United States Court of Appeals for the Federal Circuit

TEVA PHARMACEUTICAL INDUSTRIES LTD.,
Plaintiff-Appellant,

v.

ASTRAZENECA PHARMACEUTICALS LP AND IPR PHARMACEUTICALS INC.,
Defendants-Appellees.

2011-1091

Appeal from the United States District Court for the Eastern District of Pennsylvania in case no. 08-CV-4786, Judge William H. Yohn, Jr.

Decided: December 1, 2011

JEFFREY D. BLAKE, Sutherland, Asbill & Brennan, LLP, of Atlanta, Georgia, argued for plaintiff-appellant. With him on the brief was DAVID A. REED.

ERIC J. FUES, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington, DC, argued for defendants-appellees. With him on the brief were FORD F. FARABOW, JR. and RAMA G. ELLURU; and CHARLES E. LIPSEY, of Reston, Virginia. Of counsel on the brief were,

JAMIE B. BISCHOFF and MARC J. WEINSTEIN, Ballard Spahr, L.L.P., of Philadelphia, Pennsylvania, and JUDY YUN, AstraZeneca Pharmaceuticals, LP, of Wilmington, Delaware.

Before RADER, *Chief Judge*, LINN and DYK, *Circuit Judges*.

LINN, *Circuit Judge*.

Teva Pharmaceutical Industries Ltd. ("Teva") appeals from the Eastern District of Pennsylvania's entry of summary judgment in favor of AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals Inc. (collectively "AstraZeneca") invalidating claims 1, 26, 42, and 52 ("asserted claims") of Teva's U.S. Patent No. RE39,502 ("'502 patent") based on AstraZeneca's prior invention of the subject matter claimed therein. Because the district court correctly concluded that AstraZeneca's earlier development of the accused CRESTOR® drug ("AstraZeneca's drug") formulation satisfied the requirements for prior invention under 35 U.S.C. § 102(g)(2), this court affirms.

I. BACKGROUND

Statins are a class of compounds useful in the treatment of dyslipidemia. Statins are inherently unstable and, to be medically viable, must be manufactured in stabilized formulations. As relevant to this appeal, Teva's '502 patent is directed to statin formulations stabilized exclusively by an amido-group containing polymeric compound ("AGCP compound") or by an amino-group containing polymeric compound. The '502 patent is a reissue of a patent that claims the benefit of a provisional application filed on April 10, 2000. The earliest date by which Teva asserts that it conceived and reduced to

practice its claimed invention is December 1, 1999. Claim 1 of the '502 patent is representative of the asserted claims and recites:

> 1. A stabilized pharmaceutical composition for the treatment of dyslipidemia,
>
> comprising
>
> an active component consisting essentially of one or more compounds selected from the group consisting of (i) *an IIMG-CoA reductase inhibiting* ring-opened 7-substituted-3,5-dihydroxyheptafloic acid or a pharmaceutically acceptable acid salt thereof, and (ii) *an HMG-CoA reductase inhibiting* ring-opened 7-substituted-3,5-dihydroxyheptenoic acid or a pharmaceutically acceptable acid salt thereof, and
>
> a stabilizing effective amount of at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound, or combination thereof, wherein said stabilized pharmaceutical composition does not contain a stabilizing effective amount of another stabilizer or a combination of other stabilizers.

'502 patent col.16 ll.17-33 (underlining added, italics in original).

In October 2008, Teva sued AstraZeneca for infringing the '502 patent based on AstraZeneca's manufacture and sale of the AstraZeneca drug, a stabilized statin (rosuvastatin calcium) formulation for the treatment of dyslipidemia. This drug was designed with tribasic calcium phosphate, which is not an AGCP compound, as a stabilizer. The drug also contains crospovidone, which is an

AGCP compound. It is uncontested that AstraZeneca included crospovidone in the AstraZeneca formulation as a disintegrant, but did not understand crospovidone to have a stabilizing effect.

AstraZeneca moved for summary judgment of invalidity under 35 U.S.C. § 102(g)(2) alleging that it had conceived and reduced its drug to practice prior to Teva's first conception of the claimed subject matter. AstraZeneca made an undisputed showing that, in mid-1999, it manufactured a 10,000-unit batch of a rosuvastatin calcium formulation containing the same ingredients in the same amounts as its commercial drug. AstraZeneca made additional batches of rosuvastatin calcium in the summer and fall of 1999, also with the same ingredients in substantially the same amounts as the commercial drug. By late summer 1999, AstraZeneca had disclosed the ingredients and quantities for its rosuvastatin formulation matching those of all commercial drug dosage strengths. On the basis of these undisputed facts, the district court found that "there is no genuine issue of material fact as to whether AstraZeneca arrived at the same [AstraZeneca drug] product formulations that Teva accuses of infringement—and made batches of those formulations—before Teva conceived of or reduced to practice the subject matter of the '502 patent." *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, 748 F. Supp. 2d. 453, 464 (E.D. Pa. 2010).

