IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ANTARES PHARMA, INC.,	)	
Plaintiff,	)	
v.	)	Civ. No. 14-270-SLR
MEDAC PHARMA, INC. and MEDAC GMBH,	)	
Defendants,	)	
and	)	
BECTON DICKINSON FRANCE S.A.S. and BECTON DICKINSON AND COMPANY	)	
Intervenors.	)	

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MEMORANDUM OPINION

Dated: July 10, 2014
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On February, 28, 2014, plaintiff Antares Pharma, Inc. ("Antares") filed a complaint alleging infringement of U.S. Patent Nos. 6,565,553 ("the '553 patent") and 8,480,631 ("the '631 patent") by defendants Medac Pharma, Inc. ("Medac Pharma") and medac GmbH, (collectively "Medac"). (D.I. 1) Antares filed a motion for preliminary injunction directed to the '553 and '631 patents on March 14, 2014. (D.I. 6) On April 18, 2014, Antares amended its complaint, adding allegations of infringement of U.S. Patent Nos. RE 44,846 ("the '846 patent"), and RE 44,847 ("the '847 patent") (collectively with the '553 and '631 patents, "the patents-in-suit"). (D.I. 27) Antares amended its motion for preliminary injunction on the same day to seek an injunction directed at the '846 and '631 patents.[1] (D.I. 29)

On May 5, 2014 Medac Pharma answered the complaint and counterclaimed for invalidity and non-infringement of the patents-in-suit. (D.I. 40) The same day, Becton Dickinson France S.A.S., Becton, Dickinson and Company (collectively "Becton") filed an intervenor complaint seeking a declaratory judgment that no valid claim of the patents-in-suit is infringed by Becton and alleging that the patents-in-suit are invalid. (D.I. 39) On May 30, 2014, Antares answered the intervenor complaint and counterclaimed, alleging that Becton infringes the '553, '846 and '847 patents. (D.I. 52) The same day, Antares also answered Medac Pharma's counterclaims. (D.I. 53) On July 1, 2014, medac GmbH answered Antares' amended complaint and counterclaimed for noninfringement and invalidity of the patents-in-suit. (D.I. 77)

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[1]Replacing the original motion for preliminary injunction.

Presently before the court is Antares' amended motion for preliminary injunction. (D.I. 29) The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

II. BACKGROUND

Antares is a small, publicly traded, U.S.-based developer of automatic injection devices used to self-administer pharmaceuticals. (D.I. 27 at ¶ 2) In October 2013, the FDA approved Otrexup™, which uses Antares' proprietary automatic injection device, and in February 2014, Antares began selling Otrexup™. Otrexup™ is the first and only product approved by the FDA to administer methotrexate subcutaneously (under the skin) to treat rheumatoid arthritis (RA) and psoriasis. (D.I. 30 at 1-2)

Medac Pharma is a newly formed U.S. subsidiary of the German pharmaceutical company, medac GmbH. (D.I. 27 at ¶¶ 3-4) Medac Pharma is an innovator in injectable methotrexate, and its parent, medac GmbH, is the leader in the European market for such products. (D.I. 44 at 6) Medac GmbH commercializes hand-powered pre-filled methotrexate syringes in Europe. (D.I. 44 at 6) On September 10 2013, Medac Pharma submitted a 505(b)(2) application with the FDA for a methotrexate injection product, which will be sold under the trade name RASUVO™. (D.I. 44 at 2)

There are two patents at issue: the '631 patent, titled "Hazardous Agent Injection System," which issued on July 9, 2013; and the '846 patent, titled "Needle Assisted Jet Injector," which issued on April 15, 2014.

III. STANDARD OF REVIEW

A preliminary injunction is "an extraordinary remedy that should only be granted in limited circumstances." *Capriotti's Sandwich Shop, Inc. v. Taylor Family Holdings,*

Inc., 857 F. Supp. 2d 489, 501 (D. Del. 2012). To be successful, a movant at bar must demonstrate: (a) a reasonable likelihood of success on the merits; (b) the prospect of irreparable harm in the absence of the injunction; (c) that this harm would exceed harm to the opposing party; and (d) that granting the injunction is in the public interest. See *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008). "If either or both of the fundamental requirements—likelihood of success on the merits and probability of irreparable harm if relief is not granted—are absent, an injunction cannot issue." *Enzo Life Sciences, Inc. v. Adipogen Corp.*, Civ. No. 11–88, 2011 WL 2559610, at *2 (D. Del. June 28, 2011) (citing *McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ.*, 24 F.3d 519, 523 (3d Cir. 1994).

