

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NOVEN PHARMACEUTICALS, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 17-1777-LPS
	:	
MYLAN TECHNOLOGIES INC., MYLAN PHARMACEUTICALS INC., MYLAN INC. and MYLAN N.V.,	:	<b><u>AMENDED REDACTED</u></b> <b><u>PUBLIC VERSION</u></b>
	:	
Defendants.	:	
	:	

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**MEMORANDUM ORDER**

Pending before the Court is Plaintiff Noven Pharmaceuticals, Inc.’s (“Plaintiff” or “Noven”) Motion for a Temporary Restraining Order (“TRO”), seeking to enjoin the launch of a generic version of Noven’s Minivelle<sup>®</sup> product (“Generic Product”) by Defendants Mylan Technologies Inc., Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (“Defendants” or “Mylan”). (D.I. 155) Having reviewed the parties’ briefing and related materials (D.I. 155-62; D.I. 171; D.I. 173; D.I. 175), heard telephonic and in-person oral argument (D.I. 164; D.I. 165), and moved expeditiously to consider Plaintiff’s request for extraordinary relief in light of the present circumstances,<sup>1</sup>

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<sup>1</sup> Noven filed this case on December 8, 2017. (D.I. 1) On May 22, 2018, the Court scheduled an expedited bench trial for December 3, 2018. (D.I. 66) The parties have been providing the Court monthly status reports relating to Mylan’s Abbreviated New Drug Application (“ANDA”), which seeks approval from the U.S. Food & Drug Administration (“FDA”) to market Mylan’s Generic Product. (See, e.g., D.I. 51; D.I. 73; D.I. 102; D.I. 126; D.I. 127) While Mylan has all along advised Noven and the Court of the possibility its Generic Product would receive final FDA approval on August 15, 2018, neither Plaintiff nor Defendants appear to have believed this likely until after Mylan received an email communication from the FDA on August 3, 2018. (See D.I. 151; D.I. 152 at 2 & n.3) Between August 9 and 12, the parties wrote letters to the Court regarding their positions in respect to the seemingly imminent FDA approval. (See D.I. 147; D.I. 149; D.I. 150; D.I. 151; D.I. 152) Early in the day on August 13, the Court heard

**IT IS HEREBY ORDERED THAT:**

1. Plaintiff's motion (D.I. 155) is construed as both a motion for a TRO, to allow for further briefing and procedures to determine whether to preliminarily enjoin Mylan's launch of its Generic Product, as well as a motion for a preliminary injunction ("PI").<sup>2</sup> Thus construed, Plaintiff's motion is **DENIED** to the extent it seeks a PI, and **GRANTED** to the limited extent that *Mylan is temporarily restrained from launching its Generic Product until 4:00 p.m. on Wednesday, August 22, 2018*. At that point this limited TRO will automatically expire unless additional relief, such as a stay pending appeal, is granted either by this Court or the Court of Appeals, relief this Court will only consider if Noven files a notice of appeal and an expedited motion for a stay no later than **Tuesday, August 21 at 4:00 p.m.**

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telephonic argument from the parties on how it should proceed, and around 8:00 p.m. that night Noven filed its motion for a TRO. (See D.I. 155; D.I. 164) Mylan filed its opposition brief on the morning of August 14 and the parties appeared in Court for a lengthy oral argument later that day, which ran until the evening. (See D.I. 158; D.I. 165) At the conclusion of the hearing, Mylan agreed to refrain from launching its Generic Product until 11:59 p.m. today, Monday, August 20. (D.I. 165 at 112) The Court also ordered additional briefing, which the parties filed on August 16, 17, and 18. (See D.I. 171; D.I. 173; D.I. 175) In the meantime, Mylan did receive final FDA approval for its Generic Product on August 15, 2018. (D.I. 166)

<sup>2</sup> Both Noven and Mylan have had notice of these proceedings and a full and fair opportunity to present evidence, briefing, and oral argument on the issues raised by Noven's motion. Given the severe time constraints the parties have imposed on the Court, the important public and other interests implicated by their disputes, the fact that the issues that would be presented in a separate forthcoming PI motion would be identical to those already before the Court, and the reality that what Noven is trying to accomplish is to prevent Mylan's launch until after trial, it is appropriate to convert Noven's motion into a PI motion, and render this Order one that may be immediately appealed. See Fed. R. Civ. Proc. 65; 28 U.S.C. § 1292(c)(1); *CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc.*, 859 F. Supp. 945, 949 (D. Md. 1994) ("The Court concludes that Defendants have had sufficient notice and opportunity to be heard in the matter, such that the present proceeding may fairly be treated as one for preliminary injunctive relief."); see also generally *Washington v. Trump*, 847 F.3d 1151, 1158 (9th Cir. 2017) (exercising appellate jurisdiction despite district court stylizing its order as granting TRO and addressing issues summarily).

