NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al., **Plaintiffs,** **v.** **HANMI USA, INC., et al.,** **Defendants.**	**Civil Action No. 11-760 (JAP)** **MEMORANDUM OPINION**

BONGIOVANNI, Magistrate Judge,

This matter comes before the Court upon Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, KBI Inc. and KBI-E Inc.'s (collectively, "AstraZeneca") motion to amend their Disclosure of Asserted Claims. Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively, "Hanmi") oppose AstraZeneca's motion. The Court has fully reviewed and considered all of the arguments made in support of and in opposition to AstraZeneca's motion. The Court considers AstraZeneca's motion without oral argument pursuant to FED.R.CIV.P. 78. For the reasons set forth more fully below, AstraZeneca's motion to amend their Disclosure of Asserted Claims is GRANTED.

I. Background and Procedural History

The Court and the parties are very familiar with the facts underlying this matter as well as the issues presented in AstraZeneca's pending motion to amend their Disclosure of Asserted Claims. As such, the Court shall neither restate the facts of this case nor repeat the arguments made in support of and in opposition to AstraZeneca's motion at length.

This is a patent infringement case involving United States Patent Nos. 5,714,504 (the "'504 patent") and 5,877,192 (the "'192 patent") (collectively, the "patents-in-suit"). The patents-in-suit are directed to AstraZeneca's esomeprazole magnesium product, which is marketed under the trademark NEXIUM® and which is used to treat various gastric acid-related diseases and gastrointestinal diseases and disorders. AstraZeneca claims that Hanmi infringed the patents-in-suit by filing a New Drug Application with the United States Food and Drug Administration ("FDA") seeking approval to market esomeprazole strontium capsules that would be used to treat similar ailments to those treated by AstraZeneca's Nexium® product.

On May 12, 2011, the Court entered a Letter Order dated May 11, 2011 (the "May 11th Letter Order") via which the Court set a schedule to govern this matter through claim construction. (Docket Entry No. 56) Pursuant to the May 11th Letter Order, AstraZeneca's Disclosure of Asserted Claims was due on May 18, 2011 and Hamni's Invalidity and Non-Infringement Contentions were due on May 25, 2011. (*Id.*) Both parties timely served the information required by the Court's May 11th Letter Order.

The instant dispute arises out of AstraZeneca's request to amend their Disclosure of Asserted Claims in order to add the following three claims of the '504 patent: claims 3, 5 and 10. AstraZeneca claims that this amendment is necessary in light of the invalidity contentions and defenses asserted by Hamni for the first time in their Invalidity Contentions served on May 25, 2011.

AstraZeneca contends that they formulated their Disclosure of Asserted Claims based on the information contained in Hamni's Notice Letter and Answer to AstraZeneca's Complaint. AstraZeneca argues that the only invalidity theory under 35 U.S.C. § 112 specifically raised by

Hamni in either their Notice Letter or Answer was nonenablement. Nevertheless, AstraZeneca claims that Hamni in their Invalidity Contentions argues that the '504 patent is also invalid under 35 U.S.C. § 112 for indefiniteness and lack of written description. Specifically, AstraZeneca argues that "Hamni asserts for the first time in its Invalidity Contentions that if claims 1, 2, 4, 6, and 7 of the '504 patent read on 'alkaline salts' other than [Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$], a construction which would include the strontium used in Hanmi's NDA product, then the claim is invalid for lack of written description under 35 U.S.C. § 112." (AstraZeneca Br. at 3). AstraZeneca argues that because this theory of invalidity was not contained in either Hamni's Notice Letter or Answer, AstraZeneca "could not identify all of the claims that it should assert." (*Id*.) AstraZeneca further argues that in constructing their Disclosure of Asserted Claims, they should not have been forced to anticipate every possible defense to their patent, even where such challenges were not raised in Hanmi's Notice Letter or Answer.