Notwithstanding the inclusion of tribasic calcium phosphate—a non-AGCP-compound—as a stabilizer in AstraZeneca's drug, AstraZeneca conceded infringement for the limited purpose of advancing its summary judgment motion. Explaining that "an appreciation of the stabilizing effect of crospovidone by AstraZeneca, as opposed to its appreciation of the stabilization of its overall pharmaceutical composition that contained crospovidone, was not required," *id.* at 469, the district court

granted AstraZeneca's motion and held the asserted claims invalid over AstraZeneca's prior invention of its drug. Teva timely appealed and this court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

Summary judgment is granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "This court reviews the district court's grant or denial of summary judgment under the law of the regional circuit." *Lexion Med., LLC v. Northgate Techs., Inc.*, 641 F.3d 1352, 1358 (Fed. Cir. 2011). The Third Circuit "review[s] an order granting summary judgment de novo, applying the same standard used by the District Court." *Azur v. Chase Bank, USA, Nat'l Ass'n*, 601 F.3d 212, 216 (3d Cir. 2010) (quotation omitted). "Priority, conception, and reduction to practice are questions of law which are based on subsidiary factual findings." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). This court exercises plenary review of the district court's legal conclusions regarding the requirements of 35 U.S.C. § 102(g), applying Federal Circuit precedent. *See Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008) ("The Federal Circuit applies its own law with respect to issues of substantive patent law and certain procedural issues pertaining to patent law . . . ." (citations omitted)).

B. Arguments on Appeal

On appeal, Teva essentially argues that the district court misapplied § 102(g)(2) in failing to require Astra-

Zeneca to prove that it appreciated the stabilizing effect of crospovidone in its drug formulation. According to Teva, the district court implicitly construed the claims to encompass stabilized statin formulations containing an AGCP compound, irrespective of whether the AGCP compound acted as the sole stabilizer. The thrust of Teva's argument is that this overbroad "construction" of the asserted claims effectively relieved AstraZeneca of its burden of proving that it created the claimed subject matter and appreciated that it had done so. Teva also argues that the district court improperly applied inherency precedent from the § 102(b) context, thus further obviating AstraZeneca's need to prove appreciation. Finally, Teva argues that, if AstraZeneca was the first to invent, then the district court erred by not finding that AstraZeneca had suppressed or concealed its invention by failing to disclose that crospovidone stabilized AstraZeneca's drug.

AstraZeneca responds that the district court correctly refused to require AstraZeneca to prove that it appreciated the stabilizing effect of crospovidone. According to AstraZeneca, Teva's claim construction argument is irrelevant because AstraZeneca's limited concession of infringement established that AstraZeneca's drug falls within the scope of the asserted claims. AstraZeneca argues that § 102(g)(2) does not require it to understand its own invention in the same terms in which Teva later claimed it, but only to understand the fact of what it made. AstraZeneca also argues that inherency does apply in the § 102(g) context and that AstraZeneca was not required to recognize inherent properties of its invention. Finally, AstraZeneca responds that Teva's "suppression or concealment" argument falls with its "appreciation" argument because, if AstraZeneca was not required to appreciate that crospovidone was a stabilizer, then it cannot have been required to disclose that it was.

C. AstraZeneca's Prior Invention

Because AstraZeneca conceded infringement for the limited purpose of its summary judgment motion, and because Teva maintains the allegation of infringement upon which its suit is based, it is undisputed for the purpose of this appeal that AstraZeneca's drug is an embodiment within the scope of the asserted claims. *See Evans Cooling Sys., Inc. v. Gen. Motors Corp.*, 125 F.3d 1448, 1451 (Fed. Cir. 1997) ("Although [defendant] bore the burden of proving that the [asserted prior art/accused product] embodied the patented invention or rendered it obvious for purposes of the summary judgment motion, this burden is met by [plaintiff's] allegation, forming the sole basis for the complaint, that the [asserted prior art/accused product] infringes."). It is undisputed that AstraZeneca conceived and reduced its drug to practice before Teva's first conception of the claimed subject matter. It is also undisputed that AstraZeneca did not understand that crospovidone acted as a stabilizer in its drug prior to Teva's conception, if at all. Therefore, this appeal does not involve a dispute of fact. Thus, this court need only determine, as a matter of law, whether AstraZeneca had to understand that crospovidone stabilized its drug in order to win a priority dispute under § 102(g)(2). For the reasons discussed below, it did not.

