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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR STERILE PRODUCTS, LLC Plaintiff, v. HOSPIRA, INC. and ORION CORPORATION, Defendants.	C.A. No. 3:14-cv-05343-MLC-TJB CIVIL ACTION **FIRST AMENDED COMPLAINT**

STATEMENT PURSUANT TO L. CIV. R. 10.1

Plaintiff Par Sterile Products, LLC is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Morris Corporate Center 2, One Upper Pond Road, Building D, 3rd Floor, Parsippany, NJ 07054. Upon information and belief, Defendant Hospira, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045. Upon information and belief, Defendant Orion Corporation is a corporation organized and existing under the laws of Finland, having a principal place of business at Orionintie 1A, FI-02200 Espoo, Finland.

For its amended complaint against Defendants Hospira, Inc. and Orion Corporation, Par Sterile Products, LLC alleges as follows:

NATURE OF ACTION

1. Defendants Hospira, Inc. and Orion Corporation ("Hospira" and "Orion," collectively "Defendants") are co-assignees and share ownership in U.S. Patent No. 6,716, 867 ("the '867 patent"). Since January of 2014, Hospira has claimed that this patent entitles it to maintain its monopoly over dexmedetomidine hydrochloride injections, which it markets, as the exclusive licensee within the United States, under the brand name Precedex™. But in fact, Hospira is using the existence of the '867 patent as a façade to mask its anticompetitive scheme to prevent generic competition.

2. Precedex™ is approved for two uses: sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care unit (ICU); and sedation of non-intubated patients prior to and/or during surgical and other procedures. The '867 patent is the only unexpired patent that relates to the Precedex™ product, but does so for only one of the

drug's two FDA-approved uses—its use in the ICU setting with intubated or ventilated patients. Upon discovering that Par Sterile Products, LLC ("Par Sterile") and others planned to launch a generic dexmedetomidine hydrochloride product for the non-patented use, Hospira embarked on a scheme to extend their monopoly by blocking this generic competition.

3. First, in December 2013, Hospira moved to settle its long-running patent litigation with Sandoz over the validity of the '867 patent, *Hospira, Inc. v. Sandoz International GmbH*, No. 3:09-cv-04591 (D.N.J.). Despite the fact that this patent had already been adjudged invalid in this litigation, Hospira moved to vacate that invalidity judgment as part of the settlement so that it could maintain its monopoly for an additional period of time. Although Hospira agreed to permit Sandoz to enter the market with its generic product on December 26, 2014, (Hospira, Inc. 2013 10-K at 15), upon information and belief, Hospira was entitled to share in the profits from Sandoz's sales, allowing it to maintain supracompetitive profits and avoid full generic competition even after Sandoz's market entry.

4. Having deceptively fabricated the impression of continued validity of the '867 patent, Hospira turned to the second step of its scheme to monopolize: abuse of the Food and Drug Administration's ("FDA") procedures for evaluating generic entrants. Even though Hospira caused the FDA to list the '867 patent in the Orange Book in conjunction with the "use code" for the ICU indication for Precedex™ in 2004, and even though Precedex™ had received FDA approval for treatment of non-intubated patients prior to and/or during surgical and other procedures in 2008, it was not until January 6, 2014—just over one week prior to Par's expected generic entry—that Hospira submitted an updated "use code" for Precedex™, claiming that its '867 patent now covered the drug's use in surgical procedures as well as in the ICU

environment. This action was followed by a request to the FDA, based on this updated use code, that it not approve any generic dexmedetomidine product for any proposed uses.

5. The timing of Hospira's request was designed to cause delay in generic competition independent of any evaluation by FDA of Hospira's request. Specifically, Hospira's new use code and request for generic exclusion invoked an expected "comment period" that resulted in an approximately eight-month delay in Par's approval.

6. At the end of that delay, the FDA squarely rejected Hospira's position and on August 18, 2014, it approved Par Sterile's Abbreviated New Drug Application ("ANDA"), limited to usage in the surgical setting.

7. Undeterred, Hospira immediately filed suit against the FDA in federal court that same day, seeking an injunction to block the FDA's approval from going into effect. *Hospira, Inc. v. Burwell*, No. 14-02662 (D. Md.). This sham suit lacked any legal basis and was brought solely to further delay Par Sterile's entry as a competitor. While it considered the merits, the district court stayed the FDA's decision to approve Par Sterile's ANDA, preventing it from going into effect on August 19, 2014, just one day after it was issued. But following a review of the merits, the court granted summary judgment against Hospira on September 5, 2014, thereby paving the way for Par Sterile to complete the launch of its generic dexmedetomidine product. To further exploit their unlawful monopoly, Hospira is taking steps to evade the pressures of competition from generic entry by converting the market from the Precedex™ vial formulation (the 100 mcg base/mL product at issue in this suit) to Precedex™ "ready to use" (the 200 mcg base/mL and 400 mcg base/100 mL products). The "ready to use" products are covered by additional patents that do not expire until 2032. This transition will permit Hospira to further

extend its present, unlawfully maintained monopoly and is an attempt to weaken any potential competitors.

