United States Court of Appeals for the Federal Circuit

2006-1254

IN RE METOPROLOL SUCCINATE PATENT LITIGATION

ASTRAZENECA AB, AKTIEBOLAGET HASSLE,
and ASTRAZENECA LP,

Plaintiffs/Counterclaim
Defendants-Appellants,

v.

KV PHARMACEUTICAL COMPANY,

Defendant/Counterclaimant-
Appellee,

and

ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION,

Defendants/Counterclaimants-
Appellees,

and

EON LABS, INC.,

Defendant-Appellee.

DECIDED: July 23, 2007

Before MAYER, SCHALL, and GAJARSA, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA. Circuit Judge SCHALL dissents in part.

GAJARSA, Circuit Judge.

This is a consolidated multidistrict patent infringement litigation. Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, and AstraZeneca LP (collectively "Astra") filed multiple suits in various district courts asserting that the Abbreviated New Drug Applications ("ANDA") filed respectively by Defendants KV Pharmaceutical Co. ("KV"), Andrx Pharmaceuticals, LLC, and Andrx Corp. (collectively "Andrx"), and Eon Labs, Inc. ("Eon") under 21 U.S.C. § 355(j) infringe Astra's patents. Specifically, Astra alleged that Defendants' ANDAs seeking approval from the Food & Drug Administration to manufacture and market generic versions of Toprol-XL® infringed Astra's patents pursuant to 35 U.S.C. § 271(e). The Judicial Panel on Multidistrict Litigation consolidated the suits in the District Court for the Eastern District of Missouri. The district court found Astra's patents invalid and unenforceable, and granted Defendants' motions for summary judgment. In re Metoprolol Succinate Patent Litigation ("Summary Judgment"), No. 04-1620, slip op. (E.D. Mo. Jan. 17, 2006).

This court affirms the district court's invalidity holding based on double patenting. Because a genuine issue of material fact remains, however, we vacate the district court's inequitable conduct holding and remand the case.

I.

Astra manufactures and markets metoprolol succinate in "extended release" forms under the brand name Toprol-XL®. Metoprolol is a therapeutically active compound, which can form salts by reaction with acids and is used in the treatment of angina, hypertension, and congestive heart failure. Metoprolol succinate is the salt of metoprolol with succinic acid. See Summary Judgment, slip op. at 2-3.

A. Invention and Ownership

In 1971, an Astra employee "named Toivo Nitenberg synthesized metoprolol succinate as well as the tartrate and sulfate salts of metoprolol" at Astra's facilities in Sweden. At the time, Astra chose to commercialize the tartrate salt product. Id. at 28. Similarly in 1982, another Astra employee in Sweden named Lars Lilljequist synthesized a number of metoprolol salts, including metoprolol succinate. The parties submitted conflicting evidence as to whether two other Astra employees in Sweden, Curt Appelgren and Christina Eskilsson, had directed Lilljequist to synthesize metoprolol succinate. See id. at 28-30.

In 1983, Appelgren and Eskilsson left Astra to join another company, Lejus Medical AB ("Lejus"). In January 1984, Lejus filed a patent application (SE 8400085) with the Swedish Patent Office, describing "delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate" and naming Appelgren and Eskilsson as the inventors. In January 1985, Lejus filed U.S. application Ser. No. 690,197 (the '197 Application), claiming priority from the Swedish application. Id. at 30.

In October 1985, after noticing the publication of the Swedish application, Astra commenced a transfer of ownership action with the Swedish Patent Office asserting that Nitenberg, not Appelgren and Eskilsson, invented metoprolol succinate. Astra and Lejus subsequently settled this ownership dispute. Id. at 30-31. In the settlement agreement, Lejus agreed to divide claims to "metoprolol succinate" and to a "pharmaceutical composition, characterized in that the active substance is metoprolol succinate" from the '197 Application and to assign the divided claims to Astra. The

settlement agreement listed Appelgren and Eskilsson as the inventors of the divided metoprolol succinate claims. Astra agreed that Lejus retained the rights to the '197 Application that did not include the divided claims.

B. Astra's U.S. Patents

In March 1988 and in accordance with the settlement agreement, Lejus filed U.S. application Ser. No. 172,897 (the '897 Application), which was a continuation-in-part of the '197 Application. The record indicates that while the settlement agreement resolved the issue of ownership, disagreement remained on the issue of inventorship. Lejus filed the '897 Application with Appelgren and Eskilsson as the named inventors. Both before and after the filing, however, Astra's in-house counsel asserted to Lejus that Nitenberg, not Appelgren and Eskilsson, was the inventor of metoprolol succinate. Similarly, after Lejus transferred the prosecution of the '897 Application to Astra, Astra's in-house counsel asserted to Astra's outside U.S. patent counsel that "there remains an open question who is the proper inventor." The last mention of this issue in the record is a phone call between Astra's in-house counsel and outside U.S. patent counsel in January 1989. Summary Judgment, slip op. at 32-35.