35 U.S.C. § 102(g)(2) provides:

> A person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last

> to reduce to practice, from a time prior to conception by the other.

AstraZeneca could establish prior invention by showing that "(1) it reduced its invention to practice first . . . or (2) it was the first party to conceive of the invention and then exercised reasonable diligence in reducing that invention to practice." *Mycogen Plant Sci. v. Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001). Conception occurs "when the inventor has a specific, settled idea, a particular solution to the problem at hand . . . ." *Creative Compounds, LLC v. Starmark Labs.*, No. 2010-1445, Slip Op. 13 (Fed. Cir. Jun. 24, 2011) quoting *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). But "[a]n inventor need not understand precisely why his invention works in order to achieve an actual reduction to practice." *Parker v. Frilette*, 462 F.2d 544, 547 (CCPA 1972). In order to establish reduction to practice, the prior inventor must have (1) constructed an embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose. *Mycogen Plant Sci.*, 243 F.3d at 1332.

In *Dow Chemical Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334 (Fed. Cir. 2001), a case involving the use of isobutane as a blowing agent to manufacture polyethylene foam, the district court found that the alleged prior artist had "made a product, meeting the limitations of the . . . patents" before the priority dates of the patents and that this earlier "production of foam . . . would invalidate the relevant claims . . . if the other requirements of § 102(g) were met." *Id.* at 1339-40. In *Dow*, there was "undisputed, clear and convincing evidence in the record that [the alleged prior inventor's] employees immediately appreciated what they had made, and indeed its significance, when they made isobutane-blown foam . . . . [and]

were 'surprised' and 'elated' at the ease of making the 'beautiful,' 'good' foam that they made." *Id.* at 1341.

In deciding that a prior inventor need not be "the first to appreciate the patentability of the invention," this court explained that "the date of conception of a prior inventor's invention is the date the inventor first appreciated the fact of what he made." *Id.* In *Dow*, this court reaffirmed its predecessor court's holding that "a party who first reduced to practice, but who 'fail[ed] to recognize that he had produced a new form [of matter] . . . is indicative that he never conceived the invention.'" *Id.* (quoting *Heard v. Burton*, 333 F.2d 239, 243 (CCPA 1964)). The court likewise reaffirmed that § 102(g) "does not require that [a prior inventor] establish that he recognized the invention in the same terms as those recited in the count [because t]he invention is not the language of the count but the subject matter thereby defined." *Id.* (quoting *Silvestri v. Grant*, 496 F.2d 593, 597, 599 (CCPA 1974)). As *Silvestri* had explained, "the language of the count is but one way to define the new form and certainly not a unique definition [. . . and a]ny claim they might have written, based on this or other information specific to [the new form] would still define the same subject matter as the count even though in different terms." 496 F.2d at 601. *See also In re Kao*, 639 F.3d 1057, 1066 (Fed. Cir. 2011) ("The claimed subject matter is not presumed to change as a function of how one elects to measure it."); William Shakespeare, *Romeo and Juliette* act 2, sc. 2 ("[T]hat which we call a rose [b]y any other name would smell as sweet.").

Likewise, in *Mycogen Plant Sciences*, Monsanto argued that it was the first to reduce to practice inventions relating to a synthetic gene with improved expression of a pesticidal protein. 243 F.3d at 1331-32. Mycogen argued that the Monsanto inventors failed to appreciate the invention because they had focused on improving expres-

sion by modifying the frequency of certain nucleotides rather than of certain codons. *Id.* at 1336. This court rejected that argument, explaining that:

> Monsanto is not required to have framed its prior documentation about its reduction to practice in the exact language given in the claims . . . . The reduction to practice test does not require *in haec verba* appreciation of each of the limitations of the count. The fact that Monsanto may have described parts of its process in terms of "nucleotides" instead of "codons" is immaterial . . . . A process describing the modification of certain codons may also be described in terms of nucleotides.

Id.

More recently, in *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005), this court again explained that:

> Conception . . . requires both (1) the idea of the invention's structure and (2) possession of an operative method of making it. Thus, with regard to a claimed chemical compound, conception requires that the inventor be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it . . . . [This] require[s] more than unrecognized accidental creation. . . . In other words, conception requires that the inventor appreciate that which he has invented.