8. Par Sterile brings this action pursuant to the patent and antitrust laws of the United States to restrain anticompetitive conduct by Hospira, and to remedy the damage suffered by Par Sterile. Par Sterile seeks injunctive and monetary relief from Hospira's monopolization and attempted monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. It also seeks relief in the form of a declaratory judgment asserting the following: non-infringement and invalidity of the '867 patent pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*; that Defendants are collaterally estopped from asserting that the '867 patent is valid and/or infringed by Par Sterile; and that the '867 patent was obtained and is being exploited and used in an improper manner and is thereby invalid for patent misuse.

PARTIES

9. Par Sterile is a company specializing in sterile injectable products, sold predominantly to hospitals and clinicians. It is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at Morris Corporate Center 2, One Upper Pond Road, Building D, 3rd Floor, Parsippany, NJ 07054.

10. Hospira, Inc. is a leading provider of injectable drugs and has global reach. The corporation is organized and existing under the laws of the State of Delaware, having a principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

11. Orion Corporation develops, markets, and manufactures pharmaceuticals. It is a corporation organized and existing under the laws of Finland, having a principal place of business at Orionintie 1A, FI-02200 Espoo, Finland. Orion Corporation has subsidiaries all over

the world, including Orion Pharma, Inc., USA, which is a wholly-owned corporation that does not engage in business activities.

JURISDICTION AND VENUE

12. Par Sterile brings this action for violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26 for monetary damages and to enjoin Hospira's anticompetitive conduct, and to recover the costs of this suit and reasonable attorneys' fees. Par Sterile also alleges violations of the New Jersey Antitrust Act and claims for tortious interference arising out of the same facts and occurrences providing its federal antitrust claims. Par Sterile also seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

13. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1337(a), 1338(a), and 1367(a).

14. This Court has personal jurisdiction over Defendants based on, *inter alia*, Defendants' filing of lawsuits in this jurisdiction concerning the '867 patent, including *Hospira, Inc. and Orion Corp. v. Sandoz Int'l GmbH, Sandoz Inc., and Sandoz Canada Inc.*, No. 3:09-cv-04591 (D.N.J.). Upon information and belief, Hospira has also engaged in the sale of Precedex™ in interstate commerce and in this judicial district. Likewise, Hospira's anticompetitive conduct detailed below has had an effect on interstate commerce, including in this judicial district. Upon information and belief, Orion has also engaged in the research, development, and sale of pharmaceutical products, which are sold throughout the world, including the United States and the State of New Jersey. Upon information and belief, Defendants have purposefully availed themselves of this forum by commercializing

pharmaceutical products in the State of New Jersey and this judicial district, and deriving substantial revenues from such activities.

15. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(d), 1400(b), and Defendants' choice of forum.

FACTUAL BACKGROUND

Statutory and Regulatory Background

16. FDA regulates the approval, manufacture, and commercial sale of pharmaceuticals in the United States pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq*. (the "Act"). Congress passed the Hatch-Waxman Amendments to the Act in 1984, which permit a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA") that expedites the drug approval process. Rather than go through full clinical trials, as a branded drug is required to undertake, an ANDA filer must show that its drug is bioequivalent (as defined by FDA) to a branded drug that FDA has already approved.

17. Section 355(b)(1) of Title 21 of the United States Code mandates that a brand company submit in its NDA "the patent number and the expiration date of any patent which claims the drug for which the [brand] submitted the [NDA] or which claims a method of using such drug." 21 U.S.C. §§ 355(b)(1). Once an NDA is approved, the brand company provides the following information: (1) Whether the patent claims one or more approved methods of using the drug product for which use approval is being sought and a description of each pending method of use or related indication and related patent claim of the patent being submitted; and (2) Identification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted. 21 C.F.R. 314.53(c)(2)(ii)(P), (b)(1).

18. This description submitted by the brand company is known as a "use code." *See* 21 C.F.R. §§ 314.53(c)(2)(ii)(P)(3),(e). The brand company must attest under penalty of perjury that its submission of the patent information, including the use code, to the FDA is "true and correct." 21 C.F.R. § 314.53(c)(2)(ii)(R). FDA does not attempt to verify the accuracy of the use codes that brand companies supply, but relies on the certification of the brand company for its accuracy and specificity, and simply publishes the codes, along with the corresponding patent numbers and expiration dates, in the Orange Book.

19. If an ANDA applicant seeks approval to market a drug for which one or more method-of-use patents are listed in the Orange Book and the ANDA applicant does not seek approval for uses claimed by such patents, the ANDA must include a "section viii" statement that the method-of-use patent does not claim any of the proposed uses for which the applicant seeks approval. 21 U.S.C. § 355(j)(2)(A)(viii). FDA will not accept a section viii statement if the ANDA applicant's proposed label contains the use identified in the description in the use code. The method-of-use patent claiming the uses omitted in the labeling will thus not act as a barrier to approval of the ANDA by FDA.

20. ANDA applicants seeking FDA approval through a section viii statement are not subject to any 30-month stay of approval period, or any 180-day exclusivity period.