IV. DISCUSSION

A. Likelihood of Success on the Merits

1. The '631 patent

The '631 patent is directed to "a hazardous agent injection system," more specifically "a needle-assisted jet injector." ('631 patent, abstract, col. 45:8-14) The '631 patent distinguishes a "jet injector" (including a "needle-assisted jet injector") and an autoinjector or hand-powered syringe. (Col. 26:49-27:18) Specifically,

> whereas a medicament injected into a subject via an autoinjector or hypodermic syringe is delivered in a bolus near the needle tip, the medicament delivered from a jet injector is sprayed rapidly into the tissue, typically remotely from the needle tip, and typically does not deposit the medicament in a bolus local to a needle tip. . . . Needle-assisted jet injectors . . . have pressures and speeds that are sufficiently high so that the medicament exits the needle tip as a fluid jet.
> . . .
> Because the medicament delivered by a jet injector is essentially sprayed rapidly into the subject's tissue, remotely from the needle tip, the

> medicament does not leave the jet injector as a single drop or bolus and is thus not delivered to a subject as a bolus local to a needle tip. Therefore, by using the jet injectors disclosed herein, a medicament can be dispersed into a subject's tissue more efficiently.

(Col. 27:5-18, 32:54-61)

The court construes "jet-injector" as "a powered injector used to achieve the delivery of medicaments in a high speed stream, that is, at a pressure, force, and speed sufficiently high so that the medicament exits the needle tip as a fluid jet and not as a bolus. The critical difference between a jet injector and autoinjectors or hand-powered syringes is how the medicament is delivered - dispersed remotely from the needle-tip (jet) rather than deposited in a locus near the needle tip (bolus)."

The parties' experts compared injection with a conventional needle to injection with Medac's autoinjector using a ballistics gel block - the still images show a bolus surrounding the end of the needle. (D.I. 11 at ¶ 48; D.I. 50 at ¶ 96) Antares' expert, Fisher, opined that "Medac's methotrexate injector is a jet injection device, because it uses a jet to inject to the medicament into a patient to a depth beyond the tip of the needle." Moreover, Fisher concluded that "when Medac's injector is fired into a block of ballistics gel, the force of the injector causes the fluid to be expelled as a jet that penetrates to a deeper portion of the block, . . . in contrast to the lack of jet . . . [when] firing a manual syringe into the same type of block." (D.I. 11 at ¶ 48) Medac's expert duplicated the ballistics gel study and concluded that "[t]he [M]edac injector . . . deposits methotrexate in a bolus near the needle tip" and "Medac's injector does not have increased dispersion as compared to the hand-powered syringe." (D.I. 50 at ¶¶ 97-98) Neither party presented a comparison of Antares' jet injector with either a hand

syringe or Medac's autoinjector nor did the parties illustrate the "rapid spray" dispersion of a jet injector.[2]

During prosecution, an inventor of the '631 patent submitted a declaration to the PTO emphasizing that

> the subcutaneous deposition of methotrexate resulting from the claimed needle-assisted jet injector is important because increased dispersion of methotrexate, as compared to bolus deposition of methotrexate from a hand-powered needle and syringe, significantly impacts the methotrexate's contact and interactions with cells of the tissue into which it is injected, which in turn alters the migration of the methotrexate to the systemic circulation.

(D.I. 45, ex. 17 at ¶ 12) In contrast, Antares now avers that "increased dispersion" and the creation of a "fluid jet" are only "possible benefits" of the '631 patent. (D.I. 67 at 5, citing col. 27:1-11, 18:43-49)

Antares also argues that "Becton did human injection tests showing that drug was deposited over 17.5 mm beneath the skin with the autoinjector, something a manual injector could not do." (D.I. 67 at 5) Abry, the European Manager for Commercial Development at Becton Dickinson France S.A.S., acknowledged that one "outlier," labeled "statistically outlying values" (in a study with a total of 960 injections), showed drug penetration of 17.5 mm. (D.I. 69, ex. HH at 166:10-18) However, the results of the study "demonstrated that there was no significant difference in depth of the fluid depot between Physioject™[3] autoinjection and a manual syringe injection, finding . . .a mean depth of fluid depot of 7.75 mm for self-injection and of 7.83 mm for

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[2]With the exception of a hand drawing provided in Medac's presentation to the court.