Id. at 1063 (quotations and citations omitted). In that case, Invitrogen had invented a mutant reverse transcriptase enzyme with DNA polymerase but no RNase H activity ("RNase H minus reverse transcriptase"). *Id.* at 1058. Clontech established that scientists using a tech-

nique called "random mutagenesis" had previously prepared a panel of some 100 mutant genes for reverse transcriptase without knowing at the time where each of the mutant genes had been altered. *Id.* Later, two of these roughly 100 mutant genes turned out to code for an RNase H minus reverse transcriptase enzyme. *Id.* As the court explained, "[w]ith unrecognized accidental duplication, the invention exists but remains unrecognized. . . . In the appreciation analysis, the relevant uncertainty relates to the emerging recognition of something new." *Id.* at 1064. In vacating the district court's § 102(g) determination, the court explained that the record did not support the view that the supposed prior inventors actually knew what they had made at the relevant time and that the case therefore fit "squarely within the unrecognized, accidental duplication cases." *Id.* at 1066.

Dow, *Mycogen Plant Sciences*, and *Invitrogen* are consistent applications of the same rule. To establish prior invention, the party asserting it must prove that it appreciated what it had made. The prior inventor does not need to know everything about how or why its invention worked. Nor must it conceive of its invention using the same words as the patentee would later use to claim it. In this light, it is apparent that the district court correctly entered summary judgment.

Teva's entire argument turns on the the phrase "stabilizing effective amount." As stated in *Invitrogen*, this court must resolve questions of priority "using a properly defined invention." 429 F.3d at 1062. There is no question that AstraZeneca appreciated that AstraZeneca's drug contained an "amount" of crospovidone. And because of AstraZeneca's limited concession of infringement, there is no question that the amount of crospovidone AstraZeneca's drug contained falls within the scope of the asserted claims as defined by the limitation "stabilizing effective amount."

AstraZeneca had to appreciate that the compound it asserted as its invention was stable and what the components of this formulation were. There is no question that AstraZeneca had this appreciation. However, AstraZeneca did not need to appreciate which component was responsible for the stabilization. Teva effectively asks this court to fault AstraZeneca for not first conceiving of its drug in the same words in which Teva later chose to claim it. This case therefore falls squarely within the holdings of *Dow* and *Silvestri*. Because "[t]he invention is not the language of the [claim] but the subject matter thereby defined," Teva's argument must fail. *Dow*, 267 F.3d at 1341 (quoting *Silvestri*, 496 F.2d at 599).

While Teva relies substantially on *Invitrogen* for its argument that AstraZeneca could not satisfy § 102(g)(2) without appreciating that crospovidone stabilized its drug, its reliance is misplaced. As explained above, the alleged prior inventors in *Invitrogen* were unaware, until too late, that they had accidentally created two genes encoding RNase H minus reverse transcriptase. Here, by contrast, when AstraZeneca made the claimed invention first, it did so not by accident and it knew what it had made.

Teva argues that by characterizing the claimed subject matter as a stabilized statin formulation without emphasizing the requirement that the formulation be stabilized only by an AGCP compound, the district court implicitly adopted a broadening claim construction. According to Teva, the district court thus relieved AstraZeneca from its burden of proving that it appreciated the stablizing function of the AGCP compound. But as discussed above, the district court's decision did not resolve any dispute about the scope of the asserted claims. Teva's allegations and AstraZeneca's limited concession of infringement did that. Thus, while Teva appears to make a "claim construction" argument, it is actually asking this

court to hold that AstraZeneca needed to understand its invention in the same terms used in the asserted claims. As explained above, such a holding would directly conflict with the holdings of *Dow* and *Silvestri*. Teva's "claim construction" argument is therefore without merit.

Teva also argues that this case requires us to resolve exactly how, if at all, the doctrine of inherency applies to priority under § 102(g). But this case does not involve a factual dispute about whether or not the prior art includes a certain claim limitation (expressly or inherently). Again, Teva's allegations and AstraZeneca's limited concession of infringement took any such dispute off the table. Accordingly, there is no role for this court's inherency doctrine to play. Teva's argument is thus unavailing.

Finally, Teva argues that if AstraZeneca did conceive and reduce to practice the claimed subject matter, then it suppressed or concealed the invention. According to Teva, if AstraZeneca indeed conceived and reduced the invention to practice, AstraZeneca must have understood that the crospovidone was a stabilizer in the AstraZeneca drug formulation. Teva argues that if AstraZeneca understood this and did not disclose it, then it necessarily suppressed or concealed its understanding. But Teva's argument depends on the same premise already rejected above—that AstraZeneca needed to appreciate the stabilizing effect of crospovidone. This argument is therefore without merit for the same reasons.

Teva's remaining arguments have been considered and do not have merit.

III. CONCLUSION

For the foregoing reasons, the district court's entry of summary judgment of invalidity is affirmed.

AFFIRMED