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

PATENT OWNER ALLERGAN SALES, LLC'S PRELIMINARY RESPONSE

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ALL2002	Letter dated March 9, 2015 from Petitioner's Counsel to Allergan
ALL2003	Application to Market a New or Abbreviated Drug or Biologic for Human Use naming Ferrum Ferro Capital, LLC as Applicant
ALL2004	Print-out of all of the pages of FFC's website
ALL2005	Print-out of all of the pages of Hyacinth Sloop Capital's website
ALL2006	Decker et al., "Hedge Funds Found a New Way to Attack Drug Companies and Short Their Stock," Bloomberg Business, March 20, 2015
ALL2007	Excerpts from Trial Transcript, *Allergan, Inc. v. Sandoz, Inc.,* Civil Docket No. 2:09-CV-97 (E.D. Tex.), 8/2/11 and 8/4/11
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ALL2011	E-mail correspondence from the Board dated June 15, 2015 regarding Patent Owner's request for authorization to file a motion for sanctions
ALL2012	*Allergan Inc. et al. v. Ferrum Ferro Capital, LLC and Kevin Barnes*, Complaint for Civil Extortion, Malicious Prosecution, and Unfair Business Practices Arising from U.S. Patent Laws, 8:15-cv-00992-FM)-PLA (C.D. CA), filed June 19, 2015.

I. INTRODUCTION

Patent owner, Allergan Sales, LLC ("Allergan"), submits this Preliminary Response in accordance with 35 U.S.C. § 313 and 37 C.F.R. § 42.107, responding to the Petition for *Inter Partes* Review of United States Patent No. 7,030,149 ("the '149 patent") filed by Ferrum Ferro Capital, LLC ("FFC").

FFC is a privately held venture fund. It is not in the pharmaceutical business. Indeed, from outward appearances it is simply a shell company with a mail box. It has no scientific, technical, regulatory, or marketing expertise to market a product for treating glaucoma, as set forth in the '149 patent. Instead, FFC filed its Petition for the purpose of extorting a settlement from Allergan in return for withdrawing its Petition.

FFC challenges only claim 4 of the '149 patent. This claim was previously the subject of an infringement lawsuit that Allergan filed against Sandoz, Inc., Alcon Laboratories, Inc., Alcon Research, Ltd., Alcon, Inc., and Falcon Pharmaceuticals, Ltd (collectively, "Sandoz"), as well as several other generic companies. *Allergan, Inc. v. Sandoz Inc. et al.,* 818 F. Supp. 2d 974 (E.D. Tex. 2011). The district court upheld the validity of claim 4 and the Federal Circuit subsequently affirmed. *Allergan, Inc. v. Sandoz Inc. et al.,* 726 F.3d 1286 (Fed. Cir. 2013) (Ex. 1012), rehearing and rehearing en banc denied (Fed. Cir. 2013).

The U.S. Supreme Court denied Sandoz's petition for a writ of certiorari. 134 S. Ct. 1764 (2014).

FFC's Petition relies entirely on the same prior art that the courts considered when rejecting Sandoz's validity challenge. FFC's Petition does not add any new analysis of the already-considered prior art. Instead, the Petition relies on a newly created and indefensible claim construction grounded on an intentional misrepresentation of the Federal Circuit's opinion. Specifically, FFC 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. Petition, pp. 12-14 and 16-17. FFC then argues that the dissent's claim construction is the broadest reasonable interpretation of claim 4. *Id.*

FFC's claim construction theory is objectively baseless and relies upon a willful mischaracterization of the dissenting opinion. The majority and the dissent adopted the ***same*** claim construction. Both construed the phrase "without loss of efficacy" as an affirmative limitation, and required that proposed combinations of prior art references meet this limitation. The majority and dissent simply parted company on whether the prior art combination disclosed the limitation.

The Board should reject FFC's baseless claim construction theory and the Petition itself. The entire Petition hinges on this claim construction theory. FFC

offers no evidence to prove obviousness in the event that its claim construction is rejected and the phrase "without loss of efficacy" is properly treated as a limitation. Accordingly, under the proper construction of claim 4, the Petition necessarily fails to establish a reasonable likelihood that claim 4 is unpatentable, and should be denied.

Even more fundamentally, FFC's misrepresentations and mischaracterizations represent an abuse of the IPR process. The Petition is not a *bona fide* attempt to challenge the patentability of claim 4. Rather, it is extortion, pure and simple. Pursuant to the Board's instructions sent via e-mail on June 15, 2015 (Ex. 2011), Allergan will consider seeking sanctions against FFC and its counsel pursuant to 35 U.S.C. §316(a) and 37 C.F.R. §42.12, including dismissing the Petition and awarding attorneys' fees to Allergan, following a decision on institution.

II. THE PETITION IS BASED UPON AN ERRONEOUS CLAIM CONSTRUCTION THAT READS THE LIMITATION "WITHOUT LOSS OF EFFICACY" OUT OF CLAIM 4

FFC misconstrues claim 4 by ignoring the phrase "without loss of efficacy." This construction is inconsistent with both the plain meaning of the claim and the Federal Circuit's construction of the claim in the *Sandoz* appeal. Because FFC's obviousness attack depends entirely on an incorrect claim construction, the Board should deny the Petition.

A. The Federal Circuit interpreted claim 4 to require no loss of efficacy

The '149 patent relates to compositions and methods for treating glaucoma or ocular hypertension. Ex. 1001, '149 patent, 1:7-9. Claim 4, the only claim at issue in this proceeding, recites (emphasis added):

> 4. A method of reducing the number of daily topical ophthalmic doses of brimonidine 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.

Claim 4 reflects the inventors' discovery that certain compositions containing brimonidine (an alpha-2-agonist) in combination with timolol (a beta-blocker), when applied topically to a patient's eye, could be dosed twice a day, rather than three times a day for brimonidine alone, without loss of efficacy. Prior to the inventors' discovery, patients treated twice a day with brimonidine alone, as opposed to three times a day, experienced a loss of efficacy after 7-8 hours—the so-called "afternoon trough." *See* 726 F.3d at 1294 ("[t]he record firmly establishes 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").

Allergan sells ophthalmic compositions recited in claim 4 under the trade name "COMBIGAN®." In 2008, Sandoz filed an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of COMBIGAN®. *Id.* at 1288. Other generic applications followed. Allergan sued Sandoz and the other generic manufacturers for patent infringement in the Eastern District of Texas under the Hatch-Waxman Act. *Id.* In that litigation, Sandoz alleged that claim 4 of the '149 was invalid as obvious over DeSantis, U.S. 5,502,052 ("DeSantis") in combination with (a) Timmermans et al., "Structure-Activity Relationships I Clonidine-Like Imidazolidines and Related Compounds," *Progress in Pharmacol.,* (1980) ("Timmermans") and (b) Larsson, "Aqueous Humor Flow in Normal Human Eyes Treated with Brimonidine and Timolol, Alone and in Combination," *Arch. Ophthalmol.* (2001) ("Larsson"). *Id.* at 1289-90. This is the same ground on which FFC relies in the present IPR Petition to challenge claim 4. *See* Petition, p. 23.

The district court rejected Sandoz's invalidity arguments, holding that claim 4 was not invalid as obvious, and the Federal Circuit affirmed. 726 F.3d at 1288. In upholding the validity of claim 4, both the district court and the Federal Circuit interpreted claim 4 to require treating a patient with a composition such that the patient could be dosed twice a day without loss of efficacy as compared to three

times a day. *Id.* at 1293-94. The Federal Circuit specifically stated that "without loss of efficacy" was a limitation of the claim:

> The evidence of record does 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 (emphasis added).

In rejecting Sandoz's validity challenge, the Federal Circuit found that Sandoz had not proven that the prior art disclosed the "without loss of efficacy" limitation required by claim 4:

> Sandoz attempts to rely on DeSantis's teaching that fixed-combination drug products will have a greater reduction in intraocular pressure than either drug alone. Even if we were to accept that this generalized teaching of DeSantis is true for all fixed-combination products, ***we cannot equate a greater reduction in intraocular pressure with "no loss of efficacy," as required by claim 4***, particularly where, as the trial court found, DeSantis did not provide clinical data on any of the possible combinations it disclosed.

Id. at 1294 (emphasis added).

B. The Federal Circuit's construction of claim 4 is also the broadest reasonable interpretation

For purposes of IPR, a claim is interpreted by applying its "broadest reasonable construction in light of the specification of the patent in which it

appears." 37 C.F.R. § 42.100(b). As such, the words of claim 4 are given their ordinary meaning as understood by one of skill in the art unless that meaning is inconsistent with the specification. *See In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997) (USPTO looks to ordinary meaning of claim terms, taking into account definitions or "enlightenment" from the specification). Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the inventor's description is likely the correct interpretation." *Garmin Int'l, Inc., v. Cuozzo Speed Technologies LLC*, IPR2012-00001, Paper No. 15, p. 4 (PTAB Jan. 9, 2013), citing *Renishaw PLC v. Marposs Societa per Azioni*, 158 F.3d 1243, 1254 (Fed. Cir. 1998). *See also Microsoft Corp. v. Proxyconn, Inc.*, Nos. 2014-1542 and 1543, slip op. at 9-10 (Fed. Cir. June 16, 2015) (rejecting Board's broadest reasonable construction of claims terms as "unreasonably broad in light of the language of the claims and the specification.").

Here, the Federal Circuit's construction of the phrase "without loss of efficacy" as an affirmative limitation of claim 4 is also the broadest reasonable interpretation of the claim because it "stays true to the claim language and most naturally aligns with the inventor's description," applying the standard set forth in *Garmin*. As noted above, claim 4 reflects the inventors' discovery that certain compositions containing brimonidine in combination with timolol, when applied topically to a patient's eye, could be dosed twice a day, rather than three times a

day, without loss of efficacy. This is consistent with the specification of the '149 patent, which describes experiments, including clinical trials, that "compare the safety and efficacy of twice-daily dosed brimonidine tartrate 0.2%/timolol 0.5% ophthalmic solution combination (henceforth referred to as Combination) with that of … three-times-daily dosed ALPHAGAN® (brimonidine tartrate ophthalmic solution 0.2% (henceforth referred to as Brimonidine) …." Ex. 1001, '149 patent, 4:7-15.

The phrase "without loss of efficacy" recognizes that not all ophthalmic compositions that include 0.2% brimonidine and 0.5% timolol can be applied twice a day without loss of efficacy as compared to 0.2% brimonidine compositions applied three times a day. For example, in developing the claimed method, Allergan's inventors discovered that certain formulations containing 0.2% brimonidine and 0.5% timolol, in combination with a preservative known as Purite (the "Purite compositions"), were unstable. Accordingly, they could ***not*** be applied twice a day without loss of efficacy. See Ex. 2007-2010. The "without loss of efficacy" language in claim 4 serves the function of excluding compositions like the Purite compositions, and thus delineates the metes and bounds of the claim.

Construing claim 4 to require administering compositions twice a day "without loss of efficacy" relative to three times a day dosing is consistent with the

claim language itself and the specification, and reflects the inventors' description of their invention. It cannot be ignored without reading this language out of the claim entirely—a result that is at odds with the broadest reasonable construction standard. *See In re Suitco*, 603 F.3d 1255, 1260 (Fed. Cir. 2010) (PTO's construction that ignored plain meaning of claim language was "unreasonably broad"). Accordingly, the broadest reasonable construction of claim 4—indeed, the only reasonable construction of claim 4—is that the phrase "without loss of efficacy" is an affirmative limitation, as the Federal Circuit held, and excludes compositions that lack this property. *See Microsoft*, slip op. at 15 n. 1 (noting that the court would reach the same construction for a claim limitation under both the broadest reasonable construction standard and the *Phillips* standard).

C. FFC mischaracterizes the Sandoz dissent to support a construction that ignores the "without loss of efficacy" limitation in claim 4

FFC argues that the phrase "without loss of efficacy" is not a limitation in claim 4 under the broadest reasonable construction. Petition, p. 16. FFC attempts to reconcile its position with the Federal Circuit's construction of claim 4 by positing that the Federal Circuit construed the claim under the narrower *Phillips* standard. To support its position, FFC argues that the dissent in the *Sandoz* appeal adopted a broader interpretation of claim 4 that did not treat the phrase "without loss of efficacy" as a claim limitation, and that this allegedly broader interpretation

is the broadest reasonable interpretation of claim 4 applicable in the present IPR proceedings. *Id.*, pp. 13-14. FFC also offers testimony from its expert, Dr. Palmieri. Ex. 1005, ¶¶21-22. Neither supports FFC's proposed construction.

FFC's characterization of the *Sandoz* dissent's construction of claim 4 is simply wrong. In fact, the opposite is true. The *Sandoz* dissent adopted the ***same*** construction as the majority. The dissent wrote:

> The majority's outcome appears to rest, therefore, on the notion that claim 4 was not obvious because it ***claims*** the result of twice-a-day dosing—avoiding "a loss of efficacy in the afternoon." *See* Maj. Op. 1294.