[3]Becton's disposable autoinjector.

nurse-assisted manual injection for the 0.2 mL injections, and of 8.58 mm for self-injection and of 8.72 mm for nurse-assisted manual injection for the 1.0 mL injections." (D.I. 49 at ¶¶ 11-12, ex. A at 393, fig. 2) Similarly reported data in a Becton document "include[d] an exemplary echography of the tissue taken during the study and report[ed] that the depth of depot 'was statistically not different between the auto-injector (8.2 mm; SD: 2.5) and the prefilled syringe as alone (8.3 mm; SD: 2.2).'" (D.I. 49 at ¶ 13, ex. C at MEDAC-DE 2616)

The '631 patent specification differentiates jet injectors as providing increased dispersion and not depositing medicament in a bolus. Indeed, the patentees focused on this difference during prosecution. Moreover, Antares has not offered a comparison of its jet injector with Medac's autoinjector. Further, the still image provided of Medac's autoinjector shows a bolus near the needle tip. The court concludes that Antares has not carried its burden of showing a likelihood of success on the merits.[4]

2. The '846 patent

a. Prosecution history

The '846 patent is a reissue of U.S. Patent No. 7,776,015 ("the '015 patent"), which issued on August 17, 2010 from Appl. No. 11/002,687 ("the '687 application") filed on December 3, 2004. The '846 patent, titled "Needle Assisted Jet Injector," is described in the "Summary of Invention" as relating to "a needle assisted jet injector." (Col. 2, 54-55) In the "Background of the Invention," the patentees described the

[4]Therefore, the court does not reach Medac's invalidity arguments.

following needs that were being addressed in the field of invention,[5] that is,

> a need for a needle assisted jet injector that operates at relatively low pressure and that is capable of quickly delivering medicament. There also exists a need for such an injector having a retractable or concealed needle to prevent the medical hazards associated with exposed needles.

(Col. 2:45-50)

During prosecution, the examiner rejected the '687 application as anticipated and/or made obvious by prior art references that, according to the applicants, did not disclose a "jet injector." The following are just a few examples of the applicants' arguments in this regard:

> In the Response to Arguments section of the Office Action, the statement is made that it is allegedly "clear" that Kramer injects liquid as forcefully shooting forth from a nozzle in a stream, and that this makes Kramer a jet injector. Furthermore, the Office Action separated the term "jet" from "injection," improperly treating them as separate terms. Such a definition is improper and is contrary to the ordinary understanding in the art. The terms "jet injector," "jet injecting," "jet injection," and related phrases are well understood terms of art. The jet from a jet injector is powerful enough to penetrate through a depth of tissue, such as muscle or skin layers, instead of being deposited as a bolus. Jet injectors are often defined in terms of the combination of certain parameters like pressures, diameter of the outlet that makes the jet, and flow rate, but Kramer does not disclose these parameters to suggest a jet.
>
> * * * *
>
> With regard to the recitation of the jet injection device itself, the Examiner argued that this recitation in the preamble was not given patentable weight and cited 1976 and 1951 case law in alleging that the term "jet injector" somehow merely relates to an intended use. The recitation of "A jet injector" is definitely structural and significantly affects the structural recitations in the body of the claim. One of ordinary skill in the art would have understood that a jet injector involves significant structural features, including, for instance,

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[5]"The present invention is directed to a device for delivery of medicament, and in particular to a jet injector with a short needle to reduce the pressure at which the jet injector must eject the medicament for proper delivery." (Col. 1:24-27)

> sufficiently powerful force-generating source, a construction that can withstand high pressures of jet injectors, and a suitable orifice such as the orifice of the injection-assisting needle to produce the jet that is understood to be powerful enough to penetrate through tissue as a jet. **Several elements recited in the claim, such as the force-generating source and the needle, would have a different construction in a jet injector than in other types of injectors, such as hypodermic or auto-injectors, which are described in the specification, or such as the injector of Kramer**. Consequently, the term, "jet injection device," in the preamble is a positive recitation from which the structures of the claim body depend.