Hospira's NDA And The Patent In Suit

21. Hospira first began marketing Precedex™ in 1999, following FDA approval of its New Drug Application No. 021038 ("NDA 021038") for dexmedetomidine hydrochloride injection, EQ 200 mcg base/2 mL (EQ 100 mcg base/mL).

22. As approved by the FDA on December 17, 1999, NDA 021038 permitted Precedex™ to be used for the sedation of initially intubated and mechanically ventilated patients

in an ICU setting. On October 17, 2008, Hospira obtained FDA approval for a second indication: sedation of non-intubated patients prior to and/or during surgical and other procedures.

23. In connection with NDA 021038, Hospira, Inc. certified that U.S. Patent No. 4,910,214 ("the '214 patent"), U.S. Patent No. 5,344,840 ("the '840 patent"), and the '867 patent all either claimed the drug or a method of use for Precedex™. As a result, the FDA listed all of these patents in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

24. According to the Orange Book, the '840 patent expired on September 6, 2011, and the '214 patent expired on July 15, 2013, with an associated pediatric exclusivity period expiring on January 15, 2014. The '867 patent is the only unexpired patent listed in the Orange Book for the 100 mcg base/mL formulation of Precedex™.

25. The '867 patent, entitled "Use of Dexmedetomidine for ICU Sedation," issued on April 6, 2004. A true copy of the '867 patent is attached hereto as Exhibit A. Hospira and Orion are co-assignees of the '867 patent and share ownership of the '867 patent. On information and belief, Hospira is the exclusive licensee in the United States of Orion's ownership interest in the '867 patent. The '867 patent will expire on March 31, 2019, and an associated pediatric exclusivity period will expire on October 1, 2019.

26. The '867 patent claims methods of sedating patients in an ICU by administering dexmedetomidine to the patient wherein the patient remains arousable and orientated. Specifically, claim 1 of the '867 patent states: "A method of sedating a patient in an intensive care unit, which comprises administering to the patient an effective amount of dexmedetomidine

of a pharmaceutically acceptable salt thereof, wherein the patient remains arousable and orientated."

27. No portion of the '867 patent claims any method of use relating to administering the drug to patients in surgical procedures.

The '867 Patent Has Been Finally Adjudicated to Be Invalid

28. Defendants previously asserted the '214 and '867 patents against Sandoz International GmbH and Sandoz, Inc. in connection with Sandoz's filing of ANDA No. 91465 for its generic dexmedetomidine hydrochloride injection, 100 mcg base/mL. *Hospira, Inc. and Orion Corp. v. Sandoz Int'l GmbH, Sandoz Inc., and Sandoz Canada Inc.*, No. 3:09-cv-04591 (D.N.J.).

29. The *Sandoz* court held the '867 patent obvious under 35 U.S.C. § 103 and therefore invalid. Upon consideration of the *Graham* factors, the *Sandoz* court concluded that all claims of the '867 patent would have been obvious to a person of ordinary skill in the art. ECF No. 380 in Case No. 3:09-cv-04591.

30. After the District of New Jersey's judgment of invalidity, Hospira negotiated with Sandoz and induced Sandoz to drop its suit in exchange for Hospira permitting Sandoz to enter the market with its generic dexmedetomidine product on December 26, 2014. (Hospira, Inc. 2013 10-K at 15.) In exchange for this early entry, Hospira required Sandoz to join it in moving the district court to vacate the invalidity judgment in December 2013. This allowed Sandoz to share in the exclusivity of the '867 patent and also enjoy a period as the sole generic dexmedetomidine product. The District Court granted the parties' motion.

31. Despite the fact that the '867 patent was finally adjudicated to be invalid, and Hospira did not obtain a reversal of that adjudication on the merits, Hospira continued to maintain the patent listed in the Orange Book for the purpose of precluding generic competition.

32. Issue preclusion may apply despite the fact that an earlier judgment was vacated as a term of settlement of the case. *Sentinel Trust v. Univ. Bonding Ins.*, 316 F.2d 213, 215 (3d Cir. 2003).

Precedex™ Has Become Hospira's Marquee Drug

33. Hospira is a massive and extremely profitable company. It sold $4.1 billion worth of products worldwide in 2013. (Hospira, Inc. 2013 Annual Report at 1.) And in the past year alone it increased its cash flow from $51 million to $176 million. (July 30, 2014 Q2 Investor Conference Call Tr. at 4.)

34. Specialty injectable pharmaceuticals are particularly important to Hospira's business, accounting for 69% of net sales in 2013. (Hospira, Inc. 2013 10-K at 40.) Even within this lucrative sector, Precedex™ stands out. "In the Americas, Precedex™ represents approximately 17% of specialty injectable pharmaceutical product line Net sales." (*Id.* at 9.) But even this may understate the importance of Precedex™, which, in 2013, "represented approximately 11% of global Net sales," (*id.*), amounting to approximately $450 million.