2. A temporary restraining order or preliminary injunction is an “extraordinary remedy” that should be granted only in “limited circumstances.” *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004). Deciding whether to grant a TRO or PI requires consideration of whether the moving party can prove the following: “(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction’s favorable impact on the public interest.” *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009). “Although the factors are not applied mechanically, a movant must establish the existence of both of the first two factors to be entitled to a preliminary injunction.” *Id.* (internal citation omitted).

3. With respect to likelihood of success on the merits, Noven must show both (1) it is likely to prove that Mylan’s Generic Product will infringe the asserted patent claim on which the motion is based (claim 6 of the U.S. Patent 9,730,900 (“900 patent”)) and (2) Mylan’s challenges to the validity of that patent claim lack substantial merit. *See Abbott Labs. v. Andrx. Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006); *see also Altana*, 566 F.3d at 1006 (explaining as to invalidity, “[v]ulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial”). Noven has failed in both respects.

A. Infringement here turns on the parties’ competing constructions of the claim term “the system achieves an estradiol flux from [about] 0.0125 to about 0.05 mg/cm<sup>2</sup>/day, based on the active surface area.”

Noven has failed to persuade the Court that any of its proposed constructions for this “flux” term is correct.<sup>3</sup> All of Noven’s proposals are based on its insistence that this “flux” term

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<sup>3</sup> Noven has proposed at least the following constructions: (a) “No further construction is required beyond the defined terms used within the phrase, and a person of ordinary skill in the art (‘POSA’) would understand that the flux achieved must be determined using controlled

should be construed to require *in vitro* testing of estradiol flux, normalized in relation to a control, with Noven's prior art product Vivelle-Dot<sup>®</sup> being the primary example of such a control, because "[c]ritical to the invention is the higher flux achieved relative to Vivelle-Dot<sup>®</sup>." (D.I. 155 at 4; *see also* D.I. 156 Ex. 5 ¶¶ 48-49 (Noven's expert Dr. Adrian Williams explaining that flux of transdermal drug delivery system is *in vivo* property, but is typically measured by *in vitro* methodology)) As intrinsic evidence, Noven points to Example 3 of the '900 patent, which demonstrates, in Noven's view, that the '900 patent requires a product's measured flux to be "normalized," meaning, for instance, that when the observed experimental flux of Vivelle-Dot<sup>®</sup> on a particular skin sample is greater than 0.01 mg/cm<sup>2</sup>/day, a person of ordinary skill in the art ("POSA") knows to adjust the measured flux of the product by the same percentage necessary to reduce Vivelle-Dot<sup>®</sup> to its expected value of 0.01 mg/cm<sup>2</sup>/day. (D.I. 155 at 6-8, 19)

Mylan's view is that, notwithstanding the reality of experimental variability and the invention's novelty of increased flux as compared to a control, the proper construction of this "flux" term is based on a simple mathematical calculation: "dividing the amount of drug [estradiol] per day . . . by the active surface area." (D.I. 173 at 2)<sup>4</sup> Mylan relies on the specification's unambiguous characterization of Vivelle-Dot<sup>®</sup> as coming in five different sizes, each having a flux rate of 0.01 mg/cm<sup>2</sup>/day, which is the precise result arrived at by dividing the

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experimental conditions to account for experimental variability (e.g., skin permeability)" and (b) "the system achieves an *in vitro* estradiol flux of from 0.01125 to 0.055 mg/cm<sup>2</sup>/day relative to a system that achieves an *in vitro* estradiol flux of 0.01 mg/cm<sup>2</sup>/day, e.g., Vivelle-Dot<sup>®</sup>." (D.I. 155 at 5)

