United States District Court,
N.D. Illinois, Eastern Division.

ABBOTT LABORATORIES,
Plaintiff.
v.
SANDOZ, INC,
Defendant.

Dec. 4, 2007.

Background: Patent owner brought action against competitor alleging infringement of patents relating to extended release formulations of clarithromycin. Owner brought motion for summary judgment.

Holdings: The District Court, David H. Coar, J., held that:
(1) court could entertain new arguments regarding patent claim construction;
(2) patent claim differentiation presumption had not been rebutted;
(3) juxtaposition of polymers and excipients did not, alone, counsel for construing "pharmaceutically acceptable polymers" narrowly;
(4) phrase, "substantially equivalent to that of the immediate release composition," with regard to mean minimum plasma concentration (C-min) values meant not different than;
(5) genuine issues of material fact were present from which reasonable factfinder could conclude that maltodextrin present in accused product extended release on its own or was component responsible for matrix's release-extending ability;
(6) declaration of competitor's expert, based on his opinion, nothing more, was insufficient to refute substantial evidence presented by patent owner that pharmacokinetic (PK) limitations of patent were not inherent to prior art;
(7) purported false statement made in patentee's declaration to Patent and Trademark Office (PTO) regarding "statistically significantly lower" mean maximum plasma concentration (C-max) of extended release formulation of clarithromycin was not material to whether claimed invention differed from prior art immediate release formulation; and
(8) reasonable examiner could have considered undisclosed adverse study results on extended release formulation of clarithromycin important in deciding whether to allow patent to issue.

Motion denied in part and granted in part.

6,102,803, 6,551,616, 6,872,407, 7,056,531. Cited.

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Keith D. Parr, David B. Abramowitz, James T. Peterka, Kevin Michael Nelson, Myoka Miki Kim, Scott B. Feder, Locke Lord Bissell & Liddell LLP, Chicago, IL, for Defendant.

MEMORANDUM OPINION AND ORDER

DAVID H. COAR**, District Judge.**

Abbott Laboratories ("Abbott") filed a complaint against Sandoz, Inc. ("Sandoz") in 2005 alleging that Sandoz was about to market a generic extended release form of the antibiotic drug, clarithromycin, thereby infringing upon Abbott's U.S. Patent Nos. 6,010,718 (the "'718 patent"), 6,551,616 (the "'616 patent") and 6,872,407 (the "'407 patent") relating to its BIAXIN (R) XL product. Abbott sought a declaratory judgment that such acts would constitute infringement. On June 25, 2007, Abbott filed an amended complaint that included allegations of willful infringement against Sandoz because during the time since the filing initial complaint, Sandoz actually launched its product.

Before the Court now are Sandoz's Motion for Summary Judgment of Noninfringement and/or, Alternatively, Invalidity of Certain Claims of the ' 407 Patent and Abbott's Motion for Summary Judgment or, in the Alternative, for Summary Adjudication. Sandoz has also filed three additional motions, of which only the first two will be dealt with in this opinion: Motion to Strike the Supplemental Declaration of Professor Stanley S. Davis and the Declaration of Yihong Qiu; Motion to Strike or in the Alternative, Disregard certain paragraphs of Abbott's Rule 56.1 Statement; and a Rule 12(b)(6) Motion to Dismiss Plaintiff's Claims of Willful Infringement or in the Alternative, Rule 12(c) Motion For Judgment on the Pleadings. The parties have since dismissed their respective claims and counterclaims regarding the '407 patent and Abbott has dismissed its claim that Sandoz's infringement of the '616 patent was willful; thus leaving only the '718 patent at issue. Thus, Sandoz's Motion for Summary Judgment of Noninfringement and/or, Alternatively, Invalidity of Certain Claims of the '407 Patent is denied as moot. For the reasons stated below, Abbott's Motion for Summary Judgment or, in the Alternative, for Summary Adjudication is DENIED in part and GRANTED in part.

I. BACKGROUND

Abbott's complaint against Sandoz alleges patent infringement. Sandoz manufactures and markets generic versions of branded pharmaceuticals in the United States. Abbott sought a declaratory judgment that if Sandoz went to market with its generic products, it would infringe the '718, '616, and '407 patents. Each of these patents pertains to Abbott's branded antibiotic product, BIAXIN (R) XL, which is an extended release formulation of clarithromycin, an erythromycin derivative. Despite the imposition of this action, Sandoz entered the market for generic clarithromycin. Upon Abbott's motion, this Court granted a preliminary injunction enjoining Sandoz from further participation in the generic clarithromycin market and ordering Sandoz to recall the distributed pharmaceuticals. Abbott has since amended its complaint to include allegations of actual infringement and prayers for damages.

Clarithromycin is a macrolide antibiotic used to treat bacterial infections, particularly those of the skin and upper respiratory system. Until its patent expired on May 23, 2005, Abbott held a patent on the immediate release version of clarithromycin, marketed as BIAXIN (R). Abbott began marketing BIAXIN (R) in the United States in approximately 1991. In 2000, Abbott was issued two formulation patents (the '616 and the

'718 patents) on an extended release formulation of clarithromycin. Abbott began marketing this extended release formulation under the name BIAXIN (R) XL in 2000. As of May 2005, Abbott estimated that BIAXIN (R) XL accounted for approximately 70% of the sales in the BIAXIN (R) market. Generic competitors entered the market for immediate release clarithromycin on May 24, 2005.

Abbott also filed separate actions and sought separate preliminary injunctions against generic competitors Andrx Pharmaceuticals, Inc. ("Andrx") and Teva Pharmaceuticals USA, Inc. ("Teva"). This Court held hearings and entered preliminary injunction orders against Teva and against Andrx. The Federal Circuit Court of Appeals vacated the preliminary injunction order against Teva on June 22, 2006. Teva and Abbott subsequently entered into a settlement agreement. Andrx also appealed the preliminary injunction order entered against it. The Federal Circuit affirmed that preliminary injunction against Andrx on January 5, 2007.

Abbott sought to preliminarily enjoin Sandoz's intrusion upon the market for extended release clarithromycin products. This Court initially denied Abbott's motion for a temporary restraining order against Sandoz because it found that due to the practical effect of the Federal Circuit's holding in the Teva case, it could not issue a temporary restraining order based on the limited record before it. Abbott Laboratories v. Sandoz, Inc., No. 05 C 5373, 2006 WL 3718025 (N.D.Ill. Dec. 15, 2006); *see also* Abbott Laboratories v. Andrx Pharmaceuticals, Inc., 452 F.3d 1331 (vacating Abbott Laboratories v. Andrx Pharmaceuticals, Inc., et. al., 2005 WL 1323435 (N.D.Ill. June 3, 2005)). Abbott then sought a preliminary injunction against Sandoz. After a full hearing and much consideration, this Court construed the relevant claims of the '718 patent and found (for purposes of the preliminary injunction) that Sandoz had indeed infringed upon the '718 patent. Abbott Laboratories v. Sandoz, Inc., 500 F.Supp.2d 807 (N.D.Ill.2007) (referred to hereinafter as the "injunction opinion"). This Court also preliminarily found that Sandoz did not raise sufficiently persuasive evidence of patent invalidity to overcome the presumption that the '718 patent is valid. *See* id. Those findings and the preliminary injunction order are currently on appeal. Now both Abbott and Sandoz have moved for summary judgment on the issue of infringement as well as other ancillary matters.

II. STANDARD FOR MOTION FOR SUMMARY JUDGMENT

Summary judgment will be granted only when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. Pro. 56(c). A genuine issue of material fact exists only if there is sufficient evidence for a reasonable finder of fact to return a verdict for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A fact is material if it can affect the outcome of the case under the applicable substantive law. Id. When reviewing a motion for summary judgment, the court must view the facts in the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor. Schuster v. Lucent Technologies, Inc., 327 F.3d 569, 573 (7th Cir.2003).

The movant bears the burden of establishing that no genuine issue of material fact exists. Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). If the movant meets this burden, the non-movant must set forth specific facts demonstrating that there is a genuine issue for trial. Fed. R. Civ. Pro. 56(e); Celotex, 477 U.S. at 324, 106 S.Ct. 2548. To successfully oppose the motion, the non-movant must designate these facts in affidavits, depositions, answers to interrogatories, or admissions; the non-movant cannot rest on the pleadings alone. Celotex, 477 U.S. at 324, 106 S.Ct. 2548.