In March 1991, the '897 Application issued as U.S. Patent No. 5,001,161 (the '161 Patent). The only claim of the '161 Patent reads: "A pharmaceutical composition comprising metoprolol succinate together with a sustained release pharmaceutically acceptable carrier." Id. col.2 ll.36-38.

In January 1992, a continuation of the '897 Application issued as U.S. Patent No. 5,081,154 (the '154 Patent). The only claim of the '154 Patent simply reads, "Metoprolol succinate." Id. col.2 l.36.

The ’161 and ’154 Patents both list Appelgren and Eskilsson as the inventors, and Astra as the assignee. Astra never revealed the inventorship issue to the U.S. Patent & Trademark Office during the prosecution of the two patents. Summary Judgment, slip op. at 25.

C. Lejus’s U.S. Patent

During the same time period, Lejus’s ’197 Application issued as U.S. Patent No. 4,780,318 (the ’318 Patent) in October 1988. Lejus is the assignee of the ’318 Patent, which also lists Appelgren and Eskilsson as the inventors. While Lejus, Appelgren, and Eskilsson are not parties in this multidistrict litigation, the ’318 Patent is pertinent because the district court invalidated Astra’s ’161 and ’154 Patents as double patenting over Lejus’s ’318 Patent. Claim 6 of the ’318 Patent claims an improved release oral pharmaceutical composition having (i) “a core comprising the therapeutically active compound,” (ii) “a first inner layer coating on the core,” and (iii) “a second outer layer coating on the inner layer.” Id. col.5 ll.42-55. Claim 8 claims this composition,

> wherein the active compound is quinidine sulphate, quinidine bisulphate, quinidine gluconate, quinidine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or furosemide, 5-aminosalicylic aicd [sic], propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pk_a of 1 to 8.

Id. col.5 ll.61-68 (emphasis added).

D. Procedural History

Defendants KV, Andrx, and Eon each filed an ANDA under 21 U.S.C. § 355(j) seeking approval from the Food & Drug Administration to market metoprolol succinate formulations with the bioequivalence of Astra’s Toprol-XL®, certifying under

§ 355(j)(2)(A)(vii)(IV) that the ’161 and ’154 Patents are invalid or will not be infringed. In 2003 and 2004, Astra filed multiple infringement actions based on the ’161 and ’154 Patents against Defendant KV in the District Court for the Eastern District of Missouri and against Defendants Andrx and Eon in the District Court for the District of Delaware. The defendants counterclaimed for declaratory judgment of invalidity and unenforceability. In August 2004, the Judicial Panel on Multidistrict Litigation issued a transfer order, consolidating the actions for pretrial proceedings in the District Court for the Eastern District of Missouri.

All three defendants moved for summary judgment for invalidity of the ’161 and ’154 Patents based on double patenting and invalidity of the ’161 Patent based on anticipation. Defendant Andrx also filed, and Defendants Eon and KV subsequently joined, a motion for summary judgment for unenforceability of both patents based on inequitable conduct. Astra cross-moved for partial summary judgment for validity of the ’154 Patent.

In January 2006, the district court issued a summary judgment decision and accompanying judgment in favor of the defendants, granting both motions of the defendants and denying Astra’s motion. Observing that other claims and counterclaims remained pending, the parties correctly moved for a judgment pursuant to Fed. R. Civ. P. 54(b) before filing a notice of appeal. The district court entered judgment pursuant to Fed. R. Civ. P. 54(b). Astra appealed the grant of summary judgment for invalidity of the ’154 Patent based on double patenting and the grant of summary judgment for unenforceability of both patents based on inequitable conduct. Astra did not appeal the

grant of summary judgment for invalidity of the ’161 Patent based on anticipation and double patenting.

This court has jurisdiction of the appeal pursuant to 28 U.S.C. § 1295(a)(1).

II.

A. Standard of Review

This court reviews de novo the grant of summary judgment. Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1096 (Fed. Cir. 2003). Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986).

B. Invalidity

Astra’s opening appellate brief states explicitly that “[a]lthough Astra disagrees with the district court’s decision of invalidity of the ’161 patent, Astra is not appealing that judgment.” Appellant Br. 4. Therefore, the parties do not dispute, and we do not review, the invalidity of the ’161 Patent. Astra appeals only the judgment that the ’154 Patent was invalid for obvious-type double patenting.

“This court reviews double patenting without deference.” Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed. Cir. 2005) (citation omitted). “De novo review is appropriate because double patenting is a matter of what is claimed, and therefore is treated like claim construction upon appellate review.” Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999); cf. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967-72 (Fed. Cir. 2001) (evaluating evidentiary submissions to determine whether claims were patentably distinct in obvious-type double patenting challenge).

We have noted that "[n]on-statutory, or 'obviousness-type,' double patenting is a judicially created doctrine adopted to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." Perricone, 432 F.3d at 1373 (citation omitted).

> Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.