<sup>4</sup> Mylan's specific proposed construction is: "the system achieves an estradiol flux of from [about] 0.0125 to about 0.05 mg/cm<sup>2</sup>/day, based on active surface area, which does not include a system that provides a flux that is nominally 0.01 mg/cm<sup>2</sup>/day or less based on active surface area (e.g., a system that provides nominal *in vivo* delivery rates of 0.025, 0.0375, 0.05, 0.075, or 0.1 mg of estradiol per day from a system having an active surface area of 2.5, 3.75, 5.0, 7.5, or 10 cm<sup>2</sup>, respectively.)" (D.I. 158 at 7)

listed daily dose of estradiol by the active surface area of the patch. (See D.I. 158 at 3) (quoting U.S. Patent 9,724,310 (“’310 patent”) at 4:7-11, 13:37-41) (“For example, in some embodiments, the systems exhibit a flux greater than the 0.01 mg/cm<sup>2</sup>/day exhibited by the Vivelle-Dot<sup>®</sup> products.”)<sup>5</sup> In addition to this seemingly strong intrinsic support for how the patentee understood how flux rate was to be determined, Mylan cites support for this view from *Noven’s* own expert, Dr. Richard Guy,<sup>6</sup> as well as the inventor himself, Mr. Juan Mantelle. (See, e.g., D.I. 158 at 9; D.I. 173 at 2-4 (quoting Mr. Mantelle’s deposition testimony that he did not have “any reason to disagree that the value of 0.01 mg/cm<sup>2</sup>/day [is] derived from dividing the daily dose of Vivelle-Dot by the active surface area of Vivelle-Dot”))

The Court concludes that the appropriate claim construction to apply for purposes of evaluating *Noven’s* motion is Mylan’s proposed construction. Under this construction, *Noven* has failed to show a likelihood of proving infringement.<sup>7</sup> While *Noven* may ultimately persuade the Court that the proper construction of the flux term must mandate *in vitro* experimentation, at this point it has failed to do so, despite being provided multiple opportunities, in briefing and in argument. The Court has struggled, but failed, to understand *Noven’s* views as to how the

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<sup>5</sup> Although Mylan cites to the ’310 patent, a similar and more relevant excerpt appears in the ’900 patent. (See ’900 patent at 2:50-56, 3:41-47)

<sup>6</sup> Mylan argues that *Noven* should be collaterally or judicially estopped from challenging the testimony Dr. Guy provided previously, including during trial in a related matter before this very Court against another ANDA filer, Actavis. (See D.I. 165 at 111; see also D.I. 173 at 5) Notwithstanding *Noven’s* disagreement (see D.I. 175 at 2), Mylan may be correct – but, given the Court’s other conclusions, the Court need not resolve this question at this time.

<sup>7</sup> *Noven* insists that it can prove infringement even if the Court adopts Mylan’s construction of the flux term, citing testing it has conducted on samples of Mylan’s Generic Product. (See D.I. 155 at 11-13) Based on the unambiguous statements as to the flux value of Vivelle-Dot<sup>®</sup>, and the similarities between Mylan’s Generic Product and Vivelle-Dot<sup>®</sup>, the Court finds that *Noven* is not likely to succeed in proving infringement under Mylan’s construction.

patentee determined that the flux value for Vivelle-Dot<sup>®</sup> is 0.01 mg/cm<sup>2</sup>/day, what a POSA would understand from the patentee's unambiguous insistence that this is the flux value of Vivelle-Dot<sup>®</sup>, and why the same technique for determining the flux value of Vivelle-Dot<sup>®</sup> is (or is not) also the technique to be used to define the flux value for purposes of claim construction, infringement, and invalidity.<sup>8</sup> In seeking extraordinary relief – particularly under severe time constraints – the burden is very much on Noven, as the moving party, to persuade the Court its position is likely to be adopted. That Noven has failed to do so is fatal to its motion.