726 F.3d at 1296 (emphasis added).

Both the majority and dissent treated the language "without loss of efficacy" as a limitation. They differed with respect to whether treating a patient with a composition comprising 0.2% brimonidine and 0.5% timolol inherently achieved the claimed "without loss of efficacy" result. In arguing that claim 4 should be invalid, the dissent cited to *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.,* 246 F.3d 1368, 1376 (Fed. Cir. 2001) for the proposition that "[n]ewly discovered results of known processes directed to the same purposes are not patentable because such results are inherent." The dissent did not argue that the phrase "without loss of efficacy" was not a limitation. Rather, the dissent argued that the limitation was inherently present in the prior art.

The majority's rebuttal to the dissent underscores that both the majority and dissent viewed "without loss of efficacy" as a claim limitation, and that their differences related to whether the evidence of record proved that compositions containing 0.2% brimonidine and 0.5% timolol inherently (i.e. necessarily) could be applied twice a day, rather than three times a day, without loss of efficacy:

> The dissent would find claim 4 obvious on the grounds that it merely claims the result of treatment with an obvious composition. In 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 …. We agree with the dissent that the ***inherency doctrine*** may apply to an otherwise obvious claim as well. There is, however, a problem with applying that doctrine in this case. The evidence of record does 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 (emphasis added).

FFC's reliance on testimony from its expert, Dr. Palmieri, is equally unpersuasive. Dr. Palmieri also relies on a mis-reading of the *Sandoz* dissent. *See* Ex. 1005, ¶21. Dr. Palmieri, therefore, merely parrots FFC's incorrect claim construction.

D. FFC offers no evidence that its proposed combination describes compositions that can be applied twice a day "without loss of efficacy"

Both the majority and dissent in the *Sandoz* appeal construed "without loss of efficacy" as an affirmative claim limitation. That construction is both the *Phillips* construction and the broadest reasonable interpretation of claim 4. The majority held that on the record before it, there was no evidence that a composition comprising 0.2% brimonidine and 0.5% timolol necessarily could be applied twice a day without loss of efficacy relative to three times a day dosing. 726 F.3d at 1294 n. 1. The same is true here.

The Petition relies upon the same prior art references that were the subject of the *Sandoz* appeal (DeSantis, Timmermans, and Larsson). Both the Petition and Dr. Palmieri merely identify individual components of claim 4, and speculate as to why they might be combined. *See* Petition, pp. 20-30; Ex. 1005, ¶¶25-49. Nowhere, though, is there ***any*** evidence establishing that the proposed combinations necessarily would meet the "without loss of efficacy" requirement set forth in claim 4. This is consistent with the fact that FFC's proposed interpretation of claim 4 completely reads out this limitation.

Because FFC did not regard the "without loss of efficacy" language as a limitation, it failed to offer evidence to prove that the prior art references, if combined as Petitioner urges, disclose this limitation. This failure is fatal to the Petition, especially given that there are compositions (e.g., the Purite compositions,

discussed *supra* at 10) containing 0.2% brimonidine and 0.5% timolol that do not meet the "without loss of efficacy" requirement set forth in claim 4.

For at least these reasons, FFC has failed to demonstrate a reasonable likelihood that claim 4 is unpatentable. The Petition, therefore, should be denied.

III. FFC IS ABUSING THE IPR PROCESS

This is not a *bona fide* IPR petition. Rather, FFC filed the petition based on an intentional misrepresentation of the earlier Federal Circuit opinion so that FFC could then extort a settlement from Allergan by offering to withdraw the petition.

A. FFC is not a legitimate challenger

FFC is a privately held venture fund. Petition, p. 4; Ex. 2002, p. 1. Kevin Barnes is one of FFC's owners. Petition, p. 4. FFC has no principal place of business, maintaining merely a mail drop box located at 717 N. Union Street, #78, Wilmington, Delaware 19805. *See* Ex. 2003. A photo of that location is available at https://maps.google.com/:

Consistent with its "mail drop box" "place of business," FFC's website, http://www.ferrumferro.com, is a shell, with no information available on it about any of FFC's supposed activities. A print-out of all of the pages of FFC's website is included as Exhibit 2004. Indeed, FFC's website is almost identical to the

website of another venture fund owned by Mr. Barnes, which he has named Hyacinth Sloop Capital, LLC. A print-out of all of the pages of Hyacinth Sloop Capital's website, http://www.hyacinthsloop.com, is included as Exhibit 2005.