III. DISCUSSION

A. Motions to Strike

As an initial matter, Sandoz moves this Court to strike the supplemental declaration of Professor Stanley S. Davis and the declaration of Yihong Qiu because they are untimely and improper attempts to rehabilitate certain previous deposition testimony and other evidence. Sandoz also moves this Court to strike or in the alternative, disregard certain paragraphs of Abbott's rule 56.1 statement. A court has broad discretion in requiring adherence to local rule 56.1. *See* Koszola v. Board of Educ. of City of Chicago, 385 F.3d 1104, 1108 (7th Cir.2004). This Court has stressed in the past that it will disregard statements of fact by either party that are not supported by the record or that are mere legal conclusions. Norris v. Burlington Northern Santa Fe, No. 01C8548, 2003 WL 1810853 at (N.D.Ill.2003). The Court agrees with Sandoz that paragraphs 39, 45, 46, 47, 51, 52, 53, 56, 58, 59, 60, 61, 64, 68, 69, 73, 74, 79, and 80 of Abbott's rule 56.1 statement all contain legal conclusions, argument, and/or opinion drafted more to persuade the Court rather than to inform it. Thus, this Court GRANTS Sandoz's motion and has disregarded those elements of each of the paragraphs listed above that exhibit legal conclusions or opinions rather than fact. The Court will not strike them because the majority of these paragraphs contain fact in addition to improper conclusions and opinion.

As for the supplemental declaration of Davis and the declaration of Qui, this Court found the evidence disputed in those declarations was not determinative in deciding the motions for summary judgment. Thus, these motions are DENIED as moot.

B. Infringement

[1] [2] Patent infringement inquiries proceed in two steps. MBO Laboratories, Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1329 (Fed.Cir.2007). First, a court will determine, as a matter of law, the correct scope and meaning of the disputed claims. Id. Then, the court will compare the properly construed claims to the accused device and ascertain whether that device contains every limitation of the relevant claims or substantial equivalents thereof. Id. Sandoz contends that when properly construed, none of the claims of the '718 patent are infringed by its product. This Court has already construed the claims of the '718 patent in its injunction opinion. In doing so, the Court took into consideration the Federal Circuit opinion that held this Court's previous claim construction to be flawed. *See* 473 F.3d at 1213. Sandoz contends that this Court's most recent construction of the claims at issue was merely preliminary, flawed and should therefore be reconstrued. Sandoz is correct to the extent that the construction offered in the injunction opinion was merely preliminary; not final or conclusive. Therefore, the Court will entertain Sandoz's new arguments regarding claim construction.

[3] [4] [5] [6] [7] There is a " 'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). Claim terms should therefore be accorded their ordinary meaning unless the patentee "clearly set forth a definition of the disputed claim term in either the specification or prosecution history." Id. The ordinary and customary meaning of a claim term refers to that meaning a person of ordinary skill in the art in question would attach to the term. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed.Cir.2005) (en banc). Even though a term may have a distinct ordinary meaning to a person of ordinary skill in the art, a patentee may still "expressly define terms used in the claims." Id. at 1321. When interpreting an asserted patent claim, the court should look first to the intrinsic evidence of record, which is the patent itself, including its claims, specification, and complete prosecution history. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995)

(en banc). This intrinsic evidence is the primary and most significant source of the legally operative meaning of any claim language that is in dispute. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir.1996). However, a court may also consider extrinsic evidence such as expert declaration evidence provided from the parties. Id. at 1584.

As a threshold matter, the court must determine what constitutes a person of ordinary skill in the art for the purposes of the '718 patent. Previously, this Court defined a person of ordinary skill in the art as someone with "a Ph.D. in pharmaceutical chemistry or a related field and at least two years experience in formulating drugs" or a skilled artisan with "a Bachelor's or Master's Degree in an appropriate field and substantially more practical experience in formulating drugs." Teva, No. 05-1490, 2005 WL 1323435, at *7, n. 3. Neither party suggested that the Court should modify its previous definition and therefore, that definition was adopted and used in construing the claims in the injunction opinion and is incorporated and adopted herein.

1. Claim Construction

(a) Claim 1

[8] First, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314. Claim 1 reads as follows:

A pharmaceutical composition for extended release of an erythromycin derivative in the gastrointestinal environment, comprising an erythromycin derivative and from about 5 to about 50% by weight of a pharmaceutically acceptable polymer, so that when ingested orally, the composition induces statistically significantly lower mean fluctuation index in the plasma than an immediate release composition of the erythromycin derivative while maintaining bioavailability substantially equivalent to that of the immediate release composition of the erythromycin derivative.

U.S. Patent No. 6,010,718 col. 11 ll.28-38 (filed Apr. 11, 1997).

None of the following elements are disputed and each term is assigned its plain and ordinary meaning as understood by a skilled artisan. The term "pharmaceutical composition" means an aggregated product formed from two or more substances for use as a drug in medical treatment. The term "gastrointestinal environment" means the organs that make up the GI tract, including the stomach, intestines, and to a lesser extent the mouth, pharynx, esophagus and the anus. The term "mean fluctuation index" means the average degree of fluctuation ((Cmax Cmin)/Cavg) over a specified period of time (usually twenty-four hours) by which pharmacokineticists can distinguish rates of release into the plasma.

The term "bioavailability" in the context of the '718 patent means the total exposure of the erythromycin derivative in the bloodstream as measured by the logarithm-transformed area under the plasma concentration-time curve ("AUC"), which is a mathematical and visual representation of the aggregate amount of the drug reaching systemic circulation over a given period of time. Bioavailabilty does not encompass both the rate and effect of release because extended release and immediate release formulations have different rates of release by definition. That is also why the claim calls for a lower mean fluctuation index for the extended release formulation versus the immediate release formulation-to highlight the importance of changing the rate of release without changing the overall amount of erythromycin derivative in the plasma. Both parties agree that in claim 1, the term "substantially equivalent to that of the immediate release composition" means the extended release composition AUC values must be between 80% to 125% within a 90% confidence level as compared to the immediate release composition AUC values.

The parties do not dispute that clarithromycin is an "erythromycin derivative." The extended release composition at issue is designed for release in the gastrointestinal environment (e.g., oral administration). The patent specification defines "erythromycin derivative" as meaning "erythromycin having no substituent groups, or having conventional substituent groups, in organic synthesis, in place of a hydrogen atom of the hydroxy groups and/or a methyl group of the 3'-dimethylamino group, which is prepared according to the conventional manner." U.S. Pat. No. 6,010,718, at col. 3:ll. 34-39. The patent specification further states that the "pharmaceutically active compound" of the composition "is an erythromycin derivative." *Id.,* at ll. 58-61. It goes on, "[p]referably, the erythromycin derivative is 6-O-methoxy erythromycin A, known as clarithromycin." *Id*. The language of the claim is definite ("an erythromycin derivative") but not closed. It does not specify that the pharmaceutically active compound "is a member selected from the group consisting of A, B, and C." Thus, clarithromycin is an erythromycin derivative under this meaning.

Sandoz's product uses clarithromycin as its pharmaceutically active compound. As noted in an earlier decision, Abbott defined "erythromycin derivative" in the '718 patent in such a way as to exclude azithromycin. Azithromycin is the common name for 9a-aza-9a-methyl-9-deoxo-9ahomoerythromycin A. Pfizer, the patent holder on azithromycin, describes azithromycin as a "broad spectrum antimicrobial compound derived from erythromycin A." WO 95/30422 (the "'422 patent"). It is likely that Abbott consciously defined "erythromycin derivative" in claim 1 of the ' 718 patent so as to avoid infringing Pfizer's existing '422 patent.

[9] The primary dispute in this matter is over the meaning of the term "pharmaceutically acceptable polymer." The term is not defined in the claim. After engaging in an extensive analysis in which the arguments of both litigants, the applicable law and available facts, and the Federal Circuit's decision in Abbott Labs. v. Andrx Pharm. Inc., 473 F.3d 1196 (2007) were all considered, this Court held that a person of ordinary skill in the art who read the entire '718 patent would construe the term "pharmaceutically acceptable polymer" in claim 1 to mean "any polymer, which within the scope of sound medical judgment is suitable for use in pharmaceutical compositions involving contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections, and is capable of forming a matrix to extend drug release into the bloodstream." Such a "pharmaceutically acceptable polymer" must constitute 5 to 50% by weight of the product. Sandoz contends that this construction is incorrect and that after a fresh look and consideration of arguments that were not previously before any court, this Court should be persuaded to accept the construction attributed to the term in Abbott Labs. v. Andrx Pharm. Inc., 452 F.3d 1331 (2006). Sandoz construes the term to be "a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acids copolymers, maleic anhydride/methyl vinyl either copolymers and derivatives and mixtures thereof," based upon this Court's previous construction in Abbott, 2005 WL 1323435 at *6.

[10] [11] [12] [13] [14] The first place to look when inquiring into the meaning of a claim term is the claim language. Phillips, 415 F.3d at 1314. Even the claims of a patent that are not at issue in an infringement action are nonetheless part of intrinsic evidence to be considered during claim construction. Claim 1 of the '718 patent requires a composition that includes a "pharmaceutically acceptable polymer." col. 11:31-32. Claim 2 depends from claim 1 and further requires that the pharmaceutically acceptable polymer be "a hydrophilic water-soluble polymer." Id., col. 11: 39-40. Claim 3 depends from claim 2 and requires that "the polymer is selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose,

hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof." *Id.,* col. 11: 42-47. "The presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. Furthermore, independent claims are generally given broader scope so as to avoid rendering corresponding dependent claims redundant. Id. at 1324 (citing Dow Chem. Co. v. United States, 226 F.3d 1334, 1341 (Fed.Cir.2000)). Therefore, the language of the claims and the doctrine of claim differentiation imply that the "pharmaceutically acceptable polymer" limitation in claim 1 is most likely broader than the "hydrophilic water-soluble polymer" limitation described in claim 2 and involves more compounds than those contained in claim 3.