35. Although Hospira saw an overall decline in sales and profitability in 2013, this was not true for specialty injectable pharmaceuticals, which remained a key driver of Hospira's $1 billion in gross profits. (*Id.* at 54, 56.) This growth in specialty injectable pharmaceuticals was due to Hospira's ability to increase prices in the US and the "continued volume growth of the proprietary sedation drug Precedex™." (*Id.* at 54.)

36. Unlike Precedex™, most of Hospira's products are not protected by patents or subject to exclusivity. (*Id.* at 15.) This makes it an especially important product.

37. Indeed, Precedex™ is so important to Hospira's business, that the possibility of generic competition for the drug is mentioned multiple times throughout the annual report and investor presentations. Simply put, "[g]eneric competition to Precedex™ is expected to have a material adverse impact on Hospira's sales of Precedex™." (*Id.*)

Par Sterile's ANDA Product

38. On February 2, 2012, Par Sterile submitted to FDA an ANDA requesting regulatory approval to engage in the commercial manufacture, use, or sale of dexmedetomidine hydrochloride injection, 100 mcg (base)/mL, packaged in 200 mcg (base)/2 mL single-dose vials ("Par Sterile's ANDA Product"), which FDA assigned ANDA No. 203972. Par Sterile's ANDA included a Paragraph III certification for the '214 patent and a "section viii" statement for the '867 patent.

39. Par Sterile's "section viii" statement under 21 U.S.C. § 355(j)(2)(A)(viii) stated that the '867 patent is a method of use patent that does not claim any indication for which Par Sterile is seeking approval, as Par Sterile's ANDA omitted any description of use in an intensive care unit setting. Thus, Par Sterile's ANDA carved out the ICU use that was still covered by the '867 patent, according to the Orange Book.

40. The FDA may approve a generic product without a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(viii) when the ANDA includes a section viii statement with respect to the use claimed in the listed patent.

41. Par Sterile expected the FDA to approve its ANDA Product on January 15, 2014, following the expiration of the '214 patent—the only patent listed in the Orange Book as

covering surgical uses. In anticipation of this product launch, Par Sterile began manufacturing its ANDA Product in September 2013. Tr. of August 26, 2014 Hearing in Case No. 8:14-cv-02662, at 48; ECF No. 97 in Case No. 8:14-cv-02662, at 11, 14.

'867 Patent Use Code Amendment

42. On May 6, 2004, Hospira submitted the '867 patent for listing in the Orange Book, with use code U-572: "intensive care unit sedation." At the time of this submission, Hospira's belief was that the consequence of administering Precedex™ was "to provide a method of sedating a patient in an intensive care unit wherein the patient remains arousable and orientated, and accordingly that U.S. Patent No. 6,716,867 claims an approved use of the drug product."

43. When Hospira submitted the '867 patent with the use code U-572, Precedex™ was only approved for one indication: the "sedation of initially intubated and mechanically ventilated patients in an intensive care unit (ICU) setting."

44. On October 17, 2008, Hospira gained FDA approval for the second indication: sedation of non-intubated patients prior to and/or during surgical and other procedures.

45. On November 21, 2008, Hospira submitted the '840 patent for listing in the Orange Book, with use code U-912: "Sedation of non-intubated patients prior to and/or during surgical and other procedures." The '840 patent expired on September 6, 2011, and is no longer listed in the Orange Book for NDA 021038.

46. When Hospira submitted the '840 patent for listing, Hospira did not make any amendments to the '867 patent use code. Thus, from September 6, 2011 until January 2014, Hospira made no claim that any patent governed the usage of dexmedetomidine hydrochloride for sedation during surgical procedures. Hospira stated as much in federal court in *Hospira, Inc.*

and Orion Corp. v. Sandoz Int'l GmbH, Sandoz Inc., and Sandoz Canada Inc., No. 3:09-cv-04591 (D.N.J.). In *Sandoz*, Hospira argued that the '867 patent related only to the ICU indication, and that there was no valid patent that covered the surgical indication. During closing arguments at trial, Hospira argued that Sandoz had copied the '867 patent by choosing "only to seek approval for the '867 patent indication." When the Court asked whether the "other approved label use" is "the subject of a patent application," Hospira stated that "the other approved label use is related to the perioperative use in the '840 patent, which is now expired, so the '867 patent is the patent for ICU sedation." Even more explicitly, the Court asked Hospira to confirm that "there's no patent on the second approved use as distinguished from the compound itself," to which Hospira represented: "Not on the method of use, that's right." ECF No. 397 in Case No. 3:09-cv-04591, at 2089-90. Instead, Hospira's exclusivity was based upon the patent for the underlying drug itself—the '214 patent.