B. Noven has also failed to show that the invalidity defenses Mylan raises lack substantial merit. In particular, Noven has not persuaded the Court at this stage of the proceedings that Mylan is unlikely to prove, by clear and convincing evidence, that a POSA would not believe that the inventor of the '900 patent, at the time of the invention, had possession of the portion of claim 6 that involves a patch capable of delivering estradiol via mucosa. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.”) (internal quotation marks and brackets omitted). It is undisputed that the scope of the claim encompasses placement of patches on every skin surface as well as in parts of the body lined with mucosal tissue, including “oral, buccal, nasal, rectal and vaginal mucosa.” (D.I. 155 at 17; *see also* '900 patent at 5:37-39) But the specification says

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<sup>8</sup> Noven's most recent brief, filed Saturday, August 18, confuses the Court still further, suggesting (seemingly for the first time) that sometimes flux is assessed *in vitro*, and sometimes *in vivo*, and that this somehow may differ for purposes of claim construction and infringement. (*See* D.I. 175 at 2) (“To be clear, Noven acknowledges that because *in vitro* flux studies and *in vivo* flux delivery rates approximate one another, FDA labels *can* be used to assess infringement so long as the label-derived value is not contradicted by actual *in vitro* flux studies. But where, as with Mylan's product, the label-derived value is contradicted by actual results from Noven's and Mylan's *in vitro* flux studies, a POSA would rely on the actual *in vitro* results because the claimed ranges are based on *in vitro* flux studies.”) (internal citation omitted)

very little about such embodiments and the Court is not persuaded that a POSA would conclude that the inventor had possession of an embodiment of, for example, a patch to be placed in a patient's nose or mouth. While clear and convincing evidence is a high burden, and the '900 patent references bioadhesives and a prior art patent (U.S. Patent No. 6,562,363) relating to the placement of patches in mucosa (*see* D.I. 155 at 17-18), the Court cannot say at this point that Mylan's written description defense lacks substantial merit. Nor can the Court say that Mylan's indefiniteness defense lacks substantial merit, particularly given Noven's confusing position with respect to claim construction.

4. Turning to the other pertinent factors, Noven has met its burden to show it will be irreparably harmed in the absence of injunctive relief because Noven, between now and trial, will be irreparably harmed by the launch of Mylan's Generic Product.<sup>9</sup> The entry of a generic competitor into the Minivelle<sup>®</sup> market will require Noven to [REDACTED] [REDACTED]. (D.I. 155 at 24 (citing D.I. 157 ¶17)) Noven will also be required to reduce its prices on Minivelle<sup>®</sup>, will lose market share, will suffer loss to its reputation, and will have reduced opportunities for research and development. (D.I. 155 at 22-24) While these facts do not automatically constitute irreparable harm – and Noven's proof that its harm will be irreparable is far from overwhelming<sup>10</sup> – it has put forward sufficient evidence to meet its burden on this factor.<sup>11</sup>

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<sup>9</sup> Of course, the Court will do its best following trial to make Noven whole, through an award of damages and any other relief that is warranted, should Noven ultimately prevail on the merits.

<sup>10</sup> Noven has, in anticipation of generic competition, been raising the price of Minivelle<sup>®</sup> and watching its market share drop, computed the economic damage it is likely to suffer, and planned for the [REDACTED]. (*See* D.I. 158 at 17-18; D.I. 165 at 66-68)

<sup>11</sup> Given the Court's conclusion to deny Noven's motion on other grounds, the Court does not consider Mylan's additional arguments against a finding of irreparable harm, namely that Noven

5. Notwithstanding the irreparable harm Noven will suffer in the absence of preliminary injunctive relief, the harm Mylan would suffer if the Court were to enjoin Mylan's launch for any lengthy period – and especially were it to do so for the four months until the December trial<sup>12</sup> – is even greater. That is, the balance of hardships does not favor granting Noven's motion. This is because of the threat that delay poses to Mylan's potential regulatory exclusivity,<sup>13</sup> and the undisputed threat to Mylan's market exclusivity and first-mover

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is part of a larger corporate entity and not the small, vulnerable drug specialty company it portrays itself as, or that Noven should have sought preliminary relief much sooner than it did. (*See* D.I. 158 at 18-21; D.I. 155 at 1-3)

<sup>12</sup> This does not even account for the additional months that would likely be necessary following a bench trial for the parties to prepare post-trial briefs and for the Court to reach a decision and write an opinion.