[15] Sandoz contends that the doctrine of claim differentiation merely creates a presumption, North American Vaccine v. American Cyanamid Co., 7 F.3d 1571, 1577 (Fed.Cir.1993), and that here the presumption is rebutted given that "the written description unequivocally discloses only one embodiment of the claimed invention," which is of a "pharmaceutically acceptable polymer" that is water soluble, hydrophilic, and selected from the specified group of polymer classes. Sandoz's Memorandum in Opposition, p. 6 (citing Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1367-68 (Fed.Cir.2000)). When the claim does not define a term, a court will turn to the specification. The claims 'must be read in view of the specification, of which they are a part, ...' because "it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (citing Vitronics, 90 F.3d at 1582). Here, the patent specification provides as follows:

The pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof. Preferably, the polymer is selected from hydroxypropyl cellulose, hydroxypropylmethyl cellulose, and methyl cellulose. More preferably, the polymer is hydroxypropylmethyl cellulose.Most preferably, the polymer is a low viscosity hydroxypropylmethyl cellulose with viscosity ranging from about 50 cps to about 200 cps. The most preferred low viscosity polymer is a hydroxypropylmethyl cellulose with a viscosity of about 100 cps, commercially available under the Tradename Methocel(TM) K 100 LV from The Dow Chemical Company.

'718 patent, col. 3: l. 65-col. 4: l. 14.

Previously, this Court found that the phrase "selected from the group consisting of" in the specification signaled a Markush group, which limited the term "pharmaceutically acceptable polymer" to the polymers listed. Claim drafters often use the term "group of" to signal a Markush group, which lists specified alternatives in a patent claim. The typical form of a Markush group is "a member selected from the group consisting of A, B, and C." *See Manual of Patent Examining Procedure* s. 803.2 (2004) (quoted in Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1372 (Fed.Cir.2005)). The Federal Circuit explained that while a Markush group can be used to limit a claim to a list of specified alternatives, a Markush group has no "meaning within the context of a written description of a patent" and a court should not rely on Markush group language to limit the construction of a claim term to certain items listed in the written description. 473 F.3d at 1210. Sandoz is free to disagree with the Federal Circuit's interpretation of the law, but it is folly to deny that it is what that court held.

[16] The presumption afforded by the doctrine of claim differentiation is not rebutted on the facts presented

here. As explained in the previous opinion and above, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. Furthermore, independent claims are generally given broader scope so as to avoid rendering corresponding dependent claims redundant. Id. at 1324 (citing Dow Chem. Co. v. United States, 226 F.3d 1334, 1341 (Fed.Cir.2000)). Therefore, the language of the claims and the doctrine of claim differentiation imply that the "pharmaceutically acceptable polymer" limitation in claim 1 is most likely broader than the "hydrophilic water-soluble polymer" limitation described in claim 2 and involves more compounds than those contained in claim 3. "The presumption is especially strong when the limitation in dispute is the *only meaningful difference* between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." SunRace Roots Enter. Co., Ltd. v. SRAM Corp., 336 F.3d 1298, 1303 (Fed.Cir.2003) (citation omitted) (emphasis added).

In North American Vaccine v. American Cyanamid Co., the Court held that "[w]hile it is true that dependent claims can aid in interpreting the scope of claims from which they depend, they are only an aid to interpretation and are not conclusive. The dependent claim tail cannot wag the independent claim dog." 7 F.3d at 1577. That holding is inapposite here. There, the patentee attempted to construe an independent claim to include difunctional molecules (when it had only claimed monofunctional molecules) by pointing to difunctional properties of products formed from specific molecules mentioned in the dependent claim. Id. There, the monofunctional limitation was readily apparent from the independent claim itself. Id. Here, in stark contrast, the independent claim is silent as to the "pharmaceutically acceptable polymer" limitation. So even though the North American Vaccine court noted that nowhere in the specification were difunctional molecules disclosed to be included in the independent claim, such absence was not the conclusive factor in determining the scope of the independent claim.

Sandoz also cited Kraft Foods, Inc. v. Int'l Trading Co. in support of its argument that the presumption of claim differentiation is rebutted in this case. 203 F.3d 1362. In Kraft, claim 1 was an independent claim that contained a limitation (amongst others) that a back panel of a food package be "relatively stiff." Id. at 1367. Claim 2 was another independent claim that did not contain the "relatively stiff" limitation, but did contain other limitations. Id. at 1365. Kraft took the position that the claim differentiation doctrine proved that the two claims were different and the "relatively stiff" limitation *should not* be read into claim 2. Id. at 1368. The Court disagreed and held that the limitation was read into claim 2 and that Kraft could not depend on the doctrine of claim differentiation because in both the written description and prosecution history, the only embodiment of the invention ever offered contained a relatively stiff back panel. 203 F.3d at 1367.

There are several differences between the circumstances surrounding Kraft and those present here that support this Court's continued application of the claim differentiation doctrine. First, unlike here, where the only difference in the claims is in regard to the "pharmaceutically acceptable polymer" limitation, the two claims in Kraft contained several other limitations. Id. at 1365. Thus, if the doctrine were rebutted and the claim were construed according to Sandoz's method, the dependent claims would become entirely superfluous and redundant. That result did not occur in Kraft. Second, the claims at issue here are independent and dependent whereas in Kraft, the claims were both independent. Title 35 U.S.C. s. 112 explains that a dependent claim must contain a further limitation than the independent claim from which it depends. *See* Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed.Cir.2006). Thus, disregarding the doctrine here would render the dependent claims invalid. *See* id.

[17] There is no question that Kraft stands for the proposition that the written description can overcome the

claim differentiation presumption in certain circumstances. Id. at 1368. But those circumstances are not present here. As the cases above show, the presumption will survive where the effect of ignoring the doctrine would render the dependent claims superfluous or even invalid, where the only embodiment of the invention provided in the description is the same one appearing through the independent and dependent claims. It should be noted that Sandoz failed to cite to a single case in which a court found the doctrine rebutted where the dependent claim's only limitation was the element separating it from the independent claim. In fact, in another patent case dealing with construction of an independent claim element, the Federal Circuit went to great lengths to construe an independent claim broader than it otherwise appeared from the specification and prosecution history. *See* Dow Chemical Co. v. United States, 226 F.3d 1334 (Fed.Cir.2000) cited in 5A-18 *Chisum on Patents* s. 18.03[6][a]. That was done mainly because the court found some support for the broader interpretation in the specification but also because the dependant claim contained a narrower limitation than the claim from which it depended. 226 F.3d at 1339-42.

Sandoz also takes issue with Abbott's use of the phrase "a pharmaceutically acceptable polymer is" and this Court's unwillingness to interpret it as unambiguous definitional language. Sandoz is of the opinion that because no authority exists for the proposition that a lexicographer must use the same method of defining terms throughout a patent and because of that, this Court erred in not concluding the phrase "the pharmaceutically acceptable polymer is" did not signal definition the term. Sandoz is correct that no authority exists for that proposition, but this Court never depended on such a proposition in reaching its conclusion. Instead, what this Court stated was that it rejected the assertion "that the phrase 'the pharmaceutically acceptable polymer is' signals the definition *here,* not because it is not explicit definitional language per se, but rather because Abbott used explicit definitional language elsewhere in the patent description to define terms susceptible to different meanings but did not use similar explicit language here." Abbott Labs. v. Sandoz, Inc., 500 F.Supp.2d 807, 833-43 (N.D.Ill.2007). This observation was made in light of the continuing and unrebutted presumption afforded by the doctrine of claim differentiation.

Sandoz also makes two new arguments regarding the '718 patent's use of "pharmaceutically acceptable excipients." First, Sandoz points out that when describing what is included within "pharmaceutically acceptable excipients," the patent uses the phrase "such as" when offering examples of what excipients, fillers and extenders come within the term's scope. Sandoz's argument is that had Abbott attempted to merely offer examples of what polymers come within the scope of the term "pharmaceutically acceptable polymer," as opposed to offering an explicit definition, it would have used terminology similar to what it used for "excipients ... such as" instead of the word "pharmaceutically acceptable polymer is". Second, Sandoz argues that since both "pharmaceutically acceptable polymers" (under the current construction) and "pharmaceutically acceptable excipients" include starches and polyethylene glycol, any distinction between the two terms is not recognized under the current construction. Thus rendering such a construction incorrect.