Eli Lilly, 251 F.3d at 968 (footnote and citations omitted).

In this case, under the heading "*Claim construction*," the district court construed Claim 8 of the '318 Patent as directed

> to an oral pharmaceutical composition that has (i) a core that contains metoprolol succinate (or one of several other drugs), (ii) the core is surrounded by an inner coating that allows a controlled release of metoprolol succinate, and (iii) an outer coating that resists dissolving in the stomach with the goal of releasing the metoprolol succinate close to or within the colon.

Summary Judgment, slip op. at 10 (emphasis added). The only claim of the '154 Patent claims "[m]etoprolol succinate," which the district court construed to be the composition itself. Id. at 17.

Next, under the heading "*Comparing the claims*," the district court compared the claims. Stating that Claim 8 of the '318 Patent "is directed to certain pharmaceutical compositions containing metoprolol succinate" and that the '154 Patent "broadly claims

any pharmaceutical compositions containing metoprolol succinate," the district court found the '154 Patent to be a genus of the species claimed by the '318 Patent. Since the species claimed by the '318 Patent issued prior to the genus claimed by the '154 Patent, the district court concluded that the '154 Patent was "void for double patenting because it is not patentably distinct f[ro]m" Claim 8 of the '318 Patent. Id. at 19-20.

The parties agree that the district court correctly construed Claim 8 of the '318 Patent and the only claim of the '154 Patent in its summary judgment decision under the heading "*Claim construction*." This court perceives no error in the district court's claim constructions, and therefore, the only issue on appeal regarding the invalidity of the '154 Patent is whether the district court correctly found the claims not patentably distinct.[1]

Astra asserts that the district court erred in concluding that Claim 8 of the '318 Patent and Claim 1 of the '154 Patent recited a species/genus relationship. Instead, Astra asserts that the claims define an element/combination relationship. This court has stated that such disputes "about the characterization of the relation between the two claims" in a double patenting context are irrelevant.

> Emert insists that the claims stand in a combination ('624 patent) and subcombination ('887 application) relationship. The PTO insists that the claims stand in a genus ('887 application) and species ('624 patent) relationship. . . . In spite of the parties' eagerness to conform the round-peg facts of the case into semantic, square holes, the critical inquiry remains whether the claims in the '887 application define an obvious variation of the invention claimed in the '624 patent.

In re Emert, 124 F.3d 1458, 1461-62 (Fed. Cir. 1997). Therefore, Astra's reliance on semantic distinctions fails.

[1] To the extent that Astra asserts that the district court changed the claim constructions improperly between headings, this unarticulated argument would simply be an attempt to recast the patentably distinct inquiry into a claim construction mold.

The holding of Emert also dictates that this court affirm the district court's finding of double patenting in this case. In Emert, this court held the claims of an application unpatentable for double patenting, finding that "the '887 application's claimed invention, an oil soluble dispersant comprising B1, while not anticipated by the '624 patent due to the slight modification of three claim limitations, would have been prima facie obvious in light of the claim to the combination [A and B]" because the patentee "effectively conced[ed] that the differences between B and B1 are not material and would have been obvious to a person having ordinary skill in the art." 124 F.3d at 1463. Similarly, in this case, Claim 1 of the '154 Patent claiming a compound (A1) is an obvious variation of Claim 8 of the '318 Patent claiming a composition comprised of one compound of an enumerated list (A1, A2, A3, etc.), an inner layer (B), and an outer layer (C). Specifically, it would have been an obvious variation of Claim 8 of the '318 Patent to omit the inner layer (B) and the outer layer (C). Astra offers no convincing reason why Emert does not apply.[2] See also Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1382-83 (Fed. Cir. 2003) (holding that later patent claiming pharmaceutical composition was obvious variant of earlier patent claiming pharmaceutical composition with "enhanced storage stability, the closed container, [and] the packaged unit-dosages").

Instead, Astra asserts that other cases favor a finding of validity in this case. First, Astra cites three decisions of the Court of Customs and Patent Appeals, one of the predecessors of this court, for the proposition that there is no double patenting

[2] Moreover, the omission of the known elements from the composition in this case is "the product not of innovation but of ordinary skill and common sense." KSR Int'l Co. v. Teleflex Inc., 550 U.S. ----, 127 S. Ct. 1727, 1742 (2007).

because an earlier claim to a combination sets forth a later claimed element. The cases cited by Astra do appear to support this proposition. See In re Walles, 366 F.2d 786 (C.C.P.A. 1966); In re Allen, 343 F.2d 482 (C.C.P.A. 1965); In re Heinle, 342 F.2d 1001 (C.C.P.A. 1965). Indeed, the dissent in Allen characterizes the decision as establishing "a new and dangerous rule" and provides a presciently appropriate hypothetical:

> Thus, as I interpret the majority opinion, an applicant would be allowed to patent a chemical combination, e.g., a wonder drug and a suitable carrier for the drug, and then later to patent the drug alone based upon an application filed after the combination application. Seventeen years after the combination of drug and carrier had been patented, the public would still not be free to use the drug with the carrier or in any other obvious manner because of the dominance of the later issued patent to the drug alone. That result is an unlawful extension of the patent . . . .

