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Paper 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FERRUM FERRO CAPITAL, LLC,
Petitioner,

v.

ALLERGAN SALES, LLC,
Patent Owner.

Case IPR2015-00858
Patent 7,030,149 B2

Before JACQUELINE WRIGHT BONILLA, SHERIDAN K. SNEDDEN and SUSAN L. C. MITCHELL, *Administrative Patent Judges.*

BONILLA, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Ferrum Ferro Capital, LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claim 4 of U.S. Patent No. 7,030,149 B2 (Ex. 1001, "the '149 patent"). Paper 1 ("Petition" or "Pet."). Allergan Sales, LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). As authorized by the panel, Petitioner filed a Reply to Patent Owner's Preliminary Response. Paper 7. We have statutory authority under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Petitioner advances one ground of unpatentability under 35 U.S.C. § 103(a) regarding claim 4 of the '149 patent. Pet. 6, 23–31. For the reasons discussed below, Petitioner has not established that there is a reasonable likelihood that it would prevail with respect to claim 4, as required under 35 U.S.C. § 314(a).

A. Related Proceedings

Petitioner identifies several district court cases regarding the '149 patent: *Allergan, Inc. v. Sandoz Inc.*, Case No. 2:09-cv-00097 (E.D. Tex.) (discussed below); *Allergan, Inc. v. Alcon Labs., Inc.*, Case No. 2:09-cv-00348 (E.D. Tex.); *Allergan, Inc. v. High-Tech Pharmacal Co.*, Case No. 2:09-cv-00182 (E.D. Tex.) (consolidated with 2:09-cv-00348); *Allergan, Inc. v. Apotex Inc.*, Case No. 2:10-cv-00200 (E.D. Tex.); and *Allergan, Inc. v. Watson Labs., Inc.*, 2:10-cv-00344 (E.D. Tex.). Pet. 5.

Both parties also discuss a relevant decision by the U.S. Court of Appeals for the Federal Circuit, *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286

(Fed. Cir. 2013) ("Federal Circuit decision" or "*Allergan v. Sandoz*" or "*Allergen*") (Ex. 1012). Pet. 8–14; Prelim. Resp. 1–13. As discussed in more detail below, the Federal Circuit, in a 2–1 majority decision, affirmed a decision by the district court in *Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d 974 (E.D. Tex. 2011), finding that defendants failed to prove by clear and convincing evidence that claim 4 of the '149 patent would have been obvious. *Allergan v. Sandoz*, 726 F.3d at 1288, 1293–95; *see also id*. at 1295–96 (Dyk, J., dissenting) (dissenting from the majority's holding that claim 4 of the '149 patent is not invalid as obvious) (Ex. 1012).

B. Proposed Ground of Unpatentability

Petitioner contends claim 4 of the '149 patent would have been obvious over DeSantis (Ex. 1006)[1] in view of Timmermans (Ex. 1007)[2] and further in view of Larsson (Ex. 1008)[3] and/or Stewart (Ex. 1009).[4] Pet. 6, 23–31. Petitioner supports its challenge with a Declaration by Anthony Palmieri, Ph.D. (Ex. 1005). Pet. 14–15.

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[1] DeSantis, U.S. Patent No. 5,502,052, filed Dec. 22, 1994, issued Mar. 26, 1996 ("DeSantis") (Ex. 1006).

[2] Timmermans et al., "Structure-Activity Relationships in Clonidine-Like Imidazolidines and Related Compounds," 3(1) PROGRESS IN PHARMACOL. 21–62 (1980) ("Timmermans") (Ex. 1007).

[3] Larsson, "Aqueous Humor Flow in Normal Human Eyes Treated With Brimonidine and Timolol, Alone and in Combination," 119 ARCH. OPHTHALMOL. 492–495 (April 2001) ("Larsson") (Ex. 1008).

[4] Stewart et al., "Comparison of the Efficacy and Safety of Latanoprost 0.005% Compared to Brimonidine 0.2% or Dorzolamide 2% When Added to a Topical β-Adrenergic Blocker in Patients with Primary Open-Angle Glaucoma or Ocular Hypertension," 16 J. OCULAR PHARMACOL. THERAPEUTICS 251–259 (2000) ("Stewart") (Ex. 1009).

C. The ’149 Patent and Claim 4

The ’149 patent is directed to the topical ophthalmic use of brimonidine in combination with timolol for the treatment of glaucoma or ocular hypertension. Ex. 1001, 1:7–9. As noted in the Specification, both brimonidine and timolol previously were commercially available, and had been combined for serial application in the treatment of glaucoma. *Id*. at 2:7–9, 1:9–13. The Specification discusses concerns about patient compliance when administering “separate medications to treat a single disease,” as well as the need for “an effective and safe topical ophthalmic pharmaceutical composition including brimonidine and timolol which has increased stability” and increased efficacy to reduce side effects. *Id*. at 1:12–27.