[18] [19] [20] As to Sandoz's first argument, Sandoz itself provides the explanation for the discrepant treatment of the terms "pharmaceutically acceptable polymers" and "pharmaceutically acceptable excipients." Drafters are under no obligation to draft terms the same way throughout the patent. One must look at the entire patent and the context within which the term is being used to correctly construe its meaning. The term "excipients" does not even appear in the claims of the '718 patent and there is no presumption created from the doctrine of claim differentiation affecting its construction. Thus, the juxtaposition of polymers and excipients does not, alone, counsel for construing "pharmaceutically acceptable polymers" narrowly to only include those specific polymers listed in the description.

Sandoz's second point is of little consequence. The current construction of "pharamaceutically acceptable

polymer" encompasses those polymers that are capable of extending release, either alone or in a matrix united with other compounds. Sandoz's own expert, Dr. Chambliss, stated that the "starches" and "polyethylene glycol" do not extend release. The discriminating feature of the "pharmaceutically acceptable polymer" is its ability to extend release while maintaining certain pharmacokinetic limitations. Thus, those compounds, even if they are polymers generally, cannot be "pharmaceutically acceptable polymers" under the current construction of the term.

Sandoz gives the following example highlighting what it regards to be the absurdity of the current claim construction: If a patentee described a "vehicle" as selected from the group consisting of bicycles,skateboards and roller blades in the specification, and she drafted an independent claim using the term "vehicle", then she should not be able to expand the definition of "vehicle" to include airplanes simply because the succeeding dependant claims specify the "vehicle" to be bicycles, skateboards or roller blades or progressively narrower subspecies of bicycles, skateboards or roller blades. A more appropriate example would be where it is apparent from the patent as a whole that the vehicle's purpose is to transport people, and the description of "vehicle" is nowhere limited to bicycles, skateboards or roller blades (the Markush group has no meaning and the term "is" does not signal explicit definitional language here) then, an airplane can fit within the term "vehicle," as long as it fulfills the unambiguous purpose of the term "vehicle" in the invention (as can best be discerned from the rest of the specification and then extrinsic evidence). In sum, Sandoz's example does not persuade the Court that its construction of the term "pharmaceutically acceptable polymer" is incorrect.

Sandoz also challenges the assumption that its construction of "pharmaceutically acceptable polymer" excludes a class of water-insoluble polymers. This argument is just another variant premised on assumptions this Court has already rejected and Sandoz only confuses the issue. Claim 1 limits the invention to the use of "pharmaceutically acceptable polymers." Claim 2 limits the invention to the use of claim 1's pharmaceutically acceptable polymers that are hydrophilic and water-soluble. Claim 3 limits the invention to the use of hydrophilic, water-soluble pharmaceutically acceptable polymers that are selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof. Although it would probably make more sense if claim 3 preceded claim 2, there is nothing contradictory or confusing about these claims. The limitation of claim 1 is broader than the limitation of claim 3. Therefore, the term "pharmaceutically acceptable polymer" from claim 1 is broad enough to encompass water-insoluble methacrylic acid copolymers while the term in claim 3 necessarily only encompasses those methacrylic acid copolymers that are water-soluble and hydrophilic. Sandoz itself presents evidence that such methacrylic acid copolymers exist and were known to exist at the relevant time.

[21] Next, Abbott makes a startling assertion that in its claims, the "pharmaceutically acceptable polymer" need not act alone to extend release in the invention. Its purported basis for this construction is the use of the term "comprising," which indicates that the patentee intended the claim to be open-ended and to allow for additional items. Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1367 (Fed.Cir.2003). In claim 1, the composition is comprised of "an erythromycin derivative and from about 5 to about 50% by weight of a pharmaceutically acceptable polymer, ..." In the description, Abbott explains that the pharmaceutically active compound is the erythromycin derivative, and the rest of the formulation consists of the pharmaceutically acceptable polymer and several optional excipients, fillers, extenders and/or lubricants.

First, it is not at all clear that the term "comprising" modifies the release-extending components of the

formulation rather than merely referring to the fact that more than just the polymer and the active ingredient can go into the composition, as evidenced by the passages on excipients, fillers and lubricants appearing in the description. Second, as observed earlier, the defining feature of any "pharmaceutically acceptable polymer" is its capability to extend release in the bloodstream. Thus, to be found to read upon the '718 patent's claim, the infringer's product at a minimum must contain a polymer that possesses release-extending properties and is, in fact, contributing to the extended release of the product.

Lastly, Sandoz argues that the claims do not contain any reference to matrices and as such, claim 1 should not be construed to include such an element. In support of this, Sandoz asserts that the liquid dosage forms of the invention listed in the description are not capable of tablet matrix formulations. It also refers to Abbott's admission (made by Dr. Davis, Abbott's pharmaceutical expert, during a deposition) that the formulation of a matrix system is not compatible with liquid dosage forms. According to Sandoz, these two facts indicate the scope of the patented invention does not embrace a matrix limitation. Abbott replies that the reference to liquid dosage forms is a mistake, a vestige of earlier attempts at drafting. It contends that the description includes embodiments in the form of tablets, pills and suspensions that can be made as matrix-forming compositions. Abbott also points out that it was known in the art that matrix-forming compositions including suspensions could extend release. Thus, for Abbott, these facts lead to the conclusion that the claim 1 necessarily encompasses matrix-forming compositions.

To properly understand why Sandoz believes matrix-forming polymers should be excluded from the definition of "pharmaceutically acceptable polymers" one must first recognize that the specified polymers of claim 3 all form gels to extend release, not matrices, and that Sandoz's product contains a polymer that, along with other ingredients, forms a matrix to extend release. Thus, this is yet another attempt by Sandoz to demonstrate that the term "pharmaceutically acceptable polymer" does not encompass polymers beyond those specifically listed in the description and in claim 3. If matrix-forming polymers are inconsistent with liquid dosage forms of the invention but consistent with tablets, pills and suspensions, one can only conclude that the universe of polymers that can be used with the various embodiments of the patented invention must include more than non-matrix forming polymers; thus supporting the broad construction of "pharmaceutically acceptable polymers" in claim 1.

Finally, it worth noting that in the background section of the patent, it is explained that past attempts at controlled release formulations of erythromycin and erythromycin derivatives had been made including one which yielded *an alginate matrix,* but did not alleviate adverse gastrointestinal effects associated with erythromycin and its derivatives. This section goes on to suggest that the present invention was a direct attempt to provide an erythromycin derivative in a pharmaceutical composition that was palatable, minimized adverse GI reactions and controlled the concentration of drug in the bloodstream like or better than the immediate release tablet and liquid dosage forms then on the market. This evidence makes it all the more certain that the patent was intended to cover more than just gel-forming or matrix-forming polymers. It is also fairly clear that the release-extending component in the patented invention be the polymer.

This Court concludes that the term "pharmaceutically acceptable polymer" in claim 1 means any polymer, which within the scope of sound medical judgment is suitable for use in pharmaceutical compositions for use in contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections, that extends drug release into the bloodstream either alone or in conjunction with other such polymers or other components, and is capable of forming a gel or a matrix to extend drug release into the bloodstream.

(b) Claim 4

(1) "C-min substantially equivalent to"

[22] The parties disagree as to the proper construction of the term "substantially equivalent to that of the immediate release composition" with regard to C-min values in claim 4. Sandoz argues that it should be construed to encompass the FDA definition of bioequivalence (measured by the use of 90% confidence levels) as applied to the term "bioavailability" in claim 1. In support of its contention, Sandoz asserts that the same words in one portion of a patent's claims should be accorded the same meaning. Fin Control Systems Pty, Ltd. v. OAM Inc., 265 F.3d 1311, 1318 (Fed.Cir.2001). Abbott argues that here "substantially equivalent" with respect to C-min values simply means not "statistically significantly different". It points out that FDA guidance does not call for bioequivalence in terms of C-min values, only in overall AUC values and usually in respect to C-max values.

[23] Like many of the other principles and presumptions utilized in claim construction, the principle of same words/same meaning is rebuttable when it is clear from the specification and the prosecution history that the words have different meanings at different appearances in the claims. Id. In the preliminary injunction hearing, this Court concluded Abbott's construction was more appropriate because the Court was persuaded that Sandoz's definition of "substantially equivalent" in this claim would exclude Abbott's own preferred embodiments from the scope of claim 4 if the 90% confidence levels advised by the FDA were applied. A claim construction that excludes preferred embodiments from the scope of the claim "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics Corp., 90 F.3d at 1583. The Sandoz construction lacked such support. Indeed, in discussing the comparison of C-min values of the claimed formulation versus the immediate release formulation, only statistical significance is discussed in general, not the use of the FDA guidelined bioequivalent 90% confidence levels. Therefore, the Court concludes that here, "substantially equivalent to" means not different than; it does not mean "bioequivalent as measured by the use of 90% confidence levels" nor does it mean "not statistically significantly different." The plain and ordinary meaning of the term "statistically significantly" means mathematically consistent to varying degrees of probability, not merely aberrational or subject to chance. Abbott uses the term "statistically significantly" elsewhere but not here, implying that when the drafters meant "statistically significantly" they incorporated the term.