343 F.2d at 1322-23 (Almond, J., dissenting).

The decisions of the Court of Customs and Patent Appeals bind this court. In re Stereotaxis, Inc., 429 F.3d 1039, 1041 (Fed. Cir. 2005) (citing South Corp. v. United States, 690 F.2d 1368, 1371 (Fed.Cir.1982) (en banc)). Where decisions of the Court of Customs and Patent Appeals conflict, however, the later issued decision controls "because the Court of Customs and Patent Appeals always sat in banc and therefore later decisions overcome earlier inconsistent ones." Celestaire, Inc. v. United States, 120 F.3d 1232, 1235 (Fed. Cir. 1997) (citation omitted).

Here, In re Schneller, 397 F.2d 350 (C.C.P.A. 1968), is a later issued decision that refutes the suggestion that under the previous holdings of Walles, Allen, and Heinle, a patentee may claim an element after claiming the combination without fear of double patenting. In Schneller, the Court of Customs and Patent Appeals affirmed a double patenting rejection where the patentee's

> first application disclosed ABCXY and other matters. He obtained a patent claiming BCX and ABCX, but so claiming these combinations as to cover them no matter what other feature is incorporated in them, thus covering effectively ABCXY. He now, many years later, seeks more claims directed to ABCY and ABCXY. Thus, protection he already had would be extended, albeit in somewhat different form, for several years beyond the expiration of his patent, were we to reverse. . . . He was shown no justification for such extended protection. He has made no effort not to extend it.

397 F.2d at 355-56. Similarly, in this case, Lejus first obtained a patent claiming (A1, A2, A3, etc.)BC in Claim 6 of the '318 Patent, and years later, Astra obtained a patent claiming A1 in Claim 1 of the '154 Patent. Moreover, Schneller explicitly limited Heinle and Allen to the "particular fact situations" of those cases. Id. at 355 (citation omitted). Therefore, Astra's reliance on Walles, Allen, and Heinle fails because Schneller controls as the later issued Court of Customs and Patent Appeals decision.

Second, citing to General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1281 (Fed. Cir. 1992), Astra asserts in its briefs that this court's "precedent makes clear that the disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even where the disclosure is found in the claims." This is true. The disclosure of the claims forming the basis of a double patenting rejection cannot be used as "prior art" for a rejection under 35 U.S.C. §§ 102, 103. The language of General Foods and of the precedents cited in the decision explain, however, that what is claimed, as opposed to what is disclosed to one skilled in the art, remains critical. See id. at 1281-82. Indeed, adopting Astra's argument that there can never be "double patenting simply because a later claimed element is set forth in an earlier claim to the combination," Appellant Br. 52, would require that this court eviscerate obviousness-type double patenting, thereby reducing invalidity based

on double patenting to the § 101 statutory prohibition against claims of the same invention. See Geneva, 349 F.3d at 1377-78 (stating that "applicants can evade this [§ 101] statutory requirement by drafting claims that vary slightly from the earlier patent" and that this "court's predecessor . . . recognized this problem and fashioned a doctrine of nonstatutory double patenting (also known as 'obviousness-type' double patenting) to prevent issuance of a patent on claims that are nearly identical to claims in an earlier patent" (footnote omitted)).

General Foods is also factually distinguishable. In General Foods, the earlier patent claimed a nine-step process for recovering caffeine. 972 F.2d at 1277. The later patent, challenged for double patenting, claimed a two-step process for decaffeinating coffee. Id. at 1276. Contrary to the district court's findings, id. at 1280, and the representations of the dissent-in-part, post at 5-6, these two processes had only one step in common—"decaffeinating raw coffee with supercritical water-moist carbon dioxide," see General Foods, 972 F.2d at 1277-78. The other eight steps of the earlier patent related to recovering caffeine, while the other step of the later patent related to recovering decaffeinated coffee. See id. Therefore, the earlier patent claimed a nine-step process comprising steps ABCDEFGHJ,[3] and the later patent claimed a two-step process comprising steps AK. Based on this construction of the claims, this court reversed the district court's holding that the later patent was an obvious variant of the earlier patent. Specifically, the district court's opinion exhibited a "distressing failure to adhere to firmly established and universally understood rules of claim interpretation" by "using nothing but the disclosure of clause (a) of claim 1 as though it were prior art, and

[3] We preserve the language of the original claim, which contains no step I. Id. at 1277.

in not reading claim 1 to determine what invention it defines-like the metes and bounds of a deed." See id. at 1280-81, 1283. By contrast, in this case, the composition of the earlier patent claim includes the compound of the later patent claim in its entirety. Specifically, the earlier patent not only discloses but also claims a composition comprised-in-part of metoprolol succinate. Therefore, General Foods does not preclude a finding that a claim on a compound (A) cannot be an obvious variant of an earlier claim on a composition comprised of compound (A), inner layer (B), and outer layer (C).