In light of the foregoing, AstraZeneca seeks to amend their Disclosure of Asserted Claims pursuant to L.Pat.R. 3.7. Specifically, AstraZeneca seeks to add claims 3, 5 and 10 of the '504 patent because these claims are limited to the six specific salts identified above, or a subset thereof, and are therefore unaffected by Hamni's 35 U.S.C. § 112 written description defense, which "is premised on an alleged lack of support for 'alkaline salt,' to the extent that term is interpreted to be any broader than the [aforementioned] six salts[.]" (AstraZeneca Reply Br. at 4). Given the fact that Hanmi did not identify a 35 U.S.C. §112 written description defense in either its Notice Letter or Answer, coupled with the fact that it was unnecessary for AstraZeneca to assert claims 3, 5 and 10 of the '504 patent absent such a defense, AstraZeneca argues that

good cause exists to permit them to amend their Disclosure of Asserted Claims to add these claims.

In addition, AstraZeneca argues that the addition of claims 3, 5 and 10 of the '504 patent will not prejudice Hanmi for the following reasons: (1) these claims do not contain any additional new claim terms; (2) their addition would not require a modification to the claim construction schedule; instead the parties could supplement their contentions concurrently with the claim construction schedule; (3) in light of Hanmi's view that the term "alkaline salt" in the previously asserted independent claims 1, 6 and 7 of the '504 patent is identical in scope to the salts listed in dependent claims 3 and 10 of the '504 patent, Hanmi's prior analysis of infringement and validity for the independent claims should apply to the new claims, resulting in little additional cost to Hanmi by their addition; and (4) there is no reason to believe that the addition of claims 3, 5 and 10 of the '504 patent would somehow render it impossible for this case to be resolved within the 30-month stay provided by the Hatch-Waxman Act. Further, AstraZeneca argues that the proposed addition of claims 3, 5 and 10 of the '504 patent is not futile because, while these claims contain limitations to specific salt forms of esomeprazole, none of which is a strontium salt like that involved in Hanmi's proposed product, Hanmi's esomeprazole strontium product or its use infringes claims 3, 5 and 10 of the '504 patent under the doctrine of equivalents.

Hanmi opposes AstraZeneca's request to amend their Disclosure of Asserted Claims arguing that good cause does not exist for the amendment, Hanmi would be prejudiced by AstraZeneca's proposed amendment and AstraZeneca's proposed amendment is futile. With respect to good cause, Hanmi argues that AstraZeneca's motion to amend should be denied under L.Pat.R. 3.7 because AstraZeneca was not diligent in asserting claims 3, 5 and 10 of the '504

patent and therefore good cause does not exist to permit the proposed amendment. In this regard, Hanmi contends that the decision over which claims are infringed is controlled by the patent-holder's assessment of its own patents and the accused product, nothing more. As such, Hanmi argues that a patent-holder does not need access to its adversary's invalidity contentions in order to determine which claims to assert. Consequently, Hanmi argues that AstraZeneca's failure to initially assert claims 3, 5 and 10 of the '504 patent resulted from a lack of diligence and, as a result, good cause does not exist to permit their addition now.

Hanmi further argues that AstraZeneca's lack of diligence is even more apparent because, contrary to AstraZeneca's assertions that they had no notice that Hanmi intended to challenge the validity of certain claims of the '504 patent under the first paragraph of 35 U.S.C. § 112 if the term "alkaline salt" is construed to encompass any salt other than Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$, Hanmi has always maintained this position. Indeed, Hanmi argues that they disclosed this very information in their Notice Letter, which stated:

> Furthermore if the claim term "pure solid state alkaline salt of the (-)- enatimomer of [omeprazole]" were not limited to the six specific salts disclosed in the '504 patent, the patent would be invalid for lack of enablement. *See Generation II Orthotics, Inc. v. Med. Tech., Inc.*, 263 F.3d 1356, 1365 (Fed. Cir. 2001). . . As explained above, claims 1-7 and 10 of the '504 patent require "a pure solid state alkaline salt of the (-)- enantiomer of [omeprazole]." However, salt selection is inherently unpredictable. *See Sanofi-Synthelabo v. Apotex, Inc.*, 492 F.Supp. 2d 353, 374 (S.D.N.Y. 2007). . . Accordingly, if the Court were to construe the claim term "pure solid state alkaline salt of the (-)- enantiomer of [omeprazole]" as being broader than the teachings of the '504 patent, the patent would be rendered invalid as failing to enable the full scope of the claimed subject matter. And, it is well-settled that "claims are generally construed so as to sustain their validity, if possible." *Whittaker Corp. v. UNR Indus., Inc.*, 911 F.2d 709, 712 (Fed. Cir. 1990).