(2) "C-max ... are lower"

In Sandoz's view, a proper construction of claim 4 would assume that the C-max for the extended release formulation would necessarily be statistically significantly lower than the C-max for the immediate release formulation even though the term "statistically significantly" does not appear in the claim.

This Court will not reconstrue claim 4 to include the term "statistically significantly" to modify "lower". First, claims are to be given their ordinary and plain meaning. "Lower" simply means less than. "Statistically significantly" carries a much more precise meaning than "lower"; the result must be mathematically consistent to varying degrees of probability and not merely aberrational. Sandoz's expert, Dr. Harmut Derendorf, explains that an ordinary person skilled in the art of pharmacokinetics would treat the term "lower" as meaningless. Just because an ordinary person skilled in the art would denigrate a term or scoff at its inclusion does not automatically mean that such a person would not understand that term's meaning in the claim. The term has some meaning, even if it is less helpful than Dr. Derendorf would like to see. Although imprecise, "lower" excludes a C-max that is "higher". Had Abbott intended for statistical

significance to be a limitation in claim 4 it would have easily added such language, as it did in claim 1.

2. Infringement

(a) Literal Infringement

[24] [25] When determining infringement, a court must compare the properly construed claim to the accused device and ascertain whether that device contains every limitation of the claim or a substantial equivalent thereof. Markman, 52 F.3d at 979. Abbott alleges that Sandoz's product infringes every limitation of claim 1 and 4 of the '718 patent. Sandoz argues that its product does not infringe upon either claim because 1) the release-extending ingredient in its product, glycerol behenate, is a non-polymer wax; 2) maltodextrin in conjunction with silicified microcrystalline cellulose ("SMCC"), which are polymers and are found in Sandoz's product, do not control or extend release, rather they speed up release and 3) Sandoz's product does not exhibit the same pharmacokinetic limitations as those claimed by Abbott. The relevant question in the preliminary injunction proceedings was whether Abbott demonstrated a substantial likelihood that SMCC and maltodextrin either alone or together have the capacity to extend the release of the drug in Sandoz' formulation. The appropriate question now is whether there are genuine issues of material fact present from which a reasonable factfinder could conclude that the maltodextrin present in Sandoz's product extends release on its own or is the component responsible for the matrix's release-extending ability. As will be discussed below, there are genuine issues of material fact sufficient to make summary judgment inappropriate for either litigant.

Claim 1 explicitly limits the invention to pharmaceutically acceptable polymers. From the specification it is clear that the pharmaceutically acceptable polymer is the component responsible for extending release either on its own or in conjunction with other ingredients. In its motion for summary judgment, Abbott alleges that maltodextrin is a pharmaceutically acceptable polymer, constituting 15% by weight of Sandoz's product, that extends release of clarithromycin through a matrix consisting of glycerol behenate and SMCC. Glycerol behenate is a wax, not a polymer. Abbott does not challenge that SMCC is a pharmaceutically acceptable polymer in its motion. Abbott asserts and has submitted evidence that maltodextrin, both independently and in combination with the other ingredients of Sandoz's product, has the capacity to extend drug release and in fact does so.

Approximately fifteen percent of Sandoz's product is maltodextrin, a water soluble hydrophilic polymer that scientific literature has shown can be used as part of a matrix to control drug release. In support of its argument, Abbott offers the patent application of a Dr. Mulye, who invented the formulation in use in Sandoz's product. That patent application states that maltodextrinhas been found to have drug retarding capabilities. Later, it states that maltodextrin in combination with a water insoluble cellulose can effectively control release of a drug. The application explicitly states "the maltodextrin used in the present invention [Sandoz's product] is to counteract the accelerated rate of release of the drug attributable to the addition of the water insoluble or partially insoluble cellulose." U.S. Pat.App. Pub. No.2004/0224017 para.para. 20, 52. When asked if maltodextrin extended release in Sandoz's product (Nostrum's product at the relevant time), Dr. Mulye equivocated and responded, "one could so conclude." However, just prior to answering that question, he stated that SMCC and maltodextrin were present in his formulation to facilitate and enhance release of the clarithromycin from the matrix.

Abbott also offers the '803 and '531 patents as evidence that maltodextrin can be used to form a polymer matrix to control release. The '803 patent claims maltodextrin as a possible polymer that swells and slows the release of a drug. U.S. Patent 6,102,803 col. 30: l. 6 (filed Aug. 10, 1998). The ' 531 patent claims that

"the powdered cellulose and the maltodextrin act to slow the disintegration of the orally administered specimen to provide a sustained release...." U.S. Patent 7,056,531 col. 30: l. 6 (filed May 4, 2001). Abbott also offers industry literature as evidence that maltodextrin is known to have release-extending capabilities and to be used as part of a matrix to control release. One article describes how matrix tablets using a combination of waxes starches, including maltodextrin, can control release. Zhou, et. al, *Matrix Pellets Based on the Combination of Waxes, Starches and Maltodextrins,* 133 Int'l J. Phar. 155 (1996). Sandoz replies that the maltodextrin referred to in this article is actually "waxy maltodextrin," which is different from the maltodextrin at issue here because it derives from waxy starches whereas maltodextrin does not.

Sandoz points to credible evidence contained in a recognized industry treatise as evidence that maltodextrin does not extend drug release. It states that maltodextrin appears to have no adverse effect on the rate of dissolution of tablet and capsule formulations ... Ainley Wade & Paul J. Weller, *Handbook of Pharmaceutical Excipients* 289 (2d ed.1994). While this Court did not treat Sandoz's evidence as persuasive in light of the overwhelming evidence presented by Abbott in the preliminary injunction proceedings, it and Sandoz's various expert testimony, suffices as contrary evidence sufficient to show a genuine triable issue for a factfinder to resolve.

Sandoz also offers evidence of internal documents that demonstrate that at one time, Abbott believed Sandoz's product did not contain a release-extending polymer. (ABBOTT 231659). Abbott does not deny that it operated under that belief in 2003 but responds that such belief was due to its reliance on the statements of Dr. Mulye's licensing agent, made well before publication of U.S. Pat.App. Pub. No.2004/0224017 and before Abbott had opportunity to test the product itself. Viewing this evidence in the light most favorable to Sandoz, this is a genuine issue of material fact.

Sandoz can relies on several dissolution experiments performed by Dr. Mulye that show maltodextrin actually accelerates release rather than extends release. While Abbott countered with a laundry list of hypertechnical reasons to discount the results of these tests, it cannot deny that the tests were performed and that the results support Sandoz's arguments. Therefore, Sandoz has demonstrated that there are genuine issues of material fact from which a reasonable factfinder could conclude its product's use of maltodextrin does not literally infringe upon claim 1 of the '718 patent. FN1

FN1. It may be useful to reiterate that on motions for summary judgement, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Valenti v. Qualex, Inc., 970 F.2d 363, 365 (7th Cir.1992) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)).

As to the pharmacokinetic ("PK") limitations of claim 1 and 4, Abbott offers Sandoz's abbreviated new drug application ("ANDA") as evidence that its product's dosage maintains an AUC substantially equivalent to the comparable immediate release dosages over a 24 hour period. The ANDA also contains evidence that Sandoz's product induces a statistically significantly lower mean DFL than the immediate release formulation because it contains a graph showing that its extended release formulation produces a flatter PK profile than the immediate release formulation, which indicates a lower DFL. The graph found in Sandoz's ANDA also shows that its extended release formulation produces lower C-maxs than the immediate release formulation, which satisfies one of claim 4's additional limitations. Lastly, Abbott has also demonstrated that graph found in Sandoz's ANDA and the data upon which the graph is based, both show that Sandoz's product produces a C-min substantially equivalent to that of the immediate release formulation.

Sandoz responds that the results of a crossover study it performed (the "Pharma Medica study") demonstrate that its product does not mimic the PK limitations claimed by the '718 patent. Abbott disputes the validity of the Pharma Medica study and offers the results of its own M06-883 crossover study (the "Abbott study"). There is no question that the two studies reach different conclusions.

In performing the Pharma Medica study, Sandoz fed its patients a high-fat breakfast. Such a high-fat breakfast was explicitly recommended for conducting bioavailability and bioequivalence studies of orally administered drug products. *Food and Drug Administration Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies,* December 2002. In performing its study, Abbott fed its participants a so-called normal-fat diet, that in the opinion of its expert Dr. Ronald Sawchuck, makes Abbott's study much more useful for studying the relative bioavailability and bioequivalence of the comparison drug products. There were other differences between the two tests such as dosing times.

