirmative judgment that Alcon's '383 and '052 patents are not infringed because Alcon neither put forward evidence of infringement nor formally obtained a dismissal of the claims involving those patents from its complaint prior to trial. Alcon responds that the district court correctly denied Barr's motion because Barr never filed a counterclaim seeking a declaratory judgment of noninfringement, which could have preserved its ability to seek an adjudication of the '383 and '052 patents after they were removed from the case.

We agree with Alcon that the district court correctly denied Barr's motion. Rule 59(e) is not a vehicle for reopening judgments to present information that was long possessed by the movant and that was directly relevant to the litigation. *Ajinomoto*, 228 F.3d at 1350. The Third Circuit has instructed that:

> A proper motion to alter or amend judgment must rely on one of three major grounds: (1) an intervening change in controlling law; (2) the availability of new evidence not available previously; or (3) the need to correct clear error of law or prevent manifest injustice.

N. River Ins. Co. v. CIGNA Reinsurance Co., 52 F.3d 1194, 1218 (3d Cir. 1995) (internal quotations omitted and alterations included). Applying those grounds here, there was no intervening change of law and the motion was not supplemented with additional evidence.

At bottom, Barr's argument is that the district court's refusal to enter JMOL on Alcon's '383 and '052 patents

was a clear error of law, but we conclude that the district court correctly applied precedent. The court assessed both what the parties expected to try given their statements and conduct and what they actually litigated at trial. *Alcon*, 2012 WL 928189, at *9–11. Alcon informed Barr of its decision to drop its claims based on those patents and Barr subsequently omitted them from the pretrial order. *Id.* at *8; J.A. 2295, 11527–28. The patents were not "litigated, or fairly placed in issue, during the trial." *Tol-O-Matic*, 945 F.2d at 1554. The record on appeal shows that neither party ever put forward any arguments or evidence on the merits of infringement or validity. A court should not render judgment with respect to claims "reference[d] in the complaint" but not raised in the pretrial statement or litigated at trial; "a reference in the complaint is not sufficient to support a judgment." *800 Adept, Inc. v. Murex Sec., Ltd.*, 539 F.3d 1354, 1367–68 (Fed. Cir. 2008). The scope of any judgment should conform to the issues that were actually litigated, as the district court did here. *See Fox Grp., Inc. v. Cree Inc.*, 700 F.3d 1300, 1308 (Fed. Cir. 2012).

Moreover, we have not previously held that a formal motion or stipulation was required to remove claims from a case and we decline to do so here. On the contrary, we recently decided that a patentee's announcement that it was no longer pursuing particular claims, coupled with its ceasing to litigate them, was sufficient to remove those claims from the case even without such formalities. *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1353 (Fed. Cir. 2012). Consistent with our precedent, the district court acknowledged that the claims regarding the '383 and '052 patents were no longer in the case as of the time of the trial and did not abuse its discretion in essentially deeming Alcon's complaint as amended to remove them. *See id.*

Finally, unlike its codefendants, Barr neither filed a counterclaim for declaratory judgment of noninfringement

nor sought leave to do so once Alcon announced that it would not assert the '383 and '052 patents. *Alcon*, 2012 WL 928189, at *7–8; J.A. 177–92. Had Barr invoked that right during the pendency of the action below, the district court might have exercised its discretion differently. *See id.* at *11. *See generally* 35 U.S.C. § 271(e)(5) and 21 U.S.C. § 355(j)(5)(C)(i)(II) (authorizing a "civil action" under 28 U.S.C. § 2201 "for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the [ANDA] applicant seeks approval"); *Dey Pharma, LP v. Sunovion Pharm. Inc.*, 677 F.3d 1158 (Fed. Cir. 2012) (upholding district court's jurisdiction over second ANDA filer's action for declaratory judgment within Hatch-Waxman framework). If an accused infringer has filed a counterclaim, then the patentee has notice that, even if it drops its infringement claims, the issue of infringement remains to be litigated. On the other hand, if the accused infringer does not file a counterclaim, then it is up to the patentee to decide what claims are to be litigated and decided at trial. Likewise, "the district court has broad discretion in deciding whether to re-open a case, after the entry of judgment, to permit another infringement trial of issues that could have been resolved concurrently, with the benefit of the expertise and effort of the first trial." *Ajinomoto*, 228 F.3d at 1351. We conclude that the court did not abuse its discretion here.

We have considered Barr's remaining cross-appeal arguments and find them unpersuasive. Accordingly, we affirm the district court's denial of Barr's motion to amend for JMOL of noninfringement.

CONCLUSION

In view of the foregoing, we conclude that the district court's assessment that Barr's ANDA products would not infringe either claim 12 of Alcon's '287 patent or claim 19 of Alcon's '062 patent was correct and we therefore affirm

that judgment. We further conclude that those claims are not invalid under § 112, ¶ 1 and accordingly we reverse the district court's contrary holding. Finally, because we conclude that the district court did not abuse its discretion in denying Barr's Rule 59(e) motion to amend for JMOL of noninfringement as to Alcon's '383 and '052 patents, we affirm that decision.

AFFIRMED IN PART and REVERSED IN PART