(Hanmi Opp. Br. at 5-6 (quoting Ex. 2, Notice Letter, Exhibit A at pages 28-29). In addition, Hanmi notes that in their Answer and Counterclaims, they included an allegation that all claims of the '504 patent are invalid under 35 U.S.C. § 112. As a result, Hanmi argues that AstraZeneca had notice that they were challenging the validity of the '504 under 35 U.S.C. § 112. Hanmi therefore contends that AstraZeneca's failure to initially assert claims 3, 5 and 10 of the '504 patent clearly results from a lack of diligence and AstraZeneca's request to now add these claims is not supported by good cause. Hanmi also contends that AstraZeneca's efforts to add claims 3, 5 and 10 of the '504 patent were not diligent because AstraZeneca waited 2½ months after receiving Hanmi's Invalidity Contentions to file their motion to amend.

In addition, Hanmi argues that even if AstraZeneca's request to add claims 3, 5 and 10 of the '504 patent was supported by good cause, the Court should nevertheless deny AstraZeneca's request because Hanmi would be prejudiced by AstraZeneca's proposed amendment. In this regard, Hanmi argues that they relied on AstraZeneca's initial determination that claims 3, 5 and 10 of the '504 patent were not infringed and invested significant time and resources in strategically selecting terms for construction, proposing claim constructions and determining relevant supporting intrinsic and extrinsic evidence for the asserted claims, *i.e.*, claims 1, 2, 4 and 6-7 of the '504 patent. Hanmi claims that they incurred substantial cost in assessing the asserted claims and developing a case strategy tailored to defending against the asserted claims and that they would incur significant additional expense if forced to alter their strategy to also account for claims 3, 5 and 10 of the '504 patent.

Further, Hanmi argues that they will also be prejudiced by any delay AstraZeneca's proposed amendment would have on the ultimate resolution of this case. In this regard, Hanmi

claims that if AstraZeneca is permitted to add claims 3, 5 and 10 of the '504 patent, the case schedule would necessarily be amended to accommodate the addition. Hanmi claims that "[a]ny delays in the present case schedule would unfairly postpone the finality of the Court's decision on the merits of Hanmi's challenges, and unfairly increase the legal uncertainty and thus the risk of any prospective product launch after FDA approval." (*Id*. at 15). In addition, Hanmi argues that AstraZeneca's present motion represents simply one of many delay tactics employed by AstraZeneca to Hanmi's prejudice; another example of which Hanmi claims was AstraZeneca's "frivolous" motion to strike Hanmi's defenses and counterclaims.

Moreover, Hanmi argues that even if AstraZeneca's proposed addition of claims 3, 5 and 10 of the '504 patent would not be prejudicial, the Court should deny AstraZeneca's motion based on the futility of the proposed amendment. Hanmi argues that claims 3, 5 and 10 of the '504 patent involve only six salts, or a subset thereof, none of which include strontium. As a result, Hanmi argues that claims 3, 5 and 10 are not literally infringed by their proposed esomeprazole strontium capsules. Further, Hanmi argues that the doctrine of equivalents is inapplicable because utilizing that theory under the facts of this case would vitiate the "species recitation of the claims." (*Id*. at 18). As a result, because claims 3, 5 and 10 are neither literally infringed by Hanmi's NDA product nor infringed under the doctrine of equivalents, Hanmi argues that the addition of these claims to AstraZeneca's Disclosure of Asserted Claims would be futile.