(D.I. 45, ex. 9 at 2-3) (emphasis added) (*see also* D.I. 45, ex. 20 at 5-6)

In June 2006 and October 2008, the applicants were still attempting to overcome the examiner's rejections under 35 U.S.C. §§ 102 and 103 over such prior art references as Kramer, arguing that "the jet injector of the present claims" is "significantly different" from the "automated injector of Kramer." (*Id.*, ex. 27 at 8) In order to "further define the invention and distinguish it from Kramer in view of all previously submitted reasons," the applicants amended independent claims 1 and 21 to add the descriptive language in bold:

> wherein the force generating source is configured such that activation of the force generating source moves the plunger to apply a pressure to the medicament in the fluid chamber . . . to expel medicament from the fluid chamber **by creating a high-speed jet of the medicament that penetrates patient tissue to a distance through and beyond[6]** . . . the injecting end **and past the insertion point to an injection site**.

(*Id.*, ex. 27 at 3, 7) The examiner issued a notice of allowance on April 6, 2010, explaining that

> [t]he claims in this application have been allowed because the prior art of record fails to disclose either singly or in combination the claimed apparatus of a jet injection device with the high speed jet with a fluid pressure between about 100 and 1000 p.s.i. to penetrate tissue through

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[6]Replacing the phrase "and eject the amount of the medicament through."

> and axially beyond the insertion point and such that the injecting end reaches a needle point at a depth of up to about 5mm below the surface along (or no more [than] 5mm) along with a mechanical member that is elastically deformed to provide the force.
>
> The closest prior art is Brennen (U.S. Patent 4,222,392), Baum (U.S. Patent 4,929,238), Kramer (U.S. Patent 5,176,643) and Haber (U.S. Patent 5,304,128), but all fail to disclose the claimed combination with the claimed penetration depth, pressure p.s.i. output, axial penetration, and elastically deformed mechanical force.

(*Id.*, ex. 28 at 2) The '687 application issued as the '015 patent on August 17, 2010.

On June 22, 2012, Appl. No. 13/531,023 was filed by the inventors of the '015 patent, presumably seeking to amend such pursuant to 35 U.S.C. § 251(a).[7] According to the record presented by the parties, new claims 23-37 were added, reciting "an injection device" comprising certain features. In responding to rejection of certain of the new claims by the examiner in September 2013, the applicants argued that neither Kramer nor any of the other cited references, alone or in combination, suggested or taught either of a "latch or spring feature, or equivalent structures, within the proximal end" of the "injecting device that is under sufficient compression to eject the medicament . . . ." (*Id.*, ex. 24 at 11, 13) The applicants remarked that "support" for the new claims could be found "throughout the specification and in particular the paragraphs (based on the column and line numbers of U.S. Patent No. 7,776,015, the basis of the current reissue application) and figures" enumerated by the applicants. (*Id.*, ex. 24 at 9) The '846 patent issued on April 15, 2014.

b. Legal standard

[7]"Presumably" is used because the parties did not see fit to include such in the record, at least not where it could be easily found by the court.

Section 251(a) of Title 35 of the United States Code provides in relevant part as follows:

> Whenever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

The Federal Circuit has found two requirements in § 251(a). The first, the "error" requirement, "limits the availability of a reissue patent to certain correctable errors," e.g., "the patentee claiming his invention too broadly or too narrowly." *Hester Indus. Inc. v. Stein Inc.,* 142 F.3d 1472, 1479 (Fed. Cir. 1998) (citation omitted). "The 'original patent' requirement is a second and independent requirement, . . . which restricts a reissue patent to 'the invention disclosed in the original patent.'" *Id.* (citation omitted). The reissue statute should be construed liberally, as it is "based on fundamental principles of equity and fairness . . . ." *In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986).