47. In view of the January 15, 2014 expiration of the exclusivity associated with its '214 patent and Hospira's understanding, obtained from its customers, that Mylan Institutional and JHP Pharmaceuticals (Par Sterile's predecessor) expected to launch generic dexmedetomidine hydrochloride products in mid-January 2014, Hospira decided to act to protect its dexmedetomidine hydrochloride monopoly. Hospira euphemistically refers to this as "life-cycle management," a key aspect of its continued profitability. (2013 Hospira, Inc. 10-K at 15.) Hospira understood that ANDA applicants were permitted to submit applications for which indications otherwise covered by patents or other exclusivities are omitted pursuant to 21 U.S.C. § 355(j)(2)(A)(viii). As such, these applicants would be immediately eligible for final marketing approval, regardless of the pendency of the '867 patent and regardless of any marketing exclusivity held by third parties, including Sandoz, the first paragraph IV filer. Without taking

action, Hospira could not prevent competition from generic applicants, specifically Par Sterile, from marketing dexmedetomidine hydrochloride for off-patent uses not claimed in the '867 patent, for example those involving surgical procedures. And, upon information and belief, Hospira knew when it heard from its own customers that JHP Pharmaceuticals was about to bring a generic product to market that these same customers were likely preparing to enter into contracts with JHP Pharmaceuticals for the purchase of generic dexmedetomidine hydrochloride injections.

48. To prevent the erosion of its Precedex™ profits through competition with lower-priced, non-infringing generic alternatives, on or about January 6, 2014, nine days before the pediatric exclusivity period was set to expire for the '214 patent, Hospira deceptively manipulated the ministerial procedures for use code submission for the '867 patent. Hospira sought to amend the '867 use code to "intensive care unit sedation, including sedation of non-intubated patients prior to and/or during surgical and other procedures" (U-1472), even though the claims of the '867 patent provided no basis to do so. This action was taken deliberately to prevent the FDA from "improperly approv[ing] a section viii statement" for generic dexmedetomidine products. (January 24, 2014 Comment from Hospira, Inc. at 6-7, Docket Number FDA-2014-N-0087.)

49. Hospira deliberately altered the use code for the purpose of maintaining its monopoly over both FDA-approved indications of Precedex™, even though the claims of the '867 patent cover only one such use. In submitting the altered use code, Hospira has improperly misrepresented to FDA that the '867 patent covers uses for which Hospira has no patent protection and for which Hospira has no lawful right to exclude potential competitors.

50. Hospira was neither required nor directed by FDA to change its use code for the '867 patent.

51. Hospira's manipulation of its use code for the '867 patent was designed to—and has had the effect of—delaying generic competition to Precedex™.

52. Hospira knew that the representations that it made in submitting the use code for the '867 patent in the Orange Book in connection with Precedex™ were inconsistent and deliberately misleading.

53. Hospira knew and intended that its manipulation of the use code could have the effect of requiring the FDA to push section viii filers, like Par Sterile, into certifications under Paragraph IV, which changes would have made them subject to, *inter alia*, the Hatch-Waxman notice provisions, the 30-month Hatch-Waxman stay of ANDA approval, and third party exclusivities and prevented them from coming to the market until long after Sandoz had entered.

Hospira's Use Code Change Caused an Extensive Delay

54. On or about January 8, 2014, FDA, in accordance with the ministerial manner in which it implements patent use code information, changed the use code for the '867 patent to U-1472.

55. In light of Hospira's use code change, FDA issued a "Dear Dexmedetomidine Hydrochloride Injection NDA/ANDA Applicant" letter on January 15, 2014 – the date that the '214 patent expired – and established Public Docket No. FDA-2014-N-0087 to solicit comment on certain legal and regulatory issues pertaining to Precedex™, including whether "the breadth of the new use code description for the '867 patent foreclose[s] ANDA applicants from gaining approval for any of the approved indications (or for any subset of those indications) before the '867 patent expires?".

56. In responding to this request, Hospira reiterated the validity of the '867 patent (despite the contrary holding in the Sandoz litigation), argued that the FDA lacked authority to conduct any evaluation of the patents at issue, their implication of the claimed use codes, or the overlap between Precedex™ and any generic manufacturer filing a section viii statement. It concluded by asserting that "any applicant seeking to market a generic version of PRECEDEX™ . . . must file a Paragraph IV certification." (Comment from Hospira, Inc. at 9, Docket Number FDA-2014-N-0087.) Hospira's earlier conduct, however, shows that it did not believe these arguments to be true.

57. Still, Hospira's strategy paid off, and it was not until eight months later, on August 18, 2014, that the FDA issued a determination in Public Docket No. FDA-2014-N-0087 concluding that "regardless of whether the original use code or the revised use code applies, the agency can approve an ANDA that submits a 'section viii' statement and omits labeling that discloses the protected use (as identified by Hospira). FDA further concludes that such omissions do not render the drug less safe or effective for the remaining non-protected conditions of use." As a result, the FDA approved Par Sterile's ANDA Product that same day.

58. After the FDA granted approval, Par Sterile launched its ANDA Product on August 19, 2014. Par Sterile had been prepared to launch its ANDA Product since January 15, 2014 and had prepared 1.5 months' worth of inventory, which it started shipping to wholesale distributor customers the moment that it got approval. Tr. of August 26, 2014 Hearing in Case No. 8:14-cv-02662, at 58-59. Par Sterile sold millions of dollars' worth of its ANDA Product on August 19, 2014.

59. Rather than accept the FDA's decision, Hospira filed suit in federal court, seeking to block the FDA's approval of Par Sterile's ANDA. *Hospira, Inc. v. Burwell et al.*, Case No.

8:14-cv-02662-GJH (D. Md.). This suit relied on the fact that the invalid '867 patent should block Par Sterile's entry to the market for non-patented uses, despite previously having told the District of New Jersey in the *Sandoz* litigation that this patent had no relation to surgical uses. The *Burwell* suit was filed solely in an effort to delay competition. Hospira argued that "the section viii statement route is unavailable here because *there are no approved uses of the drug which are not covered by, or do not overlap with, Hospira's patented methods of use*" (emphasis in original) and "[t]here is an obvious overlap between the approved indications and Hospira's '867 patent." ECF No. 2 in Case No. 8:14-cv-02662-GJH at 16. Although this was temporarily successful when the District of Maryland issued a temporary stay of the FDA's decision on August 19, ECF Nos. 19 and 20 in Case No. 8:14-cv-02662-GJH, that stay was removed on September 5 when the court entered summary judgment against Hospira. Hospira has since filed a notice of appeal and again sought to stay the FDA's decision at the Fourth Circuit.

60. Par Sterile halted all sales of its ANDA Product as soon as it became aware of the preliminary temporary restraining order issued on August 19, 2014. Par Sterile had to turn away multiple customers due to the stay, and multiple customers contacted Par out of concern over Hospira's legal proceedings. Par Sterile resumed sales of its ANDA Product after the Court removed the stay on September 5, resulting in a loss of nearly three weeks' worth of revenue.

Hospira Is Now Attempting to Extend its Supracompetitive Profits

61. Precedex™ was approved by the FDA in 1999 in only one concentration: 100 mcg base/mL. This is the version of the drug that is covered by the patents outlined above, and is the version of the drug for which Par Sterile seeks to bring a generic to market. In March 2013, however, Precedex™ received additional approvals for 200 mcg base/mL and 400 mcg base/100 mL concentrations, which Hospira markets as "ready to use." In addition to the '214

and '867 patents described above, these "ready to use" formulations are covered by four additional patents: U.S. Patent No. 8,242,158; U.S. Patent No. 8,338,470; U.S. Patent No. 8,455,527; and 8,648,106. All of these patents expire on January 4, 2032.

62. Recognizing that it will lose its monopoly at the latest on December 26, 2014 when Sandoz enters, Hospira moved to the next stage of "life-cycle management," which required shifting consumers to the drugs that were still subject to Hospira's monopoly. The FDA approvals of these ready-to-use drugs were hailed as one of the key examples of the "considerable progress advancing our growth initiatives" that Hospira made in 2013. (2013 Annual Report at 1.)

63. Hospira is now pushing consumers to adopt these new drugs, featuring the "ready to use" formulations in multiple locations on the front page of www.precedex.com. By moving the market away from the 100 mcg base/mL product, Hospira is attempting to avoid competition and retain its monopoly profits. The ready-to-use formulations offer no medical or clinical benefit, and this strategy has been adopted solely to attempt to further stand in the way of generic competition. Indeed, they were approved as covered by the same NDA as the original formulation.

Hospira's Monopoly Power

64. The relevant product market is the sale of dexmedetomidine hydrochloride injections for sedation of patients prior to and/or during surgical and other procedures.

65. Dexmedetomidine hydrochloride injections are not reasonably interchangeable with other methods of sedation when used on non-intubated patients prior to and/or during surgical and other procedures. This is illustrated by the fact that Hospira is able to raise the price

of Precedex™ without suffering a loss in demand for the product. In fact, when Hospira raised the price of its drugs, it still sold higher volumes than in previous years.

66. Hospira has maintained 100% of the market for dexmedetomidine hydrochloride injections for sedation of non-intubated patients prior to and/or during surgical and other procedures as a result of its patents associated with Precedex™. Specifically, the '840 patent covered this method of use until 2011, and the '214 patent covered the underlying compound until January 15, 2014. Since January 6, 2014, however, Hospira has abused the FDA processes to extend its monopoly beyond the expiration of the '214 patent. These actions, described above, have prevented any entry into the market by generic competitors, and have permitted Hospira to maintain complete control of the market.

67. In addition, the FDA approval process, even when functioning without interference such as that provided by Hospira here, establishes substantial barriers to entry that will further limit the ability of competitors to emerge.

68. The relevant geographic market is the United States. Hospira does not limit its sales to any one part of the country, but sells to consumers all over the United States.

69. At all times, and continuing until today, Hospira has acted with the specific intent of securing monopoly power and charging supracompetitive prices.

Par Sterile Has Standing To Sue

70. An actual and justiciable controversy exists between Defendants and Par Sterile. Hospira has stated that generic manufacturers seeking to market dexmedetomidine hydrochloride, such as Par Sterile, must first establish that they do not infringe Hospira's rights under its method-of-use patent before the FDA can allow generic versions of Precedex™ on the

market. As of the date of this amended complaint, Par Sterile has made substantial efforts to market the Par Sterile ANDA Product, and has made, used, sold, and offered to sell the Product.