II. Analysis

A. Standard of Review

Local Patent Rule 3.7 governs "amendments of . . . disclosures . . . required to be filed or exchanged pursuant to the[] Local Patent Rules[,]" including AstraZeneca's proposed amendment of their Disclosure of Asserted Claims. Pursuant to L.Pat.R. 3.7, an amendment "may be made only by order of the Court upon a timely application and showing of good cause." (Emphasis in original). L.Pat.R. 3.7 sets forth a "[n]on-exhaustive" list of "examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause[.]" While non-exhaustive, the list of circumstances included in L.Pat.R. 3.7 establishes that a dominant consideration in determining whether good cause exists to permit a requested amendment is the diligence of the moving party.

The Local Patent Rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases." *Computer Accelerations Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819, 822 (E.D. Tex. 2007). Indeed, they "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Atmel Corp. v. Info. Storage Devices, Inc.*, No. C 95-1987 (FMS), 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998). As such, unlike proposed amendments of the pleadings, which are liberally granted pursuant to Rule 15, amendments to disclosures required by the Local Patent Rules are governed by a more conservative standard. *See Id*. (noting that "the philosophy behind amending claim charts is decidedly conservative and designed to prevent the 'shifting sands' approach to claim construction.") Thus, while L.Pat.R. 3.7 certainly "is not a straitjacket into which litigants are

locked from the moment their contentions are served," the "modest degree of flexibility" that the Rule provides must be viewed in the context of the Local Patent Rules' overarching goal of having the parties establish their contentions early on. *Comcast Cable Communs. Corp. v. Finisar Corp.*, No. C 06-04206 WHA, 2007 WL 716131, at *2 (N.D. Cal. March 2, 2007).

B. Discussion

Here AstraZeneca seeks to amend their Disclosure of Asserted Claims in order to add claims 3, 5 and 10 of the '504 patent. Unlike the claims initially asserted by AstraZeneca, these three claims are limited to the following six salts, or a subset thereof: Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$. AstraZeneca seeks to add claims 3, 5 and 10 of the '504 patent in response to Hanmi's Invalidity Contentions, which raised invalidity defenses under 35 U.S.C. § 112 for indefiniteness and lack of written description. Specifically, Hanmi in its Invalidity Contentions asserts that if claims 1, 2, 4, 6, and 7 of the '504 patent read on "alkaline salts" other than Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$, a construction which would include the strontium used in Hanmi's NDA product, then the claim is invalid for lack of written description under 35 U.S.C. § 112.

The Court finds that there is good cause to permit AstraZeneca's proposed amendment at this juncture. While the Court recognizes that in an effort to "help narrow the focus of a generic's invalidity contentions" and to "eliminate[] speculation and added work by the generics in formulating their non-infringement and invalidity contentions[,]" the Local Patent Rules now require the patent-holder to serve its Disclosure of Asserted Claims prior to the generic's service of its Invalidity Contentions, the Court agrees with AstraZeneca that a patent-holder should not be forced to anticipate every possible defense to their patent in framing their Disclosure of Asserted Claims. *See* Explanatory Note for the 2011 Amendments to the Local Patent Rules.

Instead, the patent-holder should be able to rely on the information disclosed in the generic's Notice Letter and Answer. Any other result would run counter to the goal of streamlining these types of matters by having parties crystalize their theories early in the case.

21 C.F.R. § 314.95(c)(6)(ii) requires generics to provide the patent-holder with "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. The application shall include in the detailed statement . . . [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Despite this requirement, no where in Hanmi's Notice Letter did Hanmi ever allege that any of the claims of the '504 patent were invalid under 35 U.S.C. § 112 due to indefiniteness and lack of written description. Instead, the only 35 U.S.C. § 112 invalidity defense set forth in Hanmi's Notice Letter was nonenablement. Nonenablement is a completely different defense than indefiniteness and lack of written description and there was no reason for AstraZeneca to believe that because Hanmi was challenging certain claims of the '504 patent based on nonenablement, they were also challenging certain claims for indefiniteness and lack of written description.[1]