According to the Specification, “[u]nexpectedly it has been discovered that brimonidine in combination with timolol meets these criteria.” *Id*. at 1:27–29. In addition, the Specification discloses using a reduced amount of a potentially cytotoxic antimicrobial preservative in the disclosed combination formulations, as compared “to the FDA-approved regimen wherein brimonidine ophthalmic solution, i.e. Alphagan® ophthalmic solution is administered three times a day and timolol ophthalmic solution, i.e. Timoptic® ophthalmic solution is administered twice a day.” *Id*. at 2:28–67.

Claim 4 of the ’149 patent recites:

> 4. A method of reducing the number of daily topical ophthalmic doses of brimondine administered topically to an eye of a person in need thereof for the treatment of glaucoma or ocular hypertension from 3 to 2 times a day without loss of efficacy, wherein the concentration of brimonidine is 0.2% by weight, said method comprising administering said 0.2%

> brimonidine by weight and 0.5% timolol by weight in a single composition.

Id. at 10:10–17.

II. ANALYSIS

A. Claim Construction

For *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the patent specification. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1275–78 (Fed. Cir. 2015). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Claim 4 of the '149 patent recites a "method of reducing the number of daily topical ophthalmic doses of brimondine . . . from 3 to 2 times a day *without loss of efficacy*" in the treatment of glaucoma or ocular hypertension. Ex. 1001, 10:10–17 (emphasis added). Petitioner contends that "without loss of efficacy" is not a claim limitation under our broadest reasonable interpretation standard. Pet. 16–17. According to Petitioner, in the Federal Circuit decision (Ex. 1012) addressing the same claim and applying the *Phillips* standard of claim construction, the "majority considered it a claim limitation; the dissent did not." *Id*. at 16; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc).

Petitioner asserts that "without loss of efficacy" is not a limitation in this case because our broadest reasonable interpretation is broader than the "narrower *Phillips* standard." Pet. 16. Petitioner also asserts that "without loss of efficacy" recites an intended result of practicing the method as

claimed, not a step of the claimed method, and, therefore, should not be given patentable weight. *Id*. at 16–17 (citing *Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1380–81 (Fed. Cir. 2003)).

Patent Owner responds that Petitioner "wrongly argues that the dissent in the *Sandoz* appeal adopted a different claim construction from the majority in which the language 'without loss of efficacy' appearing in the claim was not a limitation and could be ignored." Prelim. Resp. 2. Patent Owner contends that the majority and dissent in the Federal Circuit decision adopt the same claim construction, and "simply parted company on whether the prior art combination disclosed the limitation." *Id*.

In the Federal Circuit decision, the majority and dissent both addressed the "without loss of efficacy" language at length. *Allergan* (Ex. 1012), 726 F.3d at 1293–96. As stated by the majority, the record in that case established "that when brimonidine is dosed twice per day as opposed to three times per day, there is a loss of efficacy in the afternoon—the so called, afternoon trough." *Id*. at 1294. The majority noted that the defendant did not argue that the efficacy limitation was an inherent result or property of the claimed product comprising brimonidine and timolol. *Id*. The majority also pointed out that "[i]n support of its position, the dissent cites a series of cases in which a patentee claimed either a previously unknown result or an undisclosed inherent property of an otherwise anticipated claim." *Id*. at 1294 n.1 (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). The majority explained that while "it may be true that the mere administration of 0.2% brimonidine and 0.5% timolol twice daily in any fixed combination formulation inherently produces the claimed result," the majority could not

draw a conclusion in favor of that proposition without sufficient evidence to support it. *Id*.

In his dissent, Judge Dyk pointed out that the majority affirmed the validity of claim 4 directed to dosing the recited composition twice a day "because the prior art did not disclose that this dosing regimen 'would eliminate the afternoon trough issue.'" *Id*. at 1295. Judge Dyk countered that "a newly-discovered result or property of an existing (or obvious) method of use is not patentable." *Id*. at 1295–96 (citations omitted). In this context, Judge Dyk stated "the method of claim 4 consists of a single step: applying a fixed combination of 0.2% brimonidine and 0.5% timolol twice a day," which he determined to be obvious. *Id*. at 1296. He stated "[a]voiding a 'loss of efficacy' is not a separate step, but rather a result of the claimed method," citing *Bristol-Myers Squibb*, 246 F.3d at 1374–78, and *Abbott Labs. v. Baxter Pharm. Prods.*, 471 F.3d 1363, 1369 (Fed. Cir. 2006). *Id*.

In *Bristol-Myers Squibb*, the Federal Circuit stated that "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Bristol-Myers Squibb*, 246 F.3d at 1376. In this context, the court stated that claim limitations that merely recite a newly discovered result of a known process "do not distinguish those claims over the prior art." *Id.* at 1376–77; *see also Abbott Labs.*, 471 F.3d at 1369 (citing *Bristol-Myers Squibb*, 246 F.3d at 1376; *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809–10 (Fed. Cir. 2002) (stating that one may not obtain a patent on a process having the same steps as a prior art process, in which the new process merely identifies a new, advantageous property of the prior art process)). Neither that case law, nor the dissent in *Allergan v. Sandoz*, indicates that we

should consider a recited result not to be a limitation in a method claim simply because it recites a result. Rather, as noted by the *Allergan* majority, a previously unknown claimed result fails to impart patentability if it corresponds to an inherent result or property of, i.e., the result necessarily flows from, the otherwise known recited method. *Allergan*, 726 F.3d at 1294.