Third, Astra asserts that In re Coleman, 189 F.2d 976 (C.C.P.A. 1951), requires that courts analyze "badges of distinctness." Astra does not dispute that it never raised this "badges of distinctness" argument with the district court. Even if Astra had preserved this argument, the defendants correctly point out that Coleman examined statutory "same invention" double patenting before the Court of Customs and Patent Appeals recognized the doctrine of non-statutory, obvious-type double patenting in its current form. See id. at 1159-60 ("As is usual in such cases, the issue reduces itself to a determination of whether or not the appealed claims and those in the patents are directed to one and the same invention."); General Foods, 972 F.2d at 1280 ("[T]he development of the law came to a turning point in In re Zickendraht, 319 F.2d 225 (C.C.P.A. 1963), particularly in the concurring opinion therein. Soon thereafter the obvious variant kind of double patenting came to be known as 'obviousness-type' double patenting."). Moreover, Astra fails to cite any controlling case that has applied the "badges of distinctness."

Lastly, Astra asserts that the district court's public policy statement that a contrary finding of validity "would defeat the public policy behind the double patenting

doctrine which is to allow the public to freely use a patent upon its expiration" was erroneous. Regardless of the parties' characterization of it, the district court made this statement in a concluding paragraph after already holding that the '154 Patent was invalid for double patenting. See Summary Judgment, slip op. at 20.

Therefore, based on Emert, this court agrees with the district court that Claim 1 of Astra's '154 Patent is invalid for obviousness-type double patenting. Astra does not appeal the district court's invalidity holdings regarding Astra's '161 Patent. Accordingly, we affirm the district court's summary judgment holding Astra's asserted patents invalid.

C. Unenforceability

The district court also held on summary judgment that that the '161 and '154 Patents were unenforceable based on inequitable conduct.[4] Summary Judgment, slip op. at 42-45. While Astra asserts several errors regarding this holding, we focus on the district court's factual finding of an intent to deceive.

We have stated that "'[i]ntent need not, and rarely can, be proven by direct evidence.' Rather, intent to deceive is generally inferred from the facts and circumstances surrounding the applicant's overall conduct." Impax Labs., Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1375 (Fed. Cir. 2006) (quoting Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989)). Because "[t]his court has consistently treated inequitable conduct as an equitable defense that may be adjudicated by the trial court without a jury," Agfa Corp. v. Creo Prods. Inc., 451 F.3d

[4] We reach this issue because the parties dispute whether a patentee may reinstate the validity of a patent by filing a terminal disclaimer during litigation. This court has not decided the issue. See Perricone, 432 F.3d at 1375 (stating that "while [a patentee] might still file a terminal disclaimer to overcome prospectively the double patenting basis for invalidity, this court makes no determination about the retrospective effect of such a terminal disclaimer").

1366, 1375 (Fed. Cir. 2006), a "patentee has no right to a jury trial respecting the factual element of culpable intent as part of the defense of inequitable conduct," Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1190 (Fed. Cir. 1993). "Thus, a disputed finding of intent to mislead or to deceive is one for the judge to resolve, not the jury, albeit not on summary judgment if there is a genuine dispute." Paragon, 984 F.2d at 1190 (emphasis added).

In this case, the district court inferred intent to deceive on summary judgment based on an analysis of what could have happened if Astra had disclosed the inventorship dispute to the U.S. Patent & Trademark Office.

> Not only was the issue of the dispute of inventorship highly material, Astra had a strong incentive to not disclose the dispute. If a patent examiner had learned of the dispute and found Nitenberg to be the sole inventor of metoprolol succinate, the '897 patent application would not have been entitled to priority to the January 1985 United States application. The effective filing date for the '897 patent would have been March 25, 1988. As a consequence, Astra's metoprolol succinate patents may have been denied as anticipated by the prior art of the publication of the Lejus' European application on July 17, 1985.

Summary Judgment, slip op. at 44. Based on this but for analysis, the district court found "by clear and convincing evidence that Astra's motivation to not reveal the dispute was great based on the risk of losing its metoprolol succinate inventions as anticipated by prior art. The intent to deceive is clearly present." Id. at 45.

On appeal, the parties dispute the soundness of the district court's but for analysis. Even assuming arguendo that the patents at issue would have been invalid based on anticipation if Astra had disclosed the inventorship dispute to the U.S. Patent & Trademark Office, the district court erred in equating the presence of an incentive with an intent to deceive on summary judgment. Specifically, the deposition of Astra's in-

house patent counsel indicates that he did not know of and was not concerned about the incentives identified by the district court in its but for analysis. Therefore, the record reveals a genuine factual dispute of whether Astra had an intent to deceive the U.S. Patent & Trademark Office. The district court improperly resolved this factual dispute on summary judgment and thus, erred in holding on summary judgment that the '161 and '154 Patents are unenforceable based on inequitable conduct.

III.

For these reasons, we affirm the district court's invalidity holding regarding the '154 Patent, vacate its inequitable conduct unenforceability holding regarding the '161 and '154 Patents, and remand the case.

AFFIRMED-IN-PART, VACATED-IN-PART, and REMANDED

Each party shall bear its own costs for this appeal.

United States Court of Appeals for the Federal Circuit

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Defendant/Counterclaimants-Appellees,

and

EON LABS INC.,

Defendant-Appellee.

SCHALL, Circuit Judge, dissenting-in-part.

I agree with the majority that the district court erred in granting summary judgment of unenforceability with respect to the '161 and '154 patents. I therefore join the court's opinion insofar as it vacates the judgment of unenforceability and remands the case to the district court for further proceedings on that issue. However, because I

believe that claim 1 of the '154 patent is patentably distinct from claim 8 of the '318 patent, I respectfully dissent from the court's opinion insofar as it holds that claim 1 is invalid by reason of obviousness-type double patenting.

I.

Claim 8 of the '318 patent depends from claims 6 and 7 of the patent. Claim 6 of the '318 patent claims an improved release oral pharmaceutical composition having (i) "a core comprising the therapeutically active compound," (ii) "a first inner layer coating on the core," and (iii) "a second outer layer coating on the inner layer." '318 patent, col.5 ll.42-55. Claim 7 claims a pharmaceutical composition according to claim 6 wherein the therapeutically active compound in the core has a solubility in a specified pH range. Id. col.5 ll.56-59. Claim 8 claims the composition of claim 7

> wherein the active compound is quinidine sulphate, quinidine bisulphate, quinidine gluconate, quinidine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or furosemide, 5-aminosalicylic aicd [sic], propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pk_a of 1 to 8.

Id. col.5 ll.61-68 (emphasis added).

As I think the majority does, I agree with the district court that, distilled to its essence, claim 8 of the '318 patent claims an oral pharmaceutical composition that has (i) a core that contains one of eleven possible active ingredients (metoprolol succinate being one of the eleven), (ii) an inner coating surrounding the core (that allows a controlled release of the active ingredient), and (iii) an outer coating (that resists dissolving in the stomach, with the goal of releasing the active ingredient close to or within the colon).

Claim 1 of the ’154 patent, which is the sole claim of that patent, claims the compound metoprolol succinate. ’154 patent, col.2. l.36. As just seen, metoprolol succinate is one of the possible active compounds of the composition of claim 8 of the ’318 patent.

The majority starts from the premise that claim 8 of the ’318 patent claims (i) a composition comprised of one compound of an enumerated list of eleven compounds (one of which is metoprolol succinate); (ii) an inner layer; and (iii) an outer layer. Slip op. at 10. The majority states that “the composition of the [’318] patent claim includes the compound of the [’154] patent claim in its entirety. Specifically, the [’318] patent not only discloses but also claims a composition comprised-in-part of metoprolol succinate.” Id. at 14. The majority reasons that “a claim on a compound (A)” is “an obvious variant of an earlier claim on a composition comprised of compound (A), inner layer (B), and outer layer (C)” Id. Based upon that reasoning, the majority concludes that claim 1 of the ’154 patent is invalid by reason of obviousness type double patenting because it is an obvious variation of claim 8 of the ’318 patent. Id. at 10.

II.

A double patenting analysis turns on what is claimed. General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1275 (Fed. Cir. 1992) (“[T]he law of double patenting is concerned only with what patents claim. ‘Double patenting,’ therefore, involves an inquiry into what, if anything, has been claimed twice.”) To me, the critical point is that, in this case, the compound metoprolol succinate has not “been claimed twice.” We explained in General Foods:

> [E]ach claim is an entity which must be considered as a whole. It cannot be said—though it often is, incorrectly, by the uninitiated—that a part of a claim is "claimed" subject matter. For example, a claim to a process comprising the step A followed by step B followed by step C defines, as a matter of law, only the A-B-C process and one cannot properly speak of any single step as being "claimed", for it is not; all that is claimed is the process consisting of the combination of all three steps. Such a claim, therefore, creates no patent right or monopoly in step A, no right to prevent others from using step A apart from the combination of steps A-B-C. Step A is not "patented."
>
> Another way of stating the legal truism is that patent claims, being definitions which must be read as a whole, do not "claim" or cover or protect all that their words may disclose. Even though the claim to the A-B-C combination of steps contains a detailed description of step A, that does not give the patentee any patent right in step A and it is legally incorrect to say that step A is "patented."

972 F.2d at 1274-75 (emphases in original); see also Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 25 (Fed. Cir. 2000).

Bearing the foregoing in mind, I believe that what is patented by claim 8 of the '318 patent is a three-element composition having (i) a core with any one of eleven possible compounds, one of them being metoprolol succinate; (ii) an inner coating; and (iii) an outer coating. Anything less than a compound with all three of these elements is not what is claimed. See General Foods, 972 F.2d at 1280 ("There is a claim 1 [of the '619 patent] and the first step of its 9 recited steps is designated '(a).' . . . [S]tep (a) is not 'claimed' in the '619 patent, nor is it 'patented' or 'covered' . . . What is patented by claim 1 of '619 is a 9-step caffeine recovery process, nothing more and nothing less." (emphases in original)). In contrast, what is claimed by claim 1 of the '154 patent is a single compound: metoprolol succinate.

In my view, a comparison of the inventions actually patented by the two claims reveals that claim 1 of the '154 patent is patentably distinct from claim 8 of the '318 patent. Far from claiming an obvious variation on the three-element composition

claimed in the '318 patent, the '154 patent, I think, lacks any semblance to the second two elements in the three-element composition of claim 8. The patent does not claim any type of inner coating or outer coating whatsoever. While the first element of claim 8 of the '319 patent does disclose metoprolol succinate as one possible active ingredient, that disclosure does not equate to a claim for metoprolol succinate or render obvious the '154 patent claim to that compound. In short, the two claims involve different inventions. See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 344 (1961) (recognizing that "if anything is settled in the patent law, it is that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant"); Leeds & Catlin Co. v. Victor Talking Mach. Co., 213 U.S. 301, 318 (1909) (noting that "[a] combination is a union of elements, which may be partly old and partly new, or wholly old or wholly new. But, whether new or old, the combination is a means—an invention—distinct from them").

I believe the law is that there is no double patenting simply because a later claimed element is set forth in an earlier claim to a combination. Significantly, in General Foods, claims 1 and 4 of a later issued patent, the "decaffeination patent," defined a process of decaffeinating raw coffee with supercritical water-moist carbon dioxide and recovering the decaffeinated coffee. 972 F.2d at 1277-78. The district court relied on claim 1 of an earlier issued patent, the "caffeine recovery patent," to invalidate the later issued decaffeination patent claims based on double patenting. Id. at 1274. The earlier caffeine recovery patent defined a 9-step process of obtaining caffeine from green coffee. Id. at 1280. The first step recited "the essence of the very same process claimed in the [later issued] patent in suit." Id. at 1280. The district court

determined that the first step of the earlier caffeine recovery patent anticipated, or at least rendered obvious, claims 1 and 4 of the later decaffeination patent because every step of claims 1 and 4 were set forth in the first step of the caffeine recovery patent. On appeal, this court concluded that the district court had erroneously used the disclosure in the first step of the caffeine recovery patent as though it was prior art. Id. at 1281. After describing the claimed inventions, this court stated: "It should be amply clear by now that the decaffeination invention and the caffeine recovery invention are separate and distinct inventions, directed to different objectives, and patentably distinguishable one from the other." Id. at 1277 (emphases in original). In sum, General Foods held that a later patent claim to step A is patentably distinct from an earlier patent claim to steps A-B-C-D. To me, it follows that, in this case, a later patent claim to compound A is patentably distinct from an earlier patent claim to composition A-B-C. See also In re Walles, 366 F.2d 786 (CCPA 1966) (finding that patent claims to a hair setting composition, in which the resin of the appealed claims provided one component, were not a bar per se to the application claims to the resin itself); In re Allen, 343 F.2d 482 (CCPA 1965) (holding no double patenting between the claims on appeal, directed to a whaler bracket per se, and patent claims directed to a combination of walls, headed tie rods having spacing washers and positioning means, and a whaler bracket); In re Heinle, 342 F.2d 1001 (CCPA 1965) (reversing Patent Office Board of Appeals double patenting rejection of claims to a single element E based on a patent claim to a combination of A, B, C, D, and E).[1]

[1] The district court determined that claims 1 and 8 were in a genus/species relationship and found double patenting on that basis. While the majority does not

While the majority recognizes General Foods and Walles, Allen, and Heinle, it states that the former is distinguishable from this case, while the authority of the latter three was undermined by the decision of the Court of Customs and Patent Appeals in In re Schneller, 397 F.2d 350 (CCPA 1968). I am unable to agree with the majority on either point.

The facts of General Foods are set forth above. As far as I can tell, the only difference between General Foods and this case is that General Foods dealt with method claims, while this case involves product claims. That seems to me to be a distinction without a difference. Neither am I able to agree that In re Schneller overruled Walles, Allen, and Heinle. Briefly, in Schneller, the court upheld the rejection of application claims to the combination ABCY as double patenting in light of earlier patent claims to the combination ABCX. The court noted that the patented claims to ABCX

(Cont'd. . . .)
resolve this issue, I do not think that this case presents a genus/species situation. As explained in In re Bronson,

> In patent law it is axiomatic if claims are to be considered as being in the same genus and species relationship, they must fall into the same statutory class, and that a genus claim must be for the same combination of elements as the species claims, and define broadly the elements or steps which are variants in the several species. A generic claim should include no material element in addition to those recited in the species claim, and must comprehend the organization covered in each of the species claims.