While Hanmi argues that AstraZeneca's decision over which claims Hanmi infringed was controlled solely by AstraZeneca's assessment of their own patents and the accused product, Hanmi fails to acknowledge that the same can be said for Hanmi's detailed explanation of invalidity: Hanmi did not need any information beyond AstraZeneca's patent itself to set forth

[1]Hanmi's Answer and Counterclaim does nothing to alleviate this issue as Hanmi's Answer and Counterclaim merely lists (effectively in a string cite) Section 112 of Title 35 of the United States Code among several other sections of the same Title and states, without any additional explanation, that the claims of the '504 patent are invalid under these sections.

the grounds on which they believed the claims of the '504 patent were invalid. For some reason, Hanmi elected not to set forth indefiniteness and lack of written description in the detailed explanation of invalidity contained in their Notice Letter. Why Hanmi decided not to do so is at this juncture irrelevant. What matters is that they did not.

AstraZeneca, like all patent-holders, served its Disclosure of Asserted Claims after receiving Hanmi's Notice Letter. AstraZeneca's decision regarding which claims to assert was most certainly affected by the information contained in Hanmi's Notice Letter. While Hanmi argues that "[a]s a hedge against the possibility that an independent claim might be held invalid, every plaintiff has every incentive to assert every allegedly infringed dependent claim" and "[t]he fact that AstraZeneca deliberately chose not to assert claims 3, 5 and 10 simply means it concluded that it could not, in good faith, pursue infringement of claims directed to wholly different compounds[,]" Hanmi's conclusion is purely speculative.

Based on the detailed explanation of invalidity contained in a generic's Notice Letter, coupled with its assessment of its patent and the generic product, a patent-holder, like AstraZeneca, could easily conclude that it would not only be unnecessary, but also uneconomical and/or inefficient to litigate certain potentially infringed claims.[2] Here, based on the information

[2]The Court notes that Hanmi requests permission to conduct discovery into AstraZeneca's otherwise privileged communications regarding the reasons why AstraZeneca did not previously assert claims 3, 5 and 10 of the '504 patent in their initial Disclosure of Asserted Claims. The Court has broad discretion in managing requests for discovery and determining the appropriate scope of discovery. *See Salamone v. Carter's Retail, Inc.*, Civil Action No. 09-5856 (GEB), 2011 WL 310701, *5 (D.N.J. Jan. 28, 2011). Here, the Court exercises its discretion to deny the requested discovery. There is no more reason to permit Hanmi to gain access to AstraZeneca's privileged communications concerning their reasons for asserting particular claims and not others than there is to permit AstraZeneca to discover Hanmi's privileged communications concerning the reasons they did not set forth an indefiniteness or lack of written description defense in their Notice Letter or Answer. Simply put, under the circumstances of this case, any such discovery

available to them at the time their Disclosure of Asserted Claims was due, AstraZeneca believed that it was unnecessary to assert claims 3, 5 and 10 of the '504 patent and made a calculated decision not to assert them. Thereafter, Hanmi served invalidity contentions that raised a new theory of invalidity: namely, that if the term "alkaline salts" is construed to include salts other than Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$, such as the strontium salt used in Hanmi's NDA product, then claims 1, 2, 4, 6 and 7 of the '504 patent are invalid for lack of written description under 35 U.S.C. § 112. Based on the inclusion of this previously undisclosed theory of invalidity, AstraZeneca now believes it is necessary to assert and pursue claims 3, 5 and 10 of the '504 patent. Under these circumstances, the Court finds that there is good cause, absent prejudice to Hanmi, to permit AstraZeneca to add claims 3, 5 and 10 of the '504 patent. In reaching this conclusion, the Court not only finds that AstraZeneca was diligent in seeking to assert these claims after receiving Hanmi's Invalidity Contentions, but also that their efforts to move to amend after learning that Hanmi would not consent to same were diligent too. Further, while AstraZeneca may face an uphill battle establishing that Hanmi's NDA product infringes claims 3, 5 and 10 of the '504 patent, all of which are specifically limited to the six specific salts delineated above, or a subset thereof, the Court finds that AstraZeneca's proposed addition of these claims is not futile.