With respect to the "error" requirement, "[o]ne of the most commonly asserted 'errors' in support of a broadening reissue is the failure of the patentee's attorney to appreciate the full scope of the invention during the prosecution of the original patent application." *Hester*, 142 F.3d at 1479. In determining whether such an error actually supports the new claims, a review of the prosecution history of the original patent must be undertaken to ensure that a patentee does not regain "'through reissue . . . subject matter that he surrendered in an effort to obtain allowance of the original claims.'" *Id.* at

1480 (citation omitted). The "recapture rule" addresses the above concern.

As explained by the Federal Circuit in *Hester*,

> "[u]nder [the recapture] rule, claims that are 'broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution' are impermissible.". . . Application of the recapture rule begins with a determination of whether and in what respect the reissue claims are broader than the original patent claims. . . . A reissue claim that does not include a limitation present in the original patent claims is broader in that respect. . . .

Id. If the reissue claims are determined to be broader, under the recapture rule the court must "next examine whether these broader aspects relate to surrendered subject matter. . . . 'To determine whether an applicant surrendered particular subject matter, [the court] look[s] to the prosecution history for **arguments** and changes to the claims made in an effort to overcome a prior art rejection.'" *Id.* (citation omitted) (emphasis in original).

> [A]s a general proposition, in determining whether there is a surrender, the prosecution history of the original patent should be examined for evidence of an admission by the patent applicant regarding patentability. . . . In this regard, claim amendments are relevant because an amendment to overcome a prior art rejection evidences an admission that the claim was not patentable. . . .
>
> Arguments made to overcome prior art can equally evidence an admission sufficient to give rise to a finding of surrender.

Id. at 1481. If the court concludes that there has been a surrender, it "must next determine whether the surrendered subject matter has crept back into the asserted reissue claims." *Id.* at 1482.

If the above described prongs of the recapture rule have been satisfied, the rule can be avoided only if the reissue claims "are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow

the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects." *Id.* at 1482-83. Therefore, "[u]nless the claims are materially narrowed in a way that avoids substantial or whole recapture of the surrendered subject matter, the surrendered subject matter has crept into the reissue claims and they are barred under the recapture rule." *In re Youman*, 679 F.3d 1335, 1344-45 (Fed. Cir. 2012).

c. Analysis

Although it is not clear to the court that the parties provided the entire prosecution history of either the '015 patent or the '846 patent in connection with the instant preliminary injunction proceeding, the court has reviewed the record as submitted and concludes that the recapture rule applies to the facts at bar, despite plaintiff's arguments to the contrary: "There are two different claimed aspects, the 'jet' aspect in the original application and the safety features aspect in the reissue. . . . As Medac's expert admitted, the claim 31 safety features can be used with any autoinjector, not just jet injectors. . . . In this situation, . . . '[a]s for obtaining claims on reissue which are different, no prohibition arises merely because of the language of the reissue statute.'" (D.I. 67 at 4, citing *In re Wadlinger*, 496 F.2d 1200, 1207 (C.C.P.A. 1974))

The court respectfully disagrees with plaintiff's reasoning. The prosecution history of the '015 patent is replete with arguments and amendments made to distinguish such prior art references as Kramer, wherein the distinguishing feature of the invention was characterized as a "jet injector." Indeed, the applicants argued in this regard that the structural recitations in the original claims were affected by the fact that

it was a "jet injection device" that was claimed; to wit, "the term, 'jet injection device,' in the preamble is a positive recitation from which the structures of the claim body depend." (D.I. 45, ex. 9 at 3) On multiple occasions, the applicants argued that "the jet injector of the present claims" is "significantly different" from the automated injector of Kramer. (*Id.*, ex. 27 at 8) The applicants amended claims 1 and 21 to further buttress the fact that their invention was different from other injectors, in that the medicament was expelled "from the fluid chamber **by creating a high-speed jet of the medicament** . . . ." (*Id.*, ex. 27 at 3, 7) Each of the original 22 claims refers to a "jet injection device," and the specification is written in the context of a "jet injection device."[8]

Applying the recapture rule to the above facts, the reissue claims are broader, in that they do not recite the limitation "jet injection device" but, rather, "an injection device." Given the prosecution history related above, there is every indication that the applicants surrendered all injectors but for "jet injectors," understood by those of skill in the art at the time to include only those injectors having a "jet . . . powerful enough to penetrate through a depth of tissue, such as muscle or skin layers, instead of being deposited as a bolus." (*Id.*, ex. 9 at 2) Likewise, the applicants argued that "jet injectors" affected the structural recitations in the body of the original claims[9] and, as noted, the structural features now claimed in the '846 patent were described in the specification of the '015 patent only in the context of a jet injector. Without the

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[8]The specification and the claims mention "jet injection," "jet injector," and like phrases over 75 times.