<sup>13</sup> Much time was spent during the August 14 hearing, and much of the post-hearing briefing has been directed to, the complicated issues of whether Mylan has already forfeited its regulatory exclusivity due to its failure to market and/or its failure to obtain tentative approval. (*See, e.g.*, D.I. 165 at 10-46; *see also* D.I. 149; D.I. 164; D.I. 171; D.I. 173; D.I. 175; 35 U.S.C. §§ 505(j)(5)(D)(i)(I), 505(j)(5)(D)(i)(IV)) The parties agree that it will be for the FDA to decide if Mylan still possesses regulatory exclusivity and that the FDA will only do so if another ANDA filer obtains FDA approval and seeks also to launch its generic product. (*See* D.I. 171 at 3; D.I. 173 at 1) Neither side has been entirely consistent, nor persuasive, in what it has argued on this highly-complex question of statutory interpretation. To the Court, the pertinent point is that it cannot dismiss the possibility that Mylan is correct as to each of the following: that (i) Mylan has not yet forfeited its period of regulatory exclusivity, (ii) Mylan's view is supported by previously-published FDA guidance and the FDA's August 3 communication to Mylan (which does not state nor imply Mylan has already forfeited regulatory exclusivity), (iii) Mylan will forfeit its regulatory exclusivity the moment another ANDA filer, who has already obtained a consent judgment of non-infringement of "Orange Book-listed" patents, obtains tentative FDA approval; (iv) another ANDA filer, Alvogen, has obtained a consent judgment of non-infringement of "Orange Book-listed" patents, is currently seeking FDA approval, and is not subject to an automatic 30-month stay of FDA approval, notwithstanding the existence of litigation between it and Noven in this Court (*see* C.A. No. 17-1429-LPS), and (v) Mylan feels a business imperative to launch its Generic Product as soon as possible to avoid forfeiting its regulatory exclusivity. Noven has not persuaded the Court that any of the foregoing is clearly incorrect.

advantage.<sup>14</sup> While Mylan's lost exclusivities might be largely compensable with money damages, Mylan would not have a claim against Noven to recover that money.<sup>15</sup> Thus, if the Court now preliminarily enjoins Mylan's launch, yet Mylan ultimately prevails at trial, and in the meantime another ANDA filer comes to market, Mylan will have irretrievably lost its opportunity for any period of generic market exclusivity.

6. While there are important public interests on both sides of this case – Noven's interest in enforcement of valid patent rights, and protection of the attendant incentive to invest large sums of money in research and development of new medicines, *see Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 931 (Fed. Cir. 2012), and Mylan's interest in bringing more affordable medicines to more members of the public at earlier dates, *see AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 579, 614 (D.N.J. 2009), *aff'd*, 633 F.3d 1042 (Fed. Cir. 2010) – at this point in this case the public interest favors Mylan. Mylan has not been found to have infringed a valid patent claim. Mylan has filed an ANDA and obtained FDA approval to market its Generic Product. Mylan is not subject to an automatic 30-month stay. Mylan is a sophisticated company, with vast experience in ANDA litigation, and nothing in the record

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<sup>14</sup> The parties agree that Mylan is currently the only ANDA filer with final FDA approval. Therefore, there is no dispute that every day the Court prevents Mylan from launching its Generic Product is a day of generic market exclusivity irretrievably lost by Mylan. (*See* D.I. 171 at 3 (Noven: "All that is at stake for Mylan is the potential shortening of the *de facto* exclusivity it will obtain prior to Alvogen's approval by virtue of being the first on this market . . ."); D.I. 173 at 1 (Mylan: "[R]egardless of whether [Mylan] has already forfeited its exclusivity (as Noven contends), the risk faced by [Mylan] is very similar – *i.e.*, [Mylan] currently has the only approved ANDA but cannot enjoy the benefits of market exclusivity."))

<sup>15</sup> Noven has not addressed the amount of bond it would be willing to post should its requested relief be granted. *See generally* Fed. R. Civ. Proc. 65(c) ("The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.").

suggests it could not pay Noven's lost profits should Noven ultimately prevail in this case. Under these circumstances, the fact that Mylan – despite the very significant risks of being on the hook for an enormous damages award – is ready, willing, and anxious to launch at-risk persuades the Court that Noven's requested relief would “disserve the public interest.” *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017).

**IT IS FURTHER ORDERED** that because this Memorandum Order is being issued under seal, and is being docketed early in the morning, the parties shall meet and confer and, no later than today, **August 20, at 2:00 p.m.**, submit a proposed redacted version. Thereafter, the Court will release a public version.

August 20, 2018  
Wilmington, Delaware

  
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HONORABLE LEONARD P. STARK  
UNITED STATES DISTRICT COURT