An amendment is futile if it "is frivolous or advances a claim or defense that is legally insufficient on its face." *Harrison Beverage Co. v. Dribeck Imp., Inc.,*, 133 F.R.D. 463, 468 (D.N.J. 1990) (internal quotation marks and citations omitted). In determining whether an

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would amount to an unwarranted fishing expedition into an adversary's privileged communications and work product.

amendment is "insufficient on its face," the Court employs the Rule 12(b)(6) motion to dismiss standard (*see Alvin*, 227 F.3d at 121) and considers only the pleading, exhibits attached to the pleading, matters of public record and undisputedly authentic documents if the party's claims are based upon same. *See Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993). When considering whether a pleading would survive a Rule 12(b)(6) motion, the Court must accept all facts alleged in the pleading as true and draw all reasonable inferences in favor of the party asserting them. *Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2004). "[D]ismissal is appropriate only if, accepting all of the facts alleged in the [pleading] as true, the p[arty] has failed to plead 'enough facts to state a claim to relief that is plausible on its face[.]'" *Duran v. Equifirst Corp.*, Civil Action No. 2:09-cv-03856, 2010 WL 918444, *2 (D.N.J. March 12, 2010) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). In other words, the facts alleged must be sufficient to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). Here, while claims 3, 5 and 10 of the '504 patent are clearly not literally infringed by Hanmi's esomeprazole strontium product, the Court finds that AstraZeneca's theory that claims 3, 5 and 10 of the '504 patent are infringed under the doctrine of equivalents is plausible on its face and sufficient to raise AstraZeneca's "right to relief above the speculative level." *See Twombly*, 550 U.S. at 555.

The Court thus turns to the last remaining question: whether permitting AstraZeneca to add claims 3, 5 and 10 of the '504 patent would unduly prejudice Hanmi. The Court finds that it would not. In this regard, the Court finds that regardless of whether AstraZeneca is permitted to add claims 3, 5 and 10 of the '504 patent, Hanmi would have had to invest significant resources

in evaluating the claims asserted in AstraZeneca's initial Disclosure of Asserted Claims. As a result, the time and money spent by Hanmi assessing these claims was certainly not wasted and the Court finds that Hanmi was not unduly prejudiced by this expenditure. The Court appreciates that Hanmi will have to invest additional resources in evaluating claims 3, 5 and 10 of the '504 patent and that the inclusion of these claims in this matter will likely also require Hanmi to adjust their case strategy going forward. The Court, however, is not convinced that the addition of claims 3, 5 and 10 of the '504 patent will require Hanmi to "incur significant additional expense[.]" (Hanmi Opp. Br. at 17). Instead, the Court finds that Hanmi's conclusion to this effect is unsupported. Indeed, to the extent Hanmi believes that the term "alkaline salts" should be limited to the six salts listed in claims 3 and 10 of the '504 patent, then it would appear that much of the infringement and invalidity analysis undertaken by Hanmi with respect to the earlier asserted independent claims will also apply to newly added dependent claims 3 and 10. Moreover, it bears keeping in mind that good cause exists for AstraZeneca's proposed amendment because the lack of written description invalidity theory included in Hanmi's Invalidity Contentions was not included in Hanmi's Notice Letter or Answer. Most importantly, however, is the fact that the Court is convinced that whatever schedule modifications need to be made in light of AstraZeneca's addition of claims 3, 5 and 10 of the '504 patent, those modifications will in no way prevent this matter from being tried before the 30-month stay expires. As a result, the Court finds that Hanmi will not be unduly prejudiced by the addition of claims 3, 5 and 10 of the '504 patent.

III. Conclusion

For the reasons stated above, AstraZeneca's motion to amend their Disclosure of Asserted Claims to add claims 3, 5 and 10 of the '504 patent is GRANTED. An appropriate Order follows.

Dated: November 14, 2011

s/Tonianne J. Bongiovanni
HONORABLE TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE