UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC., Plaintiffs, -v- SERENITY PHARMACEUTICALS, LLC, and REPRISE BIOPHARMACEUTICS, LLC, Defendants.	No. 17-cv-9922 (RWS) ECF CASE
SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, and AVADEL SPECIALTY PHARMACEUTICALS, LLC, Counterclaim-Plaintiffs, -v- FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC., Counterclaim-Defendants.	No. 17-cv-9922 (RWS) ECF CASE

MEMORANDUM OF LAW IN SUPPORT OF SERENITY, REPRISE, AND AVADEL'S MOTION FOR A PRELIMINARY INJUNCTION

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TABLE OF ABBREVIATIONS

Abbreviation	Description
Serenity	Movant Serenity Pharmaceuticals, LLC
Reprise	Movant Reprise Biopharmaceutics, LLC
Dr. Fein	Dr. Seymour H. Fein
Ferring	Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc.
Avadel	Movant Avadel Specialty Pharmaceuticals, LLC
FDA or Agency	U.S. Food and Drug Administration
PTO	U.S. Patent and Trademark Office
'203 patent	U.S. Patent No. 7,405,203
'321 patent	U.S. Patent No. 7,579,321
'761 patent	U.S. Patent No. 7,799,761
Nocdurna	The orodispersible desmopressin acetate product described in Ferring's NDA 022517
NOCTIVA	*NOCTIVA*™ -- the recently approved product developed by Serenity and protected by Dr. Fein's patents
Vellturo Decl.	Declaration of Dr. Christopher Vellturo
Divis Decl.	Declaration of Gregory J. Divis
Cheng Decl.	Declaration of Linda L.Y. Cheng
Ex. __	Exhibits A-DD attached to the Declaration of Christopher J. Harnett, Esq., filed with this brief

Note: All emphasis added unless otherwise indicated.

I. OVERVIEW

In accordance with Rule 65(a), Fed. R. Civ. P., Defendants/Counterclaimants Serenity, Reprise and Avadel (also, collectively, "Movants") respectfully submit this memorandum in support of their Motion for a Preliminary Injunction ("PI"). Grant of a PI will maintain the *status quo* and avoid severe and irreparable harm to Movants through completion of trial on the merits -- which has already been set under a highly accelerated schedule to commence just a few months from now on January 7, 2019.

The PI that Movants seek would prevent Ferring from destroying the lawfully-obtained market position that Movants are in the process of establishing for their pioneering *NOCTIVA* product. *NOCTIVA*, which is protected by Dr. Fein's patents in suit, is the first ever product approved by the FDA for treatment of nocturia due to nocturnal polyuria. Administration of Ferring's proposed product, Nocdurna, will infringe several claims of Dr. Fein's '203 and '321 patents. By virtue of unequivocal assertions made by Ferring in the 2012 litigation before this Court, Ferring has ***already*** conceded the validity and considerable value of those patents. Although Ferring's Nocdurna product was approved by the FDA on June 21, 2018, it is not yet on the market. Nonetheless, Ferring has refused to refrain from an at-risk launch during the accelerated pendency of trial and, instead, insists that it is free to sell that product in head-to-head competition with *NOCTIVA* [redacted]

Under the circumstances, as we explain below, the four-part test for grant of a PI is met here. Specifically, Movants can establish: (1) a likelihood of success on the merits; (2) that Avadel, Serenity and Reprise will be irreparably harmed by any improvident launch of Ferring's Nocdurna product; (3) that the public interest would be advanced by the requested injunctive relief; and (4) that the balance of hardships favors imposition of a preliminary injunction.

Factor 1: Movants are likely to succeed on the merit-based issues. The Court has extensive experience with the '203 and '321 patents that the PTO granted to Dr. Fein. Those patents were the subject of the lawsuit brought by Ferring in this Court back in 2012. In the course of the lengthy 2012 litigation, Ferring strenuously argued that the patents were directed to "significant" and "inventive" subject matter supposedly contributed by Ferring's own scientists. Ferring also asserted that Dr. Fein's patents were worth tens of millions of dollars, even before any product covered by those patents had been approved for sale in the United States. (12-cv-2650, D.I. 1 ¶ 103.) In presenting those assertions -- and by vigorously litigating its desire to own Dr. Fein's patents -- Ferring effectively conceded their validity.

Ferring articulated its irreconcilable contentions that Dr. Fein's patents are now somehow invalid in the Delaware district court only ***after this Court*** issued a series of rulings that Ferring could not properly challenge ownership of those patents. Ferring's about-face on the issue of validity cannot be taken seriously -- particularly in view of the PTO's rejection of the validity attacks launched by Ferring's outside patent counsel in the 2010 reexamination proceedings. After reexamination, the PTO expressly upheld the '203 patent claims. As such, ***Ferring has already taken its best shots at Dr. Fein's patents and has failed spectacularly.***

Ferring fares no better on the question of infringement. To demonstrate a likelihood of success, Movants need only to show by preponderance of the evidence that ***one*** of the many claims included in Dr. Fein's patents likely covers the use of that product. Such a showing is straightforward. For example, claims 1 and 6 of the '203 patent are reproduced immediately below:

> 1. A method of treating nocturia, primary nocturnal enuresis, or incontinence, or for inducing voiding postponement, said method comprising administering to a patient in need thereof a pharmaceutical composition comprising a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/serum

concentration no greater than 10 pg/ml and maintaining the concentration within the range of about 0.5 pg/ml and 10 pg/ml for about four to six hours.

6. The method of claim 1, comprising administering said composition by transmucosal delivery.

Claim 1 of the '203 patent is directed to "a method for treating nocturia" reflecting Dr. Fein's low-dose discovery to "achieve a maximum desmopressin plasma/serum concentration of no greater than 10 pg/ml" and maintaining the concentration within the range of "about 0.5 pg/ml and 10 pg/ml" for "about four to six hours." Claim 6 further specifies "transmucosal delivery" such as the sublingual administration that Dr. Fein proposed for use with low-dose desmopressin treatment. Ferring's product development records -- including the belatedly-produced Nocdurna NDA -- demonstrate unequivocally that administration of Nocdurna will embody Dr. Fein's patented discoveries.

To assist the Court in confirming the likelihood that Movants can show that the use of Ferring's Nocdurna product would meet the limitations of at least one claim of the patents in suit, Movants submit herewith a claim chart detailing exact correspondence between '203 patent exemplary claims 1 and 6 and language from Ferring's own documentation about low-dose, sublingual administration of its orodispersible desmopressin products. (Ex. A.)

Factor 2: Movants would be irreparably harmed if Ferring were to improvidently launch its infringing Nocdurna product. Serenity, along with its new marketing partner, Avadel, recently launched its innovative *NOCTIVA* product. Due to its outstanding safety and efficacy profile, *NOCTIVA* is the first ever product approved by the FDA for the treatment of nocturia due to nocturnal polyuria. Because of its strong patent protection and prompt regulatory approval, Avadel has earned a lawfully-obtained exclusive market position allowing it to meet and expand the demand for low-dose administration of desmopressin for patients suffering from

that condition. Reprise, as the owner of Dr. Fein's patents, and Serenity as Avadel's licensor, will similarly derive income from the sales of *NOCTIVA*, which is protected by those patents.

In order to accomplish the recent introduction of *NOCTIVA*, Movants invested vast amounts of time and money and were forced to overcome relentless interference by Ferring. Any effort by Ferring to now launch its Nocdurna product in the face of Dr. Fein's valid patents would cause irreparable and incalculable harm to Movants. As we explain below, the irreparable harm that would befall Movants as a consequence of Ferring's launch could not be rectified through an after-the-fact award of monetary damages.

To assist the Court in addressing the issue of irreparable harm, Movants submit herewith the declaration of Dr. Christopher Vellturo, an economist with extensive experience addressing intellectual property issues and assessment of harm resulting from an "at-risk" launch prior to adjudication on the merits. As Dr. Vellturo attests, because Ferring's launch would prevent Serenity and Avadel from ever accomplishing the full measure of market exclusivity that they earned through years of lawful efforts, the ***full extent*** of the harm cannot be calculated with precision or compensated after the fact. (Vellturo Decl. ¶ 15.) Moreover, such an improvident launch would deprive Serenity and Avadel of their first-mover advantage, which is enormously valuable. (Vellturo Decl. ¶¶ 11-14.) The irreparable harm would further include potentially irreversible price erosion, destruction of *NOCTIVA* marketing plans, and an inability of Movants to conduct follow-on research and development on new and next generation products. (Vellturo Decl. ¶¶ 19-21.)

An at-risk launch of Nocdurna would also cause reputational harm and resulting loss of goodwill in the medical community because of, *inter alia*, the labelling restrictions that the FDA imposed on Ferring as a condition of Nocdurna's approval. Specifically, Ferring's product label

includes severe limitations on how Nocdurna can be used with patients, including detailed restrictions on patient fluid intake both before and after Nocdurna is administered in order to minimize the likelihood of hyponatremia -- a potentially life-threatening side effect. (Ex. A-1.) The FDA did not require Movants' *NOCTIVA* product to include those restrictions as a consequence of: (1) its innovative formulation, which accomplishes greater bioavailability even with dramatically lower amounts of active drug being introduced to the patient's body; and (2) more robust clinical study design. Since both Nocdurna and *NOCTIVA* have the same active ingredient -- desmopressin -- the restrictive labeling that the FDA imposed on Ferring could lead to a reluctance among prescribing physicians to prescribe ***any*** desmopressin product, which would severely damage Movants' groundbreaking *NOCTIVA* franchise. (Vellturo Decl. ¶¶ 16-17; Divis Decl. ¶¶ 8-10.)

Factor 3: The public interest favors a PI. Courts and commentators have long recognized that the exclusive rights attendant to a patent benefit society by encouraging further innovation. Indeed, the U.S. Constitution established the patent system to "promote the Progress of Science and useful Arts" by providing inventors with exclusive rights to their discoveries. U.S. Const., art. I, § 8, cl. 8. This is not theoretical rhetoric. The fuel that the patent system provides for future innovation is particularly important in the pharmaceutical industry. For every product that is commercially successful, pharmaceutical companies such as Serenity and Avadel must investigate many that do not bear fruit. Such investigations require huge sums of money, the overwhelming majority of which comes from one place: the profits made from the few drugs that secure approval and attain commercial success. Without enforcement of the patent grant -- i.e., the right to exclude -- most new drug products would never be developed.

Moreover, as Avadel's Chief Operating Officer (Mr. Divis) attests in his declaration submitted herewith, [redacted]. (Divis Decl. ¶ 4.) Accordingly, the public interest would not be advanced by depriving Movants of the first-mover advantage earned as a consequence of more than a decade of development work, exemplary clinical investigation, and Dr. Fein's valuable patents.

Factor 4: The balance of hardships favors Movants. In contrast to the irreparable harm that would befall Movants were Ferring permitted to launch its Nocdurna product, grant of the short-duration PI sought here would present only minor inconvenience to Ferring. The recently approved *NOCTIVA* product is [redacted]. (Cheng Decl. ¶¶ 4-5.) Avadel is a small pharmaceutical company and *NOCTIVA* is its first and only urology product. (Divis Decl. ¶ 3.) On the other hand, Ferring (a comparatively large company with diverse sources of income) has no legal entitlement to sell a product that violates Dr. Fein's valid patent rights in an effort to destroy *NOCTIVA's* exclusive market position.

Beyond that, the scope of the injunction that Movants seek is modest: Movants are simply asking the Court to maintain the *status quo* for a limited time through resolution of an accelerated trial on the merits, which is scheduled to commence in early January 2019. In that regard, Ferring should not be heard to argue that any supposed "delay" militates against a PI here. Indeed, it was Ferring's unilateral decision to run off to Delaware to file its declaratory judgment action -- rather than filing it in this Court, where a closely related litigation directed to the patents in suit had been pending for nearly six years. At the time Ferring filed in Delaware, that court's extreme backlog of patent cases and the impending vacancies of 50% of the district

judge positions were well publicized. Because of Ferring's efforts to avoid this Court, the better part of a year was spent waiting for the Delaware court to address Serenity and Reprise's meritorious motion to transfer the case back to the SDNY, where it belonged from the outset.

Moreover, because of Ferring's questionable clinical study design choices and refusal to comply with the FDA's earlier request for additional clinical studies, Nocdurna was repeatedly rejected by the FDA for nearly nine years before the FDA recently granted approval -- an approval that was ultimately subject to restrictive labeling provisions. (Exs. A-1; C.) Deferring launch for a few months to permit Movants to prepare for the accelerated trial at which they will demonstrate that the use of Nocdurna infringes Dr. Fein's valuable patents will not harm Ferring.

* * *

Ferring's conduct in this litigation further confirms the strength of Movants' case for a PI. As Movants detail below, Ferring has relied upon improper procedural roadblocks and misrepresentations to prevent the Court from considering evidence that Movants would be irreparably harmed by an at-risk launch of Ferring's infringing Nocdurna product. For example, even though Ferring filed its declaratory judgment action nearly 15 months ago in April 2017, Ferring refused to provide the Nocdurna NDA (i.e., the key document proving infringement) to Defendants/Counterclaimants until the beginning of this month. And, until just a few days ago, Ferring refused to permit Movants to access for purposes of this case information that Ferring produced in the 2012 litigation ***even on an attorneys'-eyes-only basis*** ***-- notwithstanding the fact that Movants have the same counsel in both the 2012 and present litigations***. In view of Ferring's obstructionism, Movants expressly reserve the right to submit supplemental support for the present PI motion.

II. PROCEDURAL HISTORY

A. Ferring's Efforts To Avoid This Court

This PI motion finds its origin in the lawsuit filed by Ferring in this Court on April 5, 2012, naming Serenity, Reprise, Dr. Fein and Dr. Nardi as defendants. In that action (C.A. No. 12-cv-2650), Ferring sought a ruling that Ferring's scientists -- not Dr. Fein -- are the proper inventors of the '203, '321 and '761 patents in suit. During five years of litigation, Ferring took extensive discovery about those patents and their prosecution before the PTO. Ferring had the opportunity, for example, to review thousands of pages of documentation pertaining to the patents in suit and take extensive deposition testimony from Dr. Fein. Throughout the litigation, Ferring maintained its claims that: (1) Ferring was the rightful owner of the three patents in suit; (2) the patents include "significant" and "inventive" contributions of Ferring scientists; and (3) Ferring was entitled to recover the value of (and proceeds from) those patents which, as stated by Ferring, exceeded $40 million at the time. (*See* 12-cv-2650, D.I. 1 ¶¶ 1, 330, 335.)

Then, ***only after*** this Court issued a series of rulings providing that Ferring could not properly challenge ownership of Dr. Fein's patents, Ferring filed a new lawsuit on April 28, 2017-- not in this Court -- but in the U.S. District Court for the District of Delaware. In that action, notwithstanding its earlier representations to this Court that the patents in suit were inventive and extremely valuable, Ferring did an about-face and alleged that they were somehow worthless because they are: (1) invalid for lack of enablement; (2) invalid for lack of written description; (3) invalid for indefiniteness; (4) invalid under 35 U.S.C § 102(e); (5) invalid under 35 U.S.C. § 102(f); and (6) unenforceable for alleged inequitable conduct. (D.I. 18.)

In response to Ferring's Delaware filing, Serenity and Reprise moved to transfer the case to the SDNY because, *inter alia*, this Court already had extensive knowledge about the patents in suit, the underlying technology, and the ongoing disputes between the parties. In that regard,

Serenity and Reprise explained that Ferring's efforts to proceed in Delaware reflected an improper desire to present arguments that were irreconcilable with arguments previously presented to this Court. (D.I. 12, 25.) In earlier submissions, Movants detailed Ferring's gymnastic efforts to avoid having this Court consider the subject matter of the declaratory judgment complaint that it filed in Delaware -- both before and after Judge Sleet granted Serenity and Reprise's motion to transfer. (*See, e.g.*, Ex. D.) Those efforts included a December 22, 2017 opposition to Movants' Statement of Relatedness when the transferred action was initially wheeled to Judge Hellerstein and a "motion for reargument" on the Delaware Court's transfer order. (D.I. 61; 63.)[1]

Ultimately, this case was properly lodged in the SDNY before Judge Sweet who convened an initial status conference on February 20, 2018. At that time, the Court set a March 14, 2018 oral argument on Serenity's and Reprise's motion to dismiss for lack of subject matter jurisdiction, which was immediately withdrawn following Ferring's notification that the FDA had approved the Nocdurna product.

B. Ferring's Resistance To Orderly Presentation Of Issues Pertinent To Maintaining The *Status Quo*

During the pendency of Serenity and Reprise's motion to dismiss, Ferring refused repeated requests to provide information about the FDA's substantive review of the Nocdurna NDA. (*See, e.g.*, Ex. E.) Consequently, on Tuesday, June 5, 2018, Movants wrote to Ferring's counsel to address: (1) the FDA's nominal June 21, 2018 action date relating to Ferring's Nocdurna NDA; and (2) Ferring's refusal to voluntarily defer initiation of launch activities so

[1] Notably, in its motion for "reargument," Ferring represented to the Delaware court that Ferring had been unaware of Serenity and Reprise's relationship with Avadel. In response, Movants provided the Delaware court with irrefutable proof that Ferring had, in fact, known for months about Serenity and Reprise's relationship with Avadel under which Avadel obtained license rights to the patents in suit so that it could market *NOCTIVA*. (D.I. 62 at 2-4.)

that the parties could approach the Court in an orderly fashion to address the issues of anticipated TRO/PI motion practice. (Exs. F; G.) In that letter, Movants advised Ferring that the following morning, "in accordance with Paragraph 2G of Judge Sweet's Individual Practices" Movants intended to present an Application for an Order To Show Cause why a TRO would not issue ("TRO Show Cause Application"). (*Id.*)

In response, Ferring notified Movants that, notwithstanding the provisions of this Court's Individual Practices, Ferring would not appear the following day to discuss the TRO issues. Instead, Ferring stated that it would not address those issues until Friday, June 8. (Ex. H.) Movants promptly wrote back alerting Ferring that, "[u]nless Judge Sweet advises otherwise," Movants will proceed in accordance with the terms of Paragraph 2G of the Court's Individual Practices. (Ex. I.) Accordingly, the following morning, Movants reported to the SDNY Court Clerk's office and were directed to chambers at which time Judge Sweet's law clerk asked whether Ferring had been notified about the TRO application. Movants responded in the affirmative and presented Ferring's e-mail suggesting that the conference with the Court be delayed. The Court then directed the Law Clerk to contact Ferring's counsel by telephone to secure their appearance later that day. Attempts to reach Ferring's counsel by phone were unsuccessful. The Court subsequently issued an Order directing Ferring's counsel to appear the next day (Thursday, June 7). (Ex. J.)

Remarkably, at that time, Ferring represented to the Court that Movants had not previously inquired whether Ferring would voluntarily refrain from product launch to allow for the possibility of TRO/PI motion practice. Ferring's representation, however, was not true. Indeed, on May 25, 2018 Movants wrote to Ferring's counsel: "[W]e now ask for a response to this question . . . will Ferring agree to defer launch activities so that the parties can approach the

Court in an orderly fashion to address the issue of 'emergency motion practice' that you referenced during the March 14 oral argument?" (Ex. K at p. 2.) On May 31, 2018, Ferring's counsel responded: "Your letter also asks . . . will Ferring agree to delay launch activities so that the parties can approach the Court in an orderly fashion to address the issue of 'emergency motion practice?' At present, we cannot agree to your request." (Ex. E at p. 2.)

Nonetheless, during the June 7 conference, only ***after*** Movants prepared and presented their Show Cause TRO Application, [redacted] (D.I. 100 (Sealed Stipulation).) During that same conference, Movants confirmed, in the event that the FDA approved Nocdurna, they would respond to Ferring's declaratory judgment complaint within seven days. Accordingly, on June 28, Movants served their Answer, Affirmative Defenses and Counterclaims, which included counts that use of Ferring's Nocdurna product infringes Dr. Fein's '203 and '321 patents and that such infringement is willful. (D.I. 101.)

Ferring subsequently advised the Court and Movants that Ferring would be seeking an accelerated discovery schedule and a November 9 trial date for this case. In view of that proposed schedule, Movants asked Ferring if it would agree to defer product launch through resolution of that accelerated trial. Ferring said no. (Ex. L at p. 2.) Movants then asked Ferring if it would agree to a briefing schedule for the Court to address the present PI motion. Ferring would not agree to that either. (Ex. M at p. 3.) Instead, Ferring stated that it would ask the Court to "collapse the preliminary injunction briefing and motion hearing into a trial on the merits." (*Id.*) Ferring, however, never explained how it could reconcile its refusal to defer launch

pending resolution of trial (scheduled for January 2019) with its proposal to "collapse" PI proceedings and trial on the merits. Ferring's two positions cannot possibly be reconciled.

III. A PRELIMINARY INJUNCTION IS WARRANTED HERE

A. The Legal Standard For Preliminary Injunctive Relief

Four factors must be considered when determining whether a PI is appropriate: (1) the movant's likelihood of success on the merits, (2) whether the movant will suffer irreparable harm absent an injunction, (3) the balance of the hardships between the parties, and (4) whether the public interest would be disserved by granting a PI. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344-45 (Fed. Cir. 2008); *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1200-01 (Fed. Cir. 2007); *Park Irmat Drug Corp. v. Optumrx, Inc.*, 152 F. Supp. 3d 127, 131 (S.D.N.Y. 2016). "The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981).

B. Movants Will Likely Succeed On The Merits

1. Ferring Has Already Conceded Validity

Despite the voluminous briefing it has submitted in this matter, Ferring has never been able to legitimately reconcile the inconsistency between its 2012 "inventorship" action claiming Dr. Fein's patents as its own valuable property and its Delaware declaratory judgment action seeking to invalidate those very same patents. In its 2012 complaint, Ferring contended that Dr. Fein's patents included "significant inventive contributions" of Ferring's own employees. (12-cv-2650, D.I. 1 ¶ 103.) Ferring also sought, *inter alia*, to disgorge the $43 million that Serenity and Reprise received from Allergan in return for access to the patent rights. (*Id.* ¶¶ 330, 335.)

During a March 14, 2018 hearing, arguments presented by Ferring's counsel further demonstrated that its declaratory judgment "counts" relating to invalidity are not well-founded.

Ferring argued, for example: "[Dr. Fein's] patent[s] are Ferring's intellectual property ***assets*** and, quite frankly, if we can't get them back from an ownership standpoint, we don't want them being used as a sword against us for our soon-to-be-approved product." (March 14, 2018 Hr'g Tr. at 22-23.) That argument is inconsistent with Ferring's duty to have a good faith basis before it presents ***any*** claims to ***any*** U.S. district court.

Indeed, the majority of the "invalidity" charges included in Ferring's declaratory judgment complaint are rooted in 35 U.S.C. § 112 -- *i.e.*, supposed indefiniteness, lack of written description and lack of enablement. Such Section 112 defenses relate to technical requirements of the patent "specification" and "claims" that are evident from the four corners of the patent documents. 35 U.S.C. § 112 ¶¶ 1-2; *see also, e.g.*, *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). In 2012, Ferring surely must have undertaken a careful review of the three patents in suit before telling this Court that those patents were Ferring's own valuable and significantly inventive property. Surely, Ferring would not have made such claims if it had concluded in its pre-suit review of those patents that they were technically defective under 35 U.S.C. § 112. (This may explain why Ferring's patent counsel who subscribed to the 2012 representations have not made an appearance in the present case.) In any event, Ferring should not be heard to argue the exact opposite now.

2. The PTO Previously Confirmed Validity

Ferring is also unlikely to succeed on the merits because of the basic provisions of 35 U.S.C. § 282, under which "[a] patent shall be presumed valid" and "[t]he burden of establishing invalidity . . . shall rest on the party asserting" it. 35 U.S.C. § 282(a). A party seeking to overcome the presumption has to "persuade the factfinder of [invalidity] by clear and convincing evidence." *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 97 (2011). Ferring cannot meet this heavy burden.

Indeed, in 2010, Ferring tried to invalidate one of the patents in suit (the '203 patent), by filing a reexamination proceeding in the PTO through a "third party requester." Specifically, on October 12, 2010, Ms. Adriana L. Burgy of Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., filed a request for *ex parte* reexamination of the '203 patent. Ferring does not -- and cannot -- dispute that Ms. Burgy is counsel for Ferring. (12-cv-2650, D.I. 161 ¶ 24.)

In the reexamination proceedings, Ferring's counsel argued that certain prior art anticipated or rendered obvious the independent claims of Fein's '203 patent. (Ex. N.) On January 19, 2011, the PTO rejected Ferring's request for reexamination, finding the cited prior art did ***not*** anticipate Dr. Fein's '203 patent claims. (Ex. O.) The PTO also found that the invention claimed in Dr. Fein's '203 patent demonstrated unexpected results and, therefore, were ***not*** rendered obvious by the prior art cited by Ferring.

Having failed in its reexamination gambit and having failed in the 2012 "inventorship" lawsuit due to this Court's equitable estoppel ruling, Ferring included supposedly "new" invalidity counts in its 2017 complaint. In one of those counts, Ferring asserts that Dr. Fein did not himself invent the subject matter claimed in the patents in suit and, therefore, the patents fail to comply with 35 U.S.C. § 102(f). That is nothing more than a re-hash of Ferring's argument from the 2012 action -- that Ferring's scientists supposedly invented the subject matter claimed in Fein's patents -- and yet another effort to get around the Court's equitable estoppel ruling. Ferring also asserted that the patents in suit cannot claim priority to the GB 0210397 and cited a PCT application as intervening prior art against Dr. Fein's patents under 35 U.S.C. § 102(e). Those assertions also fail because, as this Court has previously found, Ferring's own General Counsel provided Dr. Fein's patent counsel with the GB priority application for him to perfect

his priority claim to this application. (12-cv-2650, D.I. 190 ¶¶ 30-48.) Thus, Ferring will not be able to succeed on the merits of its "new" § 102 invalidity claims, either. (*Id.*)

3. Ferring's "Inequitable Conduct" Charge Is Without Merit

Like its newly-minted invalidity contentions, Ferring's "inequitable conduct" claim is also baseless -- it is little more than an effort to take an end run around this Court's rulings that Ferring cannot challenge Dr. Fein's inventorship of the patents in suit. As a preliminary matter, inequitable conduct is a highly disfavored claim. *See Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague."). Moreover, inequitable conduct charges rarely succeed because of the requirement to prove by clear and convincing evidence both: (1) that an intent to mislead is the "single most reasonable inference;" and (2) that the supposed misstatement or omission rises to the level of "materiality." *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329-30 (Fed. Cir. 2009).

Ferring's inequitable conduct claim here distills down to the far-fetched proposition that, by representing to the Patent Office that he is the inventor of his own patents, Dr. Fein somehow made a highly material misstatement and acted with intent to deceive the Patent Office. Ferring has already made similar claims in the 2012 case -- and failed. Ferring is not likely to succeed in relitigating those claims now under the guise of a cause of action with a different name that is even more difficult to prove.

4. Administration Of Ferring's Nocdurna Product Would Infringe Several Of Dr. Fein's Patent Claims

Ferring's own actions in this litigation show that Movants are likely to succeed in showing that the patents in suit would cover the use of Nocdurna. For example, in Count VI of its amended complaint seeking "Declaratory Judgment of Noninfringement of the Patents in

Suit," Ferring does not provide any information whatsoever to support its allegation that "Ferring's [Nocdurna] and the use of Ferring's [Nocdurna] do not and will not infringe any valid claim of the Patents in Suit as properly construed." (D.I. 18, ¶ 151.) Moreover, Ferring's dogged resistance to producing its NDA and documents from the 2012 case (which provide additional proof on the question of infringement) -- speaks volumes.

Nonetheless, the evidence presently available to Movants demonstrates conclusively that use of Ferring's Nocdurna product will be covered by several claims of Dr. Fein's patents in suit -- including, for example, at least claims 1 and 6 of the '203 patent. That evidence includes: (1) the Nocdurna NDA; (2) public documents that describe Nocdurna; (3) the Nocdurna product label; (4) clinical study reports; and (5) documents describing the orodispersible dosage form of desmopressin that Ferring sells in Australia and Canada.

As stated above, '203 patent claim 1 is directed to a method of treating nocturia involving the administration of low-dose desmopressin (measured as plasma/serum concentrations of no greater than 10 pg/ml) with those plasma/serum concentrations being maintained for about four to six hours. And, as also stated above, '203 patent claim 6 includes the additional limitation of "transmucosal delivery" such as sublingual delivery with an orodispersible dosage form. The administration of Ferring's Nocdurna product satisfies each and every limitation of those claims and, therefore, infringes them.

Ferring's infringement is depicted graphically in the claim chart submitted herewith as Exhibit A. [redacted] Consequently, there is no room for Ferring to present any legitimate non-infringement argument.

C. Movants Will Suffer Irreparable Harm Absent An Injunction

As Movants demonstrate in their accompanying declarations, the evidence that the harm to Movants would be irreparable is overwhelming. Following enormous research and development investments and extensive clinical trials, *NOCTIVA* became the first ever product approved by the FDA to treat nocturia due to nocturnal polyuria. *NOCTIVA* is Avadel's first and only urology product. [redacted]. (Cheng Decl. ¶¶ 4, 6.) The patents issued to Dr. Fein not only protect the *NOCTIVA* product; [redacted] (Cheng Decl. ¶ 5).

The exclusive market position that *NOCTIVA* has lawfully earned through Movants' patented innovations and rigorous clinical studies will be irreparably diminished if Ferring is permitted to enter the market with its Nocdurna product -- a product that violates Dr. Fein's patents. For example:

- ***There will be loss of first-mover advantage***. This first-mover advantage is critical for Serenity and Reprise to recoup the investment into the development of this effective therapy. That advantage would be lost if a second drug -- such as Ferring's Nocdurna -- were to enter the market. The impact of losing first-mover advantage in this nascent marketplace would be considerable. Avadel is poised to establish a market position and a steep strategic advantage to capture an initial base of loyal patients and prescribing physicians who will not be incentivized to switch to a second mover (Ferring) offering a product that it, undoubtedly, will claim to be similar. (Vellturo Decl. ¶¶ 11-14.)

- ***There will be loss of market share and reduction in sale price and profitability***. *NOCTIVA* is the first product approved for the treatment of nocturia due to nocturnal polyuria. If allowed to

enter the market, Ferring will sell Nocdurna in head-to-head competition with *NOCTIVA*. (Vellturo Decl. ¶ 19.) The existence of a second entrant in the market for nocturnal polyuria treatments will inevitably lead to aggressive price-based competition. (Vellturo Decl. ¶ 19; Divis Decl. ¶ 6.) To date, despite repeated requests to do so, Ferring has not produced documents about its proposed Nocdurna pricing. (*See e.g.*, Ex. P.) That, again, speaks volumes.

- ***There may be permanent price erosion***. If, after full trial on the merits, Ferring is required to withdraw Nocdurna from the market, it may not be possible for Avadel to restore *NOCTIVA* to the price levels in place prior to Ferring's at-risk launch, depending on the existence of intervening events. (Vellturo Decl. ¶¶ 18-19; Divis Decl. ¶ 6.)
- ***Destruction of marketing plans***. [redacted]. (Vellturo Decl. ¶ 20; Divis Decl. ¶¶ 4-5.)
- ***Research and development resources will be reduced***. [redacted] (Divis Decl. ¶ 7; Cheng Decl. ¶¶ 6-7.) Competition by Ferring in violation of Dr. Fein's patents will [redacted] (Vellturo Decl. ¶ 21.)
- ***There will be reputational harm and loss of goodwill***. As a consequence of years of development efforts, strong patent protection, and exemplary clinical trial design, Movants have earned a reputation as innovators and market leaders. Introduction of Ferring's product in violation of Dr. Fein's patents will tarnish that reputation. Beyond that, the harm to Movants is

compounded by the differences between *NOCTIVA* and Ferring's infringing Nocdurna product. *NOCTIVA* is a novel formulation for the intranasal delivery of desmopressin. It has a unique oil-in-water emulsion formulation that utilizes permeation enhancer and delivers the active desmopressin ingredient in a unique spray pattern with a differentiated pharmacokinetic profile. This results in a consistent administration of a very low dose of desmopressin, rapid absorption and improved bioavailability.[2]

In contrast, Ferring's Nocdurna is a lower dose sublingual form of desmopressin (marketed for years in a non-sublingual form as DDAVP), approved for a new indication. Ferring's decade-long struggle to obtain regulatory approval for Nocdurna and the FDA's concerns with the safety and efficacy of the drug, including due to the risk of hyponatremia, are well-publicized. (*See* Ex. C.) Significantly, although the FDA ultimately approved Nocdurna, the product label includes severe, detailed limitations on patient fluid intake before and after drug administration to reduce the likelihood of hyponatremia. Specifically, patients and physicians are instructed as follows:

> Limit fluid intake to a minimum from 1 hour before administration until 8 hours after administration. Use of NOCDURNA without concomitant reduction of fluid intake may lead to fluid retention and hyponatremia. Advise patients to avoid drinks containing caffeine or alcohol before bedtime. (Ex. A-1.)

Movants' *NOCTIVA* product is not subject to these highly-restrictive labeling provisions.

Accordingly, the Nocdurna label and product approval history is likely to taint the safety reputation of *NOCTIVA*, which includes the same active ingredient as Nocdurna, and is the only

[2] NOCTIVA demonstrates a bioavailability of 8%. (Ex. Q at p. 8.) By comparison, Nocdurna has a bioavailability of 0.25%. (Ex. A-1.) Ferring's oral formulation of desmopressin, DDVAP, which has been marketed for years for other indications, has a bioavailability of 0.08-0.16%, and a previously marketed intranasal formulation of desmopressin has a bioavailability of around 3%. (Ex. R at p. 1; Ex. S at p. 1.)

other drug approved for the nocturia indication. Indeed, the restrictive labeling on the Nocdurna product presents a substantial risk that physicians will be reluctant to prescribe ***any*** desmopressin product -- including *NOCTIVA* -- for the nocturia indication. (Divis Decl. ¶¶ 8-10; Vellturo Decl. ¶¶ 16-17.)

D. The Temporary Restraints That Movants Seek Serve The Public Interest

The hallmark of a patent grant is exclusivity. Such exclusivity is the reward for innovation, and it fosters additional innovation. The Federal Circuit has "long acknowledged the importance of the patent system in encouraging innovation. Indeed, the 'encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.'" *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006); *see also Endo Pharm. Inc. v. Amneal Pharm., LLC*, No. 12-cv-8060-TPG, 2016 WL 1732751, at *7 (S.D.N.Y. Apr. 29, 2016). The Federal Circuit has noted that "the patent system provides incentive to the innovative drug companies to continue costly development efforts." *Sanofi-Synthelabo*, 470 F.3d at 1383.

During the June 25, 2018 status conference with the Court, Ferring made reference to stock language from the FDA that the approval of multiple products for the same indication is in the interest of public health. In view of that language, Ferring argued that Movants could not satisfy the public interest prong of the four-part preliminary injunction test. Ferring is wrong -- virtually every company that infringes the patents of a competitor in the pharmaceutical industry makes that same argument and courts routinely reject it. *See, e.g.*, *Celsis In Vitro, Inc. v. Cellzdirect, Inc.*, 664 F.3d 922 (Fed. Cir. 2012); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008); *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196 (Fed. Cir. 2007).

Indeed, the FDA's policy favoring multiple available products in no way trumps the public interest in protecting the exclusive rights attendant to pharmaceutical patents because,

without that exclusivity, there would be little if any product development in the first place. *See Celsis In Vitro, Inc.*, 664 F.3d at 931-32. That is why courts frequently grant PIs in the context of medical products when the at-risk launch of an infringing product prior to trial on the merits would likely cause irreparable harm to the patent holder. *See, e.g.*, *id.* at 930.

Moreover, the Federal Circuit has already considered and expressly rejected the "choice of drugs" argument Ferring is making here:

> [E]liminating a choice of drugs is not, by itself, sufficient to disserve the public interest. Under such an approach, courts could never enjoin a drug because doing so would always reduce a choice of drugs. ***That, of course, is not the law*** . . . [A] reduction in choice of drugs cannot be the sole reason for a district court to deny an injunction.

Amgen Inc. v. Sanofi, 872 F.3d 1367, 1381 (Fed. Cir. 2017). Judge Young's findings in *Amgen, Inc.* v. *Hoffman-LaRoche LTD*, F. Supp. 2d 160 (D. Mass 2008) -- a case about a recombinant erythropoietin product used to enhance the production of red blood cells -- are similarly instructive:

> After taking evidence for four days and entertaining oral argument and extensive briefing, the Court cannot conclude with any certainty that MIRCERA will save lives or money. Failure to enter a permanent injunction, however, ***would risk undermining the incentives for innovation that have produced, and hopefully will continue to produce, medical advances that extend and enhance the value of life***. The Court therefore concludes that ***the public interest will not be disserved*** by a permanent injunction.

581 F. Supp. 2d 160, 227 (D. Mass. 2008), *rev'd in part on other grounds*, 580 F.3d 1340 (Fed. Cir. 2009).

E. The Balance Of Hardships Favors Movants

As stated above, unlike Ferring, which is an established company with a diversified product portfolio, [redacted]. (Cheng Decl. ¶ 4.) *NOCTIVA* is Avadel's first and only urology product. (Divis Decl. ¶ 3.) The Fein

patents, which protect the *NOCTIVA* product, are [redacted] (Cheng Decl. ¶ 5.)

Moreover, Movants have agreed with Ferring's proposal to adopt an accelerated discovery and trial schedule so that the issues concerning Ferring's infringement of Dr. Fein's patents in suit can be considered by the Court just a few months from now in January 2019. The irreparable harm caused by Ferring's at-risk launch of Nocdurna during the pendency of the accelerated litigation (which would destroy Movant's legally-obtained exclusive market franchise) eclipses any inconvenience experienced by Ferring as a consequence of waiting a few months to launch. And, as a matter of law and logic Ferring has no right whatsoever to sell Nocdurna if the use of that product infringes even one valid claim of Dr. Fein's patents. *See* 35 U.S.C. §§ 154; 271.

IV. FERRING SHOULD NOT BE HEARD TO ARGUE ABOUT "DELAY"

As Movants explained previously, Ferring -- not Movants -- injected considerable delay into these proceedings as a consequence of running off to Delaware to file its declaratory judgment action, notwithstanding this Court's extensive familiarity with the parties, the patents in suit and the underlying technology derived from five years of attention to the ongoing 2012 litigation. Beyond that, the record of this case demonstrates -- notwithstanding Ferring's protestations to the contrary -- that Ferring has sought to delay providing Movants with the discovery they need to show Ferring's infringement and, consequently, Movant's entitlement to injunctive relief.