[9]*See, e.g.,* D.I. 45, ex. 9 at 2-3.

structural context of a jet injector, the court concludes that the surrendered subject matter - prior art injectors that would not be considered "jet injectors" to those of skill in the art at the time - has crept into the reissue claims.[10]

With respect to the final prong of the analysis, that is, whether the recapture rule can be avoided because the applicants did not recapture everything they surrendered, the analysis proceeds on a limitation-by-limitation basis. *See North American Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1350 (Fed. Cir. 2005). To avoid recapture for claims that are broader in some respects and narrower in others,[11] "the narrowing must relate to the subject matter surrendered during the original prosecution . . . ." *In re Mostafazadeh*, 643 F.3d 1353, 1359 (Fed. Cir. 2011). Here, the "jet injector" and needle length limitations of the claims were entirely eliminated on reissue and no new restriction was imposed on the injector or needle that would avoid the recapture rule.

d. Conclusion

The '015 patent claimed certain features of a "jet injector." The '015 patent issued over prior art references that arguably disclosed those same features but in a different injector. The patentees ultimately prevailed in convincing the examiner that the "jet injector," as known to those of skill in the art, had distinct characteristics and

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[10]To the extent that the structural limitations of the reissue claims only make sense in the context of a jet injector, e.g., a syringe does not require a spring or a latch, then the court construes "an injecting device" consistent with its construction of "jet injector" in the '631 patent and relies on the related infringement analysis *supra*.

[11]By adding the "latch" limitation, e.g., the asserted claims are arguably narrower than the original claims.

structure not found in the cited prior art. To allow the patentees to remove this limitation and claim features that were only described in the context of a jet injector does not fit within the realm of corrections contemplated within § 251. As discussed above in the analysis of the '631 patent, Antares has not carried its burden of showing likelihood of success on the merits that Medac's product infringes claims directed to a "jet injector."

B. Irreparable Harm

Antares' currently has the only available subcutaneous injector for methotrexate on the market, with Medac set to launch its competing product as early as July 10, 2014. (D.I. 8 at ¶ 14; D.I. 30, exs. F, EE at 14) Insurance companies and other third party payors place drugs into formulary "tiers," which determine the level of co-pays and reimbursements. This impacts the sales of the drug and a company's ability to grow the market. Otrexup™ is now a "tier 3" product, which allows for substantial insurance coverage. (D.I. 8 at ¶¶ 27-28) Antares argues that the launch of a competing product would force the renegotiating of the current tier and pricing structure. Moreover, Antares has identified the types of harm that traditionally have qualified as not easily compensable by money damages—price erosion and threatening its brand. *See, e.g., Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013) ("Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.") (quoting *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012)). While Medac responds that any losses to Antares are measurable and would be compensable by money damages, the court finds Antares' reasoning more persuasive on this issue, particularly with respect to

the tier pricing. *See, e.g., Nutrition 21 v. U.S.*, 930 F.2d 867, 872 (Fed. Cir. 1991) (stating that some evidence and reasoned analysis for the inadequacy of money damages should be proffered.) Antares has carried its burden of demonstrating irreparable harm.

C. Balance of Harms and Public Interest

While Antares' sales would suffer if Medac's product were introduced and later found infringing, delaying Medac's launch would also cause monetary damages. The balance of harms is neutral. As to the public interest, Antares avers that its product is available and in use for the same indications as Medac's product, i.e., rheumatoid arthritis and psoriasis. Medac responds that the products are not interchangeable as RASUVO™ provides additional dosing flexibility not offered through OTREXUP™. As over 90% of prescribed doses are for the standard doses that Antares already sells, this factor is neutral.

V. CONCLUSION

On the record presented, the court denies Antares' motion for a preliminary injunction. An order shall issue.