Without diving too deeply into the differences of the two studies for purposes of issuing this opinion, this Court concludes that there is a genuine issue of material fact as to the efficacy of the studies' results and their utility. This Court is inclined to agree with Abbott that the more appropriate testing conditions were those followed by its study, primarily because the meals and dosing most clearly mirror the protocols described in the patent itself. However, there is no indication the claims were limited to those conditions. Abbott suggests that this Court construe the claims of the '718 patent such that infringement will be found whenever the PK limitations are met by an accused product under any reasonable food conditions. This Court will not do so. There is no evidence that the PK claims of the '718 patent encompass food conditions. Abbott itself concedes there is no mention in the specification of a particular caloric or fat content under which the inventive formulations are to be compared to the immediate-release formulations. Besides, Sandoz already submitted evidence that the FDA suggests high fat meal conditions for such comparison testing.

Lastly, Sandoz argues that its product does not form a matrix under Abbott's own definitions. According to Abbott, a matrix is a system of embedded materials. However, Abbott's own expert, Dr. Davis, declared that typically, matrix systems operate differently than so-called reservoir systems and the manner in which he categorized the two systems in his deposition leaves this Court with the impression that he was definitely explaining that matrix systems and reservoir systems are separate and distinct. Thus, there is disputed evidence concerning a genuine issue of material fact such that summary judgment on the issue is inappropriate.

(b) Doctrine of Equivalents

The parties did not address the doctrine of equivalents on Abbott's motion for summary judgment.

C. Validity

1. Anticipation

[26] [27] Title 35 U.S.C. s. 102 provides for a patent to be invalid on the basis of anticipation. A court will find that a patent claim is anticipated if a single piece of prior art is found to disclose each and every limitation appearing in that claim. Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed.Cir.1987). Also "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing feature is necessarily present, or inherent, in the single anticipating reference." SmithKline

Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343 (Fed.Cir.2005) (citation omitted).

[28] Sandoz claims that claim 1 and 4 of the '718 patent are anticipated by Eli Lilly's European Patent Publication 0280571 B 1 ("the '571 publication"). It is undisputed that the '571 publication discloses the same structural limitations as the '718 patent. It discloses the hydrophilic polymer as being about 5% to about 29% of the composition by weight, with HPMC as the most preferred polymer. It also discloses an acrylic polymer, including those sold as Eudragit, which comprises from about 0.5% to about 25% of the composition by weight. Id. at 3:41-54. The patent limits the total weight of the hydrophilic and acrylic polymers to "less than 30% by weight of the formulation." Id. at 2:49. The '571 publication also discloses the same method for making sustained release compositions as the method disclosed in the '718 patent. Sandoz's expert, Dr. Chambliss, states that because the ' 571 publication discloses the same structural limitations and method of manufacture as the '718 patent, it would certainly permit one of ordinary skill in the art to produce analogous extended release tablet formulations if erythromycin were used in place of the drug substances reported in the examples (and importantly, such a composition would inevitably possess the same PK limitations of claim 1).

However, the '571 publication does not disclose the specific PK limitations of the '718 patent. The '571 publication does not offer any formulations that include erythromycin. It does not offer any *in vivo* dissolution data. It does not even offer the PK profile of its own formulations. Sandoz presents one item of evidence from which a reasonable factfinder can conclude "the natural result flowing from [the '571 publication] would result in" the claimed PK limitations of the '728 patent. *See* SmithKline Beecham Corp., 403 F.3d at 1343 (citation omitted). That one piece of evidence is the declaration of Dr. Chambliss, based on his opinion, nothing more. FN2 Even taken in a light most favorable to Sandoz, such evidence is insufficient to refute the substantial evidence presented by Abbott that the PK limitations are not inherent to the '571 publication. The Court hereby concludes that the '571 publication does not anticipate the claims of the ' 718 patent.

FN2. That is why, given the facts presented in this case, Sandoz's reliance on case law that states a chemical compound and its properties are inseparable is of little use to its invalidity arguments. *See e.g.* In re Papesch, 315 F.2d 381, 391 (Cust. & Pat.App.1963).

2. Obviousness

[29] [30] Sandoz contends that claims 1 and 4 of the '718 patent are obvious in light of the following three pieces of prior art: PCT Application WO 95/30422 (the "WO '422 publication") in combination with Abbott's own U.S. Patent No. 5,705,190 (the "'190 patent") and the '571 publication. Title 35 U.S.C. s. 103(a) provides that a patent will be held invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Obviousness depends on four factual inquiries including (1) determining the scope and content of the prior art, (2) identifying the differences/similarities between the prior art and the claimed invention, (3) ascertaining the level of ordinary skill in the art, and (4) accounting for secondary objective considerations such as commercial success, the need for better solutions, and unexpected results. Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).

[31] [32] First, every claim limitation of the invention at issue must be found to exist in the prior art

references. *See* Velander v. Garner, 348 F.3d 1359, 1363 (Fed.Cir.2003). Then a court will determine whether there was a teaching, motivation, or suggestion to combine those limitations found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art because a "patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Int'l Co. v. Teleflex Inc., 550U.S. 398, ----, 127 S.Ct. 1727, 1741, 167 L.Ed.2d 705 (2007). However, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." Id. at 1742.

The WO '422 publication discloses sustained release dosage forms of azithromycin in general and discloses a sustained release formulation created from combining azithromycin with HPMC (utilized in Abbott's preferred embodiment) in particular. The '190 patent discloses the use of an alginate polymer in making sustained release formulations and discloses the use of clarithromycin. In KSR, the Supreme Court stated that the obviousness "analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." 127 S.Ct. at 1741. Thus, to demonstrate a genuine issue of material fact for summary judgment purposes on obviousness, Sandoz need only produce evidence indicating that the PK limitations were disclosed in the prior art or were at the very least inherent to the structural limitations of the prior art compositions and there was some motivation, teaching or suggestion to combine the elements.

Sandoz presents its case circumstantially. First, it points to a memo made by one of Abbott's inventors, Al-Razzak, in which she references the WO ' 422 publication and suggests that Abbott develop an extended-release formulation of clarithromycin to overcome the GI adverse effects of the immediate-release product and protect its business interests as Pfizer had done with azithromycin. This evidence provides possible motivation and a probable starting point for Abbott's inventive process.

Next, Sandoz points to the WO '422 publication's examples of extended-release azithromycin formulations that are very similar in their composition to the preferred embodiment of the '718 patent as evidence of substantial similarities between the claimed invention and the prior art. Sandoz also identifies specific language in the WO '422 publication where it teaches that its extended-release formulation could be employed for various drugs of a shorter-half life than azithromycin, thereby reducing dosing frequency and fluctuations in plasma concentration. Clarithromycin has a shorter half-life than azithromycin. Lastly, it is the opinion of Sandoz's expert that one of ordinary skill in the art would read the WO '422 publication and assume the specific PK limitations claimed in the '718 patent were inherent to several of the formulations therein discussed. This evidence can support a finding that there was a teaching, motivation, or suggestion to combine those structural limitations found in the prior art.

[33] However, Abbott has established that the WO '422 publication did not mention clarithromycin nor did it contain *in vivo* data. Thus, there is strong support for Abbott's position that the specific PK limitations were not inherent in the teachings of the WO '422 publication nor disclosed. Abbott discounts the similarities between azithromycin and clarithromycin because in its view, Sandoz has not offered any evidence from which one skilled in the art would conclude 1) the azithromycin composition could display the same PK characteristics of the '718 patent and 2) substituting clarithromycin for azithromycin would not affect those PK characteristics. While Abbott argues that the '190 patent claims are not limited to compositions having the specific PK characteristics of the '718 compositions, it points out itself that the claims of the '190 patent are directed to *any compositions* that slow drug release in some way compared to

immediate-release formulations. This fact is not dispositive of obviousness though because Federal Circuit precedent explains that a patentee's earlier invention is not prior art when read against her own claims. In re Stencel, 828 F.2d 751, 755 (1987).

In the preliminary injunction proceedings, this Court was persuaded that it was more likely than not that the PK limitations were not inherent to the structural limitations of the claims at issue. One crucial finding there was that a person skilled in the art would not be motivated to look at the WO '422 publication and interchange clarithromycin for azithromycin because the '190 patent did not disclose the PK profile of the '718 patent. Although previously rejected, Sandoz adheres to its argument that the PK limitations are inherent in the WO '422 publication. Here on summary judgment, this Court is of the opinion that Sandoz has presented enough evidence to support its argument with references to the WO '422 publication itself, the memo of Abbott's inventor and the testimony of its expert. Thus, there is a disputed genuine issue of material fact with regard to the interchangeability of azithromycin and clarithromycin that the Court may not simply disregard.

[34] In regard to the '571 publication, which discloses the same structural limitations as the '718 patent, the result is the same as it was before in the anticipation discussion. The '571 publication does not disclose the specific PK limitations of the '718 patent. The '571 publication does not offer any formulations that include erythromycin. It does not offer any *in vivo* dissolution data. It does not even offer the PK profile of its own formulations. Sandoz presents one item of evidence from which a reasonable factfinder can conclude "the natural result flowing from [the '571 publication] would result in" the claimed PK limitations of the '728 patent. *See* SmithKline Beecham Corp., 403 F.3d at 1343 (citation omitted). That one piece of evidence is the declaration of Dr. Chambliss, based on his opinion, nothing more. Even taken in a light most favorable to Sandoz, such evidence is insufficient to refute the overwhelming evidence demonstrated by Abbott. The Court hereby concludes that the '571 publication does not render the claims of the '718 patent obvious.

[35] Generally a showing that there is an established structural relationship between a prior art composition and the claimed composition demonstrates a *prima facie* case of obviousness. Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1302-03 (Fed.Cir.2007) (citation omitted). But a patentee can rebut such a *prima facie* showing an absence of motivation in the prior art to make the modifications necessary to arrive at the claimed invention or by showing the prior art does not disclose all of the claim limitations. *See* id. Therefore, just as the absence of the PK limitations in the '571 publication was sufficient to defeat an anticipation claim; it is also sufficient here to defeat Sandoz's obviousness challenge. Abbott has demonstrated that there is no genuine issue of material fact with regard to whether the '718 patent claims are rendered obvious in light of the '571 publication.

D. Inequitable Conduct

Sandoz alleges that Abbott engaged in inequitable conduct when prosecuting the '718 and '616 patents. This Court preliminarily found that Sandoz could not demonstrate inequitable conduct. Now this Court is faced with the same questions regarding the '718 patent, however this time, Sandoz is afforded all reasonable inferences. A finding of inequitable conduct that would warrant holding the patents at issue to be unenforceable would render the other disputed issues moot. Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 877 (Fed.Cir.1988).

1. Standard for Inequitable Conduct

[36] [37] [38] Inequitable conduct occurs when a patent applicant violates the "duty of candor and good

faith ..., which includes a duty to disclose to the Patent Office all information known to the [applicant] to be material to patentability...." 37 C.F.R. s. 1.56(a) (2007); Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1350-1 (Fed.Cir.2005). A court will hold a patent unenforceable due to inequitable conduct if there is clear and convincing evidence that while prosecuting the patent at issue, the applicant (1) either made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information; and (2) intended to deceive the U.S. Patent and Trademark Office ("PTO"). Impax Labs., Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1374 (Fed.Cir.2006). Both the elements of intent and materiality are questions of fact and must be proven by clear and convincing evidence. Young v. Lumenis, Inc., 492 F.3d 1336, 1345 (Fed.Cir.2007) (citing J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc., 747 F.2d 1553, 1559 (Fed.Cir.1984)). The burden of proof is on Abbott to demonstrate that there are no genuine issues of material fact from which a reasonable fact-finder could conclude that Abbott acted inequitably while prosecuting the ' 718 patent.

2. C-max data

Sandoz contends that during the prosecution of the '718 patent, Abbott failed to disclose material information, selectively withheld information that contradicted assertions made in its patent claims and submitted information to the PTO that contained material misrepresentations of fact. Abbott submitted a Rule 132 declaration to the PTO made by one of its pharmacokineticists, Dr. Linda Gustavson, in support of the '718 patent prosecution. In this declaration, Gustavson claimed that a statistical test demonstrated the maximum plasma concentration ("C-max") of the extended-release clarithromycin (the claimed composition) was statistically significantly lower than the C-max of a prior art composition. Sandoz contends that Abbott breached its duty of candor by submitting the Gustavson declaration because (1) it did not assert what Gustavson declared it did and (2) Gustavson never performed any test and admitted she did not know how to perform such a test.

Sandoz asserts that the data on which Gustavson relied did not show a "statistically significant" difference in C-max for the extended-release and immediate-release formulations and that Gustavson did not perform any such statistical test nor did she even know how to perform one. In Sandoz's view, a proper construction of claim 4 would assume that the C-max for the extended release formulation would necessarily be statistically significantly lower than the C-max for the immediate release formulation even though the term "statistically significantly" does not appear in the claim. As discussed above, the Court rejects this construction. Abbott asserts that the statement was immaterial because it had no bearing on any claim of the '718 patent. Claim 4 of the '718 patent states in relevant part that "... maximum peak concentrations of the erythromycin derivative are lower than those produced by an immediate release pharmaceutical composition ..." This Court previously found that the Gustavson declaration that the C-max of the extended release clarithromycin was statistically significantly lower than the C-max of the prior-art composition of clarithromycin was not material to patentability.

[39] [40] To establish materiality, a litigant must show that there is a substantial likelihood that a reasonable examiner would consider the statement important in deciding whether to allow the application to issue as a patent. *See* Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed.Cir.2007). The PTO had rejected the claims of the '718 application and issued Abbott a challenge to show that its product did not have the same PK properties of the prior art product. So, the undeniable purpose of the Gustavson declaration was to clarify to the PTO that the prior art of the '411 patent was different from the '718 patent. Thus, the statement was relevant to patentability because it contained information probative of whether there was a pharmacokinetic difference between the extended release formulation and the prior art formulation. In Refac

International, Ltd., v. Lotus Development Corporation, the Court unequivocally stated that Rule 132 affidavits were inherently material. 81 F.3d 1576, 1584 (Fed.Cir.1996). The Court based its conclusion on the fact that "an affidavit submitted to overcome a rejection is intended to be relied upon." Id. There is no meaningful distinction between an affidavit and a declaration in this regard, for Abbott can hardly argue that the Gustavson declaration was not submitted to overcome the examiner's challenge. Therefore, there is no doubt that the PTO considered Gustavson's declaration important in deciding whether to allow the '718 application to issue.

[41] Previously, this Court found it more likely than not that the PTO would not have found the "statistically significantly lower" statement to be important. The basis of that decision was that the Court preliminarily found that 1) no claim of the '718 patent requires the extended release formulation to have a statistically significant lower C-max than the immediate release formulation; 2) the data in fact showed the C-max of the extended release formulation was lower (albeit not statistically significantly lower) than the C-max of the immediate release formulation; and 3) the extended release formulation was in fact pharmacokinetically different from the immediate release suspension formulation. There is still no dispute that the extended release formulation was indeed pharmacokinetically different from the prior art immediate release suspension formulation, just as Abbott had asserted in its declaration to the PTO. Given the accuracy of the ultimate conclusion-that the extended release formulation was indeed different from the immediate release suspension formulation, this Court found that Gustavson's declaration of a "statistically significantly lower" C-max was immaterial despite the fact that it satisfied the definition of "material" provided by 37 C.F.R. s. 1.56(b).

[42] Materiality is a question of fact. Young v. Lumenis, Inc., 492 F.3d 1336, 1345 (Fed.Cir.2007). Here, the underlying facts are not disputed. Abbott submitted evidence that the C-max of the extended release formulation was lower than the C-max of the immediate release suspension formulation. Sandoz has still not submitted any evidence to the contrary. Sandoz's expert, Dr. Marcello Pagano, submits evidence that the C-max of the extended release formulation was not statistically significantly lower than the C-max of the immediate release suspension formulation. But statistical significance is not the issue. The purpose of Gustavson's declaration was show to the examiner that Abbott's product differed from the prior art. Abbott's product was different from the prior art. Therefore, even though the declaration contained a false statement, the gravamen of the declaration was not false. Since this Court finds the Gustavson statement to be immaterial, whether she possessed an intent to deceive is irrelevant.

3. Withholding DFL data

[43] Sandoz claims Abbott intentionally withheld material information regarding the DFL of the extended release clarithromycin formulation from the PTO while the '718 patent was being prosecuted. Abbott responds that the information was not material. Claim 1 of the '718 patent states in relevant part that "the [extended release] composition induces statistically significantly lower mean fluctuation index in the plasma than an immediate release composition of the erythromycin derivative ...." Abbott claimed that the mean DFL values for a modified release version of clarithromycin claimed by a prior patent, the '190 patent, were substantially equal to the mean DFL values for the immediate release version of clarithromycin. However, while the '718 patent was pending, Abbott and more specifically, Gustavson, became aware that the mean DFL values for a modified release version of clarithromycin claimed by '190 patent were actually statistically significantly lower than the immediate release composition through an internal Abbott study, Study W98-268. The final report of Study W98-268 states that the modified release formulation exhibited a statistically significantly lower mean DFL than that for the immediate release formulation. Similarly the

extended release formulation also exhibited a statisticallysignificantly lower mean DFL than that for the immediate release formulation. The specification of the '718 patent states in relevant part that "[t]he mean DFL values for the controlled release formulation and for the IR are substantially equal in value ..." FN3 ' 718 Patent, col. 11:18-19.

FN3. Here, the term "controlled release" is identical to the term "modified release".