As the Court will recall, during the March 14, 2018 oral argument, counsel for Ferring made a series of representations about the status of discovery and potential upcoming events in this case. For example, Ferring's counsel acknowledged that, if Nocdurna were to be approved, Ferring "may be faced with emergency motions and other activity." (March 14, 2018 Hr'g Tr. at

32.) Ferring's counsel then represented that Ferring had "a proposed protective order" that was ready "to provide to [Movants]" to facilitate discovery efforts. Ferring's counsel also urged the Court that "we need to get going" with discovery "because all of a sudden we're going to have approval and who knows what will happen then." (*Id*.) Ferring's subsequent actions with respect to discovery, however, were inconsistent with its representations to the Court.

Indeed, on May 4, Movants wrote the attorney for Ferring who made those representations (Ms. Bourke) in order to address them. (Ex. U.) For example, given Ferring's stated concern about the prospect of "emergency motions," Serenity and Reprise expressed surprise that Ferring had not yet provided the proposed protective order which, according to Ferring, was ready on March 14. (*Id.* at p. 1.) Movants also reminded Ferring that, in correspondence ***dating back to February***, Movants suggested a cross-use agreement under which the documents produced in the 2012 SDNY case would be considered as produced to ***all*** parties in the present litigation -- ***including Ferring***. (*Id*.)[3]

On May 7, Serenity and Reprise received a letter from a different Ferring attorney (Mr. Cox) supposedly "in response" to Movants' May 4 letter. (Ex. V.) In that May 7 letter, however, Ferring was silent about the proposed protective order. In that letter, Ferring also said absolutely nothing about a cross-use agreement. And, in that letter, Ferring did not agree to the expedited exchange of targeted information that Serenity and Reprise proposed.

Then, on May 10, another Ferring attorney (Ms. Severance) wrote to Serenity and Reprise expressing a willingness to "provide a protective order and cross-use stipulation." (Ex.

[3] Indeed, most, if not all, of the documents that Ferring needs to address the present motion would have been available to Ferring months ago had Ferring cooperated with a reasonable cross-use agreement. Ferring, plainly, was more interested in keeping the documents (which prove infringement) away from Movants. Consequently, Ferring's repeated comments about "one-sided discovery" cannot be taken seriously.

W.) That attorney, however, stated that Ferring would not do so until early in the week of May 14. But, that week also came and went without Ferring providing a cross-use agreement or proposed protective order. It was not until the following week that Ms. Severance finally sent the proposed cross-use agreement and protective order that Ferring promised ***sixty-eight days earlier***. (Ex. X.) And, even after that sixty-eight day delay, Ferring continued to impose procedural impediments by which it continued to deprive Movants with fundamental discovery.

For example, after Movants provided Ferring with comments to the proposed protective order (and the incorporated cross-use agreement), on June 22, 2018 Ferring's counsel suddenly announced that Ferring had reconsidered the terms of the cross-use stipulation (which incorporated the protective order) ***and withdrew it from consideration***. (Ex. Y at 2.) On June 25 Ferring presented a new cross-use stipulation that imposed confidentiality provisions that were incomprehensible and impractical. (Ex. Z at p.1.) When Movants pointed out the problems with Ferring's new proposed protective order and cross-use provisions, Ferring insisted yet again that, until the parties came to full agreement on the terms of a protective order and cross-use stipulation and the protective order was entered by the Court, Ferring would not permit Movants to have access to the "confidential" documents that Ferring produced in the 2012 litigation ***even on an attorneys' eyes only basis (notwithstanding the fact that Movants have the same counsel in both the 2012 and present litigations)***. (Exs. E and AA.) Ferring likewise dragged its feet in permitting Movant's independent experts -- to whom Ferring did not object on the grounds of qualifications, experience or conflicts of interest -- to have access to any of Ferring's supposedly "confidential" documents, including its belatedly-produced NDA. (Exs. AA and BB.)

Then, on July 11, ***after*** Movants and Ferring had largely come to agreement on terms for a proposed protective order and cross-use agreement, Ferring ***once again*** withdrew the cross use

agreement and substituted ***yet another version*** of that agreement, which included new, highly-objectionable provisions. (Ex. T.) Specifically, Ferring introduced for the first time provisions that would allow Ferring to reopen discovery in the 2012 case -- which is in the middle of being tried. In the e-mail that accompanied that dramatically different version of the cross-use stipulation, Ferring's counsel stated, "the protective order and cross-use stipulation go hand in hand so we need resolution on the cross-use stipulation before we can finalize the protective order." (Ex. T at p. 1.) Because Movants would not agree to Ferring's effort to further delay the 2012 counterclaim trial, Ferring persisted in its refusal to permit Movants' counsel and/or its independent experts to have access to key information on issues of infringement and irreparable harm that Ferring designated as "confidential." (Ex. CC.)[4] Ferring did not ultimately relent until July 16, 2018.

Through its dilatory tactics, Ferring prevented Movants' counsel and/or their independent experts from accessing key evidence pertinent to the present motion from April 2017 until mid-July 2018. Consequently, Ferring should not be heard to argue about any supposed "delay" militating against entry of a PI.

V. CONCLUSION

In view of the foregoing, Movants respectfully submit that the Court should grant the requested PI.

Dated: July 23, 2018
New York, New York

Respectfully submitted,

Christopher J. Harnett (CH3658)

[4] Ferring's counsel asserted that the July 11 switch in cross-use stipulations was due to a mistake. The provisions in the July 11 version, which would have allowed Ferring to re-open discovery in the 2012 case, however, were never previously raised by Ferring. Instead, they were presented for the first time the day after Movants wrote to the Court asking to resume the 2012 counterclaim trial. (Ex. DD.)

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