71. Hospira has also previously stated that the ’867 patent does not cover the surgical indication, and that there is no valid patent on the method of use of dexmedetomidine for a surgical indication.

72. By listing the ’214 and ’867 patents in the Orange Book, and previously suing other ANDA filers for alleged infringement of the ’214 and ’867 patents, Defendants’ actions inject uncertainty into the pursuit of regulatory approval and subsequent commercialization of Par Sterile’s ANDA Product. This uncertainty is further exacerbated by Defendants’ contradictory and conflicting statements to the FDA, the District of Maryland, and the District of New Jersey regarding the scope of the ’867 patent with respect to the surgical indication, which is the only indication for which Par Sterile sought FDA approval and intends to market its ANDA product for.

73. A judgment that Par Sterile’s ANDA Product will not infringe the ’867 patent and/or that the patent is invalid will remove any independent barriers to competition that may exist by virtue of Defendants’ maintenance of the listing of the patents in the Orange Book in connection with NDA 021038 for Precedex.

74. Defendants’ actions have resulted in a substantial controversy regarding the ’867 patent between Par Sterile and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that the ’867 patent is invalid and not infringed.

75. Hospira’s monopolization has harmed the competitive process. Par Sterile was prepared to enter the market in January 2014, and it was only due to Hospira’s misuse of the FDA process that such competition has been delayed for eight months. The delayed entry has

harmed Par Sterile in its business and property, because it was unable to enter the market, compete, and earn profits. Hospira's conduct has not only harmed Par Sterile but also consumers, who have been forced to pay significant overcharges for dexmedetomidine hydrochloride injections that otherwise would have been available at competitive prices.

76. Hospira's conduct has prevented Par Sterile from entering the market with a generic dexmedetomidine hydrochloride product and caused Par Sterile to suffer damages in the form of lost sales. Par Sterile was prepared to enter the market at the expiration of the '214 patent on January 15, 2014, but was unable to sell its product until August 18, 2014, as a result of the anticompetitive conduct described above. Par Sterile also was injured due to Hospira's sham litigation, which resulted in a temporary removal of its generic drug from the market, and caused additional lost sales from August 19, 2014 through September 5, 2014, by, for example, requiring Par Sterile to turn away prospective customers. Tr. of August 26, 2014 Hearing in Case No. 8:14-cv-02662, at 59.

COUNT ONE

Declaratory Judgment Regarding U.S. Patent No. 6,716,867 Against Hospira and Orion (Invalidity)

77. Par Sterile realleges paragraphs 1-76 of the Amended Complaint as if fully set forth herein.

78. The claims of the '867 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code § 1 *et seq.* (including, *inter alia*, 35 U.S.C. §§ 102, 103 and/or 112 and/or the doctrine of obviousness-type double patenting).

79. An actual and justiciable controversy exists between the parties with respect to the '867 patent, and Par Sterile is entitled to a declaratory judgment that the '867 patent is invalid.

COUNT TWO

Declaratory Judgment Regarding U.S. Patent No. 6,716,867 Against Hospira and Orion (Non-Infringement)

80. Par Sterile realleges paragraphs 1-79 of the Amended Complaint as if fully set forth herein.

81. The filing of Par Sterile's ANDA for Par Sterile's ANDA Product did not infringe any valid claim of the '867 patent.

82. The commercial manufacture, use, offer for sale, sale, or importation of Par Sterile's approved ANDA Product would not infringe any valid claim of the '867 patent.

83. An actual and justiciable controversy exists between the parties with respect to the '867 patent, and Par Sterile is entitled to a declaratory judgment that the '867 patent is not infringed by Par Sterile.

COUNT THREE

Collateral Estoppel Against Hospira and Orion

84. Par Sterile realleges paragraphs 1-83 of the Amended Complaint as if fully set forth herein.

85. Defendants are collaterally estopped from asserting claims of the '867 patent based on the adjudication of invalidity in *Hospira, Inc. and Orion Corp. v. Sandoz Int'l GmbH, Sandoz Inc., and Sandoz Canada Inc.*, Case No. 3:09-cv-04591 (D.N.J.), the entry of a vacatur order notwithstanding.

86. An actual and justiciable controversy exists between the parties with respect to the '867 patent, and Par Sterile is entitled to a declaratory judgment that Defendants are collaterally estopped from asserting that the '867 patent is valid and/or infringed by Par Sterile.

COUNT FOUR

Patent Misuse Against Hospira and Orion

87. Par Sterile realleges paragraphs 1-86 of the Amended Complaint as if fully set forth herein.

88. The '867 patent was obtained and is being exploited and used in an improper manner and is thereby invalid for patent misuse.

89. An actual and justiciable controversy exists between the parties with respect to the '867 patent, and Par Sterile is entitled to a declaratory judgment that the '867 patent is invalid for patent misuse.