168 F.2d 548, 550 (CCPA 1948). The '154 patent claim does not describe the same combination of elements as claim 8 of the '318 patent. Metoprolol succinate is the only element in the '154 patent claim, and it is narrower than the first element of claim 8 of the '318 patent, which lists eleven possible active ingredients. Even for the one element that the two claims arguably share, metoprolol succinate, there is no legal or logical support for a determination that metoprolol succinate describes a genus of the species described by "quinidine sulphate, quinidine bisulphate, quinidine gluconate, quinidine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or forosemise, 5-aminosalicylic acid, propanolol or alprenolol or a pharmaceutically acceptable salt thereof." '318 patent, claim 8.

covered the preferred embodiment of ABCXY that was disclosed in the patent because the claims were "comprising-type" claims, and that the later application claims to ABCY would also cover the preferred embodiment of ABCXY that was disclosed in the application because they were also "comprising-type" claims. In re Schneller, 397 F.2d at 354. Thus, the court stated, "anyone undertaking to utilize what [the inventor] disclosed in the patent . . . in the preferred and only form in which he described the invention, would run afoul of" the application claims. Accordingly, the court held that this timewise extension of protection was impermissible. Id. at 356. In this case, however, the '318 patent does not identify one single preferred embodiment that would be impaired by the later application claim to metoprolol succinate. Metoprolol succinate is only one of eleven possible active ingredients identified for the core of the composition claimed in claim 8 of the '318 patent. Moreover, that Schneller did not overrule the Walles, Allen, Heinle, line of cases is made clear, I believe, by the following paragraph in Schneller distinguishing Heinle:

> In re Heinle is clearly distinguishable. The issued patent claimed a mechanical combination for holding a toilet paper roll. The application claimed a separately usable and salable element of that combination, a particular core for the roll. A combination claim does not 'cover' or read on a single element. The protection of the combination afforded by the single Heinle patent claim would not have been extended by the application claims directed to the element. We refer to our opinions therein and in In re Allen, 343 F.2d 482, 52 CCPA 1315, decided the same day, for further elucidation of our thinking on the subject and for the several earlier precedents permitting patenting of a patentable element after the patenting of a combination containing it, in the absence of a terminal disclaimer.

In re Schneller, 397 F.2d at 355.

III.

In affirming the district court's holding of double patenting with respect to claim 1 of the '154 patent, the majority relies on In re Emert, 124 F.3d 1458 (Fed. Cir. 1997). Slip op. at 10. In Emert, we upheld a double patenting rejection of a claim in a patent application, which we characterized as a claim to "An oil soluble dispersant mixture useful as an additive comprising: [B_1]." Id. at 1460 (quoting U.S. Application No. 07/250,887) (alteration in original). The rejection was based on an earlier patent claim that we characterized as a claim to "An oil soluble dispersant mixture useful as an additive comprising: [A and B]." Id. at 1459 (quoting U.S. Patent No. 5,8763,624) (alteration in original). I do not believe that Emert controls this case. In Emert, both the patent claim and the application claim were to an oil soluble dispersant and the inquiry focused on whether the content of one claimed dispersant was patentably distinct from the content of the later claimed dispersant. In contrast, here we have an earlier claim to a three-element composition and a later claim to a single compound. In my view, for this reason, Emert is not controlling in this case.

IV.

The district court stated that "[i]f the '161 and '154 patents were valid, they would prevent the public from using the earlier issued invention of claim 8 of the '318 patent upon its expiration because they completely encompass claim 8 as to metoprolol succinate," and that "[s]uch a result would defeat the public policy behind the double patenting doctrine which is to allow the public to freely use a patent upon its expiration." In re Metoprolol Succinate Patent Litigation, No. 1620, slip op. at 11. "The basic concept of double patenting is that the same invention cannot be patented more than

once, which, if it happened, would result in a second patent which would expire some time after the original patent and extend the protection timewise." General Foods, 972 F.2d at 1279-80. Allowance of claim 1 of the '154 patent to metoprolol succinate will not result in the improper extension of the patent for the invention claimed in the '318 patent. That is because in this case, each patent is capable of being practiced by itself, without infringing the other. The public can practice the invention in claim 8 of the '318 patent when it expires by using any of the ten active ingredients recited in the claim other than metoprolol succinate. While some may find it desirable to use metoprolol succinate as the active ingredient in claim 8 of the '318 patent, and those individuals will be unable to do so until the '154 patent expires, that does not result in the "extension" of claim 8 in the '318 patent, or in any recognized form of double patenting.

For the foregoing reasons, I respectfully dissent from the court's opinion insofar as it holds that claim 1 of the '154 patent is invalid by reason of obviousness-type double patenting. I would reverse the decision of the district court on that issue.