Despite the "mail drop box" nature of its business, on March 9, 2015, the same day it filed the IPR Petition, FFC sent a letter to Allergan in which FFC falsely represented to Allergan that FFC was prepared to "seek FDA approval via a Paragraph III ANDA filing to produce and market a generic brimonidine tartrate/timolol maleate ophthalmic solution with [an unnamed] Contract Manufacturing Partner ("CMP")." Ex. 2002, p. 2. FFC attached to the March 9, 2015 letter, a "proposed FDA filing" for generic brimonidine tartrate/timolol maleate ophthalmic solution. Ex. 2003. However, the proposed filing is clearly fake.

In the fake "proposed FDA filing," FFC named its fictitious generic brimonidine tartrate/timolol maleate ophthalmic solution "Combivious," apparently as some kind of play on the words "COMBIGAN®" and "obvious." *Id.* The fictitious ANDA filing further lists its date of submission as "03/XX/2015." *Id.*

There is no evidence that FFC has facilities or personnel capable of conducting research and development to create a generic formulation of Allergan's COMBIGAN®, or any other pharmaceutical drug. Moreover, there is no evidence

that FFC has hired regulatory or other personnel necessary to prepare, submit and prosecute an ANDA application for any generic drug with the FDA.

From all appearances, FFC has no funding, no research and development facilities, and no established partnerships capable of formulating such a generic solution.

B. FFC used the IPR Petition to threaten Allergan

The March 9, 2015 letter (Ex. 2002) did not stop with the fake FDA filing. In an effort to place additional pressure on Allergan, FFC's March 9, 2015 letter highlighted the fact that "upon institution of the IPR by the PTAB, formerly time-barred defendants, such as [Allergan's Competitors], will have the opportunity to file petitions of their own in the ongoing invalidation proceedings." Ex. 2002, p. 2. FFC's letter further stated that "Allergan should be mindful that FFC's IPR could result in [Allergan's Competitors] joining the fast-track challenge of the '149 patent," and that FFC "is confident that at a minimum, the IPR petition for the '149 patent presents a significant and terminal threat to Allergan's exclusive rights to distribute Combigan." *Id.,* p. 2.

After pointing out the threat to Allergan's legitimate business that its IPR Petition represented, FFC stated in the March 9, 2015 letter that it "firmly believes that a company such as Allergan should be given ***a single opportunity*** to support FFC's core social and investment interests before other time-barred producers are able to file for joinder in the '149 Patent IPR, and before FFC files additional IPR

petitions against the COMBIGAN® patents and proceeds with a Paragraph III filing. As such, FFC is amenable to discussing an immediate and confidential settlement with Allergan." *Id.,* p. 3 (emphasis added). The letter set a deadline of March 18, 2015 for Allergan to contact FFC to discuss this "single opportunity" to confidentially settle the IPR petition FFC filed. *Id.*

On March 18, 2015, Allergan contacted FFC to obtain further information regarding FFC's demands. In response, FFC, including Mr. Barnes, informed Allergan that it would not disclose its demands unless Allergan first signed a non-disclosure agreement. The draft non-disclosure agreement initially provided by FFC, in addition to requiring confidentiality of settlement discussions, contained a term that barred the use of anything learned under the non-disclosure agreement as a basis for bringing an action against Mr. Barnes or FFC. Allergan refused to sign such an NDA, but ultimately did enter into a modified NDA to speak to Mr. Barnes confidentially.

While these activities were ongoing, Mr. Barnes–FFC's founder–publicly stated that he sees "multiple pathways to monetization" of the IPR filing against the '149 patent. Ex. 2006.

C. Allergan has sued FFC

Rather than succumb to FFC's tactics, Allergan filed a complaint against FFC and Mr. Barnes in the United States District Court for the Central District of

California on June 19, 2015, alleging attempted civil extortion, malicious prosecution, and violation of California Bus. & Prof. Code §§ 17200 *et seq*. A copy of the complaint is attached as Exhibit 2012.

D. FFC is abusing the IPR process

FFC is not a legitimate enterprise. It filed its IPR Petition in bad faith. Even though the statute permits "any person" to file an IPR Petition, the statute does not authorize parties to misrepresent their identities and intentions, and subvert the IPR process by using it as an extortion tool.

IV. CONCLUSION

For at least the reasons set forth above, Allergan requests that the Board deny the Petition.

Respectfully submitted,

Date:/June 22, 2015/

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4) and 42.205(b), the undersigned certifies that on June 22, 2015, a complete and entire copy of this Patent Owner Allergan Sales, LLC's Preliminary Response were provided via electronic service, to the Petitioner by serving the correspondence address of record as follows:

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