So while these study results have no direct bearing on the claims of the '718 patent, they are contradictory of Abbott's assertions in the specification that the modified release formulation and the immediate-release formulation had substantially equal DFL values, thereby casting doubt on whether that the claimed extended release formulation was really pharmacokinetically different from the modified release formulation in the prior art. When viewed in that manner, a factfinder could conclude that a reasonable examiner would have considered the undisclosed results important in deciding whether to allow the patent to issue. *See* Cargill, Inc., 476 F.3d at 1364. Abbott has submitted evidence demonstrating the Study W98-268 results differed from the results of three other studies and also showing a mean DFL value consistently lower than the mean DFL value for the IR formulation is not a static characteristic of the MR formulation. In conclusion, this Court cannot ignore that there is a genuine issue of material fact as to the materiality of the W98-268 results.

[44] [45] Intent is a highly factual inquiry that turns on the facts presented and the circumstances surrounding the act. Impax Labs., Inc., 468 F.3d at 1375 (citation omitted). Thus, the Federal Circuit has recognized that intent is rarely proven by direct evidence and can be inferred from the applicant's conduct. Id. Furthermore, the Federal Circuit has expressed a clearly disfavorable opinion of disposing of intent on summary judgment. In re Metoprolol Succinate Patent Litigation, 494 F.3d 1011, 1020 (Fed.Cir.2007) (citation omitted). Just as a factfinder could conclude that the study's results were material, she could infer from the act of withholding it that Abbott acted with an intent to deceive. Therefore, summary judgement is inappropriate on this claim.

4. Taste Perversion Data

[46] Sandoz's first argument regarding the taste perversion data found in Table VI of the '718 patent is without merit. Sandoz alleges Abbott committed inequitable conduct because it did not tell the PTO that there was no difference statistically in the adverse events of the extended and immediate release clarithromycin. Since this data was before the PTO, this Court presumes the PTO had every opportunity to review it when prosecuting claim 6. Thus, Sandoz cannot demonstrate that Abbott withheld anything. Claim 6 of the '718 patent simply states the extended release formulation has "an improved taste profile as compared to the immediate release formulation." Sandoz submits evidence via an expert biostatistician, Dr. Pagano, who concludes that the data of Table VI does not provide any support for claim 6. Declaration of Pagano, para.para. 3-11. However, Dr. Pagano's own analysis reveals that some improvement is a justifiable conclusion. Abbott was not under any obligation to show a statistical difference to support claim 6, just some improvement. Summary judgment in favor of Abbott is granted as to this claim because Sandoz cannot show any facts from which one could conclude Abbott withheld this information from the PTO or that the data in Table VI of the specification was even material to patentability since statistical significance was not an element that Abbott was obligated to prove.

[47] Next, Sandoz alleges that Abbott failed to disclose relevant data to the PTO from two of its own

studies, the double-blind Acute Bacterial Exacerbation of Chronic Bronchitis study (the "bronchitis study") and the Acute Maxillary Sinusitis study (the "sinusitis study"), which contradicted claim 6's assertion that its extended release formulation provided reduced incidence of taste perversion than its immediate release formulation. Sandoz is correct in asserting that the results of the two clinical studies were material to the patentability of the '718 patent. First, the results directly refute Abbott's claims that extended release clarithromycin results in reduced taste perversion. See 37 C.F.R. s. 1.56(b)(2) (ii) (2007). By contrast, they indicate that the extended release formulation offers no improvement over the immediate release formulation. The results were not cumulative of other evidence before the PTO; the only other evidence relating to taste perversion was the 24-subject pilot study discussed in the specification of the three patents. These results were material to the prosecution of the '718 patent because it contained a claim for improved taste perversion over immediate release clarithromycin.

[48] With respect to intent, this Court previously found that Ranbaxy had not demonstrated a substantial question that it could show intent to deceive the PTO in the prosecution of the '718 patent under the same facts as presented here. Ranbaxy Labs. Ltd. v. Abbott Labs., Nos. 04 C 8078, 05 C 1490, 2005 WL 3050608 (N.D.Ill. Nov. 10, 2005). The prosecution of the patent and the clinical studies occurred contemporaneously. This Court accepted Abbott's explanation that the difference between its submissions to the FDA and the PTO was that the "submission of studies to the FDA [was] of no moment, given that the '718 inventors' roles with respect to the FDA submission, to the extent they were involved at all, had nothing to do with adverse event data." Abbott had submitted declarations of the '718 inventors and prosecuting attorney, each stating that she was unaware of the data at the relevant times. That was an obvious finding of fact that is inappropriate for this Court to make on summary judgment.

[49] [50] Abbott is not correct that Sandoz has not offered new evidence supporting an inference of intent to deceive. Sandoz has addressed the intent issue in an indirect, tangential manner by merely stating that since Abbott did not withdraw its taste perversion claim 6 from the then-pending '718 application or make the studies' results available, Abbott's intent to deceive can be inferred from its inactions. As stated before, intent need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequence of which are presumably intended by the actor. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 (Fed.Cir.1995). Proof that non-disclosed information was highly material and that the patent applicant knew or should have known of that materiality makes it "difficult to show good faith to overcome an inference of intent to mislead." Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co., Ltd., 204 F.3d 1368, 1375 (Fed.Cir.2000) (citing Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed.Cir.1997)). The clinical study results were material to the patent at issue. Moreover, the results were Abbott's own proprietary information, at least until Abbott began to publish the results more broadly. Further undermining Abbott's position is the fact that it submitted the complete results of the two clinical studies to the FDA in May 1999 and the '718 patent did not issue until January 2000. A reasonable factfinder could find both materiality and intent to deceive on the facts surrounding these studies and the '718 patent and vice versa. Therefore, summary judgment is denied.

[51] [52] Lastly, Sandoz argues that Abbott withheld material labeling data from the PTO. Sandoz contends that the label is material because it contains information that contradicts claim 6 of the '718 patent of an improved taste profile. The label submitted in May 1999 states that the taste perversion incidence rate of the immediate-release formulation is 3% while that of the extended-release formulation is 6%. Abbott claims the label is not material because these incidence rates came from different tests involving different dosages and that incidence of side effects is related to dosage. Sandoz retorts that while the 3% figure is the same on its old labeling, the incidence rates on other adverse effects are changed, thus discrediting the excuse that the

label is merely a vestige from the past. Another fact to consider is that Dr. Gustavson and Dr. Semla, two of the inventors on the ' 718 patent, did not deny reading the label although they both testified that they could not recall reviewing the label. This fact could support a finding that Abbott was aware of the label.

Abbott responds by disputing the materiality of the label. Davis declared that the Biaxin (R) IR was administered in dosages of 500mg and 1000mg per day but that the ER product was administered primarily in dosages of 1000mg only. Abbott contends that given the differences in dosages, using the label to determine whether the extended release formulation results in an improved taste profile over the immediate release formulation would be useless. Sandoz does not address this issue at all, it merely takes issue with some of Abbott's improper factual assertions. It would have been useful had Sandoz addressed whether it was true or not or if a genuine issue of fact exists on the efficacy of a comparison using different dosages on the subjects.

[53] Materiality is determined from the point of view of the reasonable examiner, not the subjective view of the patentee. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1238 (Fed.Cir.2003). Although the labeling information deals with the incidence rates of taste perversion, Abbott has submitted evidence that demonstrates the data is not probative of whether the extended release formulation has an improved taste over the immediate release profile. While information may be material even if its disclosure would not have rendered the invention unpatentable, Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1318 (Fed.Cir.2006), information is not material if there is not a substantial likelihood that a reasonable examiner would consider the statement important in deciding whether to allow the application to issue as a patent. *See* Cargill, Inc., 476 F.3d at 1364. Therefore, this Court concludes there is no genuine issue of fact as to the materiality of the information regarding the incidence rates on the label submitted to the FDA.

IV. CONCLUSION

Sandoz's Motion for Summary Judgment of Noninfringement and/or, Alternatively, Invalidity of Certain Claims of the '407 Patent is DENIED as moot. Abbott's Motion for Summary Judgment or, in the Alternative, for Summary Adjudication is DENIED in part and GRANTED in part. Summary judgment is GRANTED in Abbott's favor on the following issues: invalidity due to obviousness and anticipation with regard to the '571 publication; inequitable conduct on the grounds of a false statement made by Gustavson to the PTO; inequitable conduct on the grounds that Abbott withheld material taste perversion data from the PTO found in Table VI of the '718 patent and; inequitable conduct on the grounds that Abbott withheld material labeling data regarding incidence rates of adverse effects. All other claims remain. The Court GRANTED Sandoz's Motion to Strike or in the Alternative, Disregard certain paragraphs of Abbott's Rule 56.1 Statement but DENIED as moot its Motion to Strike the Supplemental Declaration of Professor Stanley S. Davis and the Declaration of Yihong Qiu. Sandoz's Rule 12(b)(6) Motion to Dismiss Plaintiff's Claims of Willful Infringement or in the Alternative, Rule 12(c) Motion For Judgment on the Pleadings will be addressed in a separate opinion.

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