Petitioner does not persuade us that "without loss of efficacy" is not a limitation in claim 4, regardless of whether we apply the broadest reasonable interpretation or the *Phillips* standard of claim construction. That result is recited and required in claim 4, and is a limitation. The question of whether that result is inherent to the other recited aspects of claim 4, and therefore fails to imparts patentability, is a different issue, which we address when considering whether claim 4 would have been obvious over cited prior art.

B. Asserted Obviousness of Claim 4

Petitioner contends that claim 4 of the '149 patent would have been obvious over DeSantis in view of Timmermans and further in view of Larsson and/or Stewart. When considering the validity of claim 4 on appeal in *Allergan v. Sandoz*, the Federal Circuit considered all of those references except Stewart. *Allergan*, 726 F.3d at 1289–90 (Ex. 1012).

As noted by the Federal Circuit, DeSantis described fixed combinations of an alpha2-agonist, in an amount from 0.02 to 2.0% by weight, and a beta-blocker, such as timolol, in an amount from 0.01 to 3.0% by weight, for the treatment of glaucoma. *Id.*; Ex. 1006, 2:17–21, 34–35, 4:58–61, 5:32–40. Although DeSantis did not state expressly that brimonidine was an alpha2-agonist that could be used in the combination, the reference taught that relevant alpha2-agonists were described in

Timmermans, which disclosed brimonidine among other alpha2-agonists. 726 F.3d at 1290; Pet. 25; Ex. 1007, 28, Fig. 31. In addition, Larsson disclosed the topical administration of 0.2% brimonidine with 0.5% timolol in combination, spaced five minutes apart. 726 F.3d at 1290; Ex. 1008, 493, Subjects and Methods, "part 2."

Based on such references, the Federal Circuit reversed a determination by the district court, and held that claims in a related patent directed to relevant *compositions* comprising 0.2% brimonidine and 0.5% timolol by weight would have been obvious, even taking into account certain secondary considerations such as unexpected results. 726 F.3d at 1291–93, 1295. The majority affirmed a determination by the district court, however, that method claim 4 of the '149 patent was not invalid as obvious over those references, even if the composition recited therein would have been obvious. *Id*. at 1293–94.

As discussed above, the majority in *Allergan* noted that Sandoz did not argue that a dose reduction without loss of efficacy would have flowed inherently from the recited combination product. *Id*. at 1294. The majority found it dispositive that the evidence of record did not "establish that the dose reduction 'from 3 to 2 times a day without loss of efficacy' limitation is an inherent property or a necessary result of the administration of 0.2% brimonidine and 0.5% timolol in a single composition." *Id*. at 1294 n.1.

In this case, Petitioner also cites Stewart, not mentioned in the Federal Circuit decision. Pet. 26, 28–29. Stewart evaluated the efficacy and safety of 0.005% latanoprost once daily, 0.2% brimonidine twice daily, or 2% dorzolamide twice daily, when "added to a topical β-blocker over three months of chronic therapy." Ex. 1009, 251–252, 254. Petitioner cites

Stewart for its statement that "[n]o difference statistically was observed in the three-month intraocular pressure between twice and three times daily dosing for brimonidine (P = 0.45) or dorzolamide (P = 0.28), so the results from the two dosing schedules were combined for this report." Pet. 26 (citing Ex. 1005 ¶ 47), 28; Ex. 1009, 253, Results.

Petitioner's contentions in this case suffer the same failures discussed in the majority decision in *Allergan*. Even assuming Petitioner persuaded us that Stewart disclosed that reducing a dose of 0.2% brimonidine from three times to twice daily resulted in "no difference in intraocular pressure effects" in some fashion, as Petitioner and its expert witness contend in a conclusory manner (Pet. 26; Ex. 1005 ¶ 47), that disclosure would not establish sufficiently that reducing the number of doses of a single composition comprising 0.2% brimonidine and 0.5% timolol from three to two times daily would have resulted necessarily in no loss of efficacy in the treatment of glaucoma or ocular hypertension. Considering Petitioner's arguments and cited evidence of record before us, Petitioner does not establish sufficiently that the "without loss of efficacy" limitation is an inherent property or a necessary result of administering the composition as recited in claim 4.

For the reasons given above, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing in its assertion that claim 4 of the '149 patent would have been obvious over DeSantis in view of Timmermans and further in view of Larsson and/or Stewart.

III. CONCLUSION

For the foregoing reasons, the information presented in the Petition and accompanying evidence does not establish a reasonable likelihood that Petitioner would prevail in showing the unpatentability of claim 4 of the '149 patent.

IV. ORDER

It is

ORDERED that the Petition is *denied* and no trial is instituted.

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