COUNT FIVE

Violation of the Sherman Act by Hospira – 15 U.S.C. § 2 (Monopolization)

90. Par Sterile realleges paragraphs 1-89 of the Amended Complaint as if fully set forth herein.

91. At all relevant times, Hospira has possessed monopoly power in the relevant market, which is the market for sale of dexmedetomidine hydrochloride injections for use in surgical settings.

92. During the relevant period, Hospira has willfully and unlawfully maintained and extended their monopoly power by (i) negotiating a settlement agreement to keep a competitor from entering the market despite the fact that the sole patent justifying exclusion had been adjudged invalid; (ii) manipulating the ministerial use-code procedures as implemented by the FDA; and (iii) making inconsistent and deliberately misleading misrepresentations to FDA. Hospira improperly changed the use code for the '867 patent and, in doing so, incorrectly misrepresented to FDA that the '867 patent covered both FDA-approved uses of Precedex™,

when in fact Hospira knew that the '867 patent claimed only a method of use in an ICU setting wherein the patient remains arousable and orientated. This deliberate misrepresentation was made with the intent and effect of delaying generic competition to its Precedex™ monopoly from Par Sterile and other generic ANDA filers that sought to market with a use code that does not infringe the '867 patent or any other unexpired patent. Hospira then furthered this effort by making inconsistent and contradictory statements to FDA, the District of Maryland, and the District of New Jersey regarding the scope of the '867 patent with respect to the surgical indication.

93. Hospira has stated that generic manufacturers seeking to market dexmedetomidine hydrochloride, such as Par Sterile, must first establish that they do not infringe Hospira's rights under the '867 patent before the FDA can allow generic versions of Precedex™ on the market. This unjustified and unsupported attempt to extend the scope and validity of the patent permitted Hospira to monopolize the market for eight months longer than it otherwise would have.

94. There is no business necessity or other pro-competitive justification for Hospira's conduct.

95. Hospira's actions have occurred in and affected interstate commerce.

96. Hospira's actions have delayed Par Sterile's entry into the market for dexmedetomidine hydrochloride injections for use in surgical settings. As a result, Par Sterile has been injured in its business and property.

97. Consumers have been injured as well, because Hospira's actions deprived them, and will continue to deprive them, of the benefits of competition, including lower prices and choice.

COUNT SIX

Violation of the Sherman Act by Hospira – 15 U.S.C. § 2
(Attempted Monopolization)

98. Par Sterile realleges Paragraphs 1-97 of the Amended Complaint as if fully set forth herein.

99. Hospira has attempted, and continues to attempt, to maintain or re-acquire its monopoly. Its litigation before the District of Maryland and now the Fourth Circuit Court of Appeals serves no purpose but to attempt to delay entry of a generic competitor, and is both objectively and subjectively baseless.

100. Hospira also has attempted to move the market away from the vial formulation of Precedex™, where it faces generic competition, to ready-to-use formulations, where it retains its monopoly. This has been done for the sole purpose of avoiding competition and weakening any potential generic competitors.

101. Hospira has a dangerous probability of success in achieving its monopoly. It still retains an exceptionally high share of the market, and is attempting to cripple its competition before it can emerge.

102. During the relevant period, Hospira had and continues to have the specific intent to monopolize the market for dexmedetomidine hydrochloride injections for use in surgical procedures.

103. Hospira's actions have occurred in and affected interstate commerce.

104. Hospira's actions have delayed, and attempt to continue to delay Par Sterile's entry into the market for dexmedetomidine hydrochloride injections for use in surgical settings. As a result, Par Sterile has been injured in its business and property.

105. Consumers have been and will continue to be injured as well, because Hospira's actions deprived them, and will continue to deprive them, of the benefits of competition, including lower prices and choice.

COUNT SEVEN

Violation of the New Jersey Antitrust Act by Hospira, Section 56:9-4 (Monopolization and Attempted Monopolization)

106. Par Sterile realleges Paragraphs 1-105 of the Amended Complaint as if fully set forth herein.

107. Hospira's conduct also constitutes monopolization and attempted monopolization in violation of N.J. Stat. Ann § 56:9-4(a). At all relevant times, Hospira has possessed monopoly power in the relevant market, which is the market for sale of dexmedetomidine hydrochloride injections for use in surgical settings.

108. During the relevant period, Hospira has willfully and unlawfully maintained and extended their monopoly power by (i) negotiating a settlement agreement to keep a competitor from entering the market despite the fact that the sole patent justifying exclusion had been adjudged invalid; (ii) manipulating the ministerial use-code procedures as implemented by the FDA; and (iii) making inconsistent and deliberately misleading misrepresentations to FDA. Hospira improperly changed the use code for the '867 patent and, in doing so, incorrectly misrepresented to FDA that the '867 patent covered both FDA-approved uses of Precedex™, when in fact Hospira knew that the '867 patent claimed only a method of use in an ICU setting wherein the patient remains arousable and orientated. This deliberate misrepresentation was made with the intent and effect of delaying generic competition to its Precedex™ monopoly from Par Sterile and other generic ANDA filers that sought to market with a use code that does not infringe the '867 patent or any other unexpired patent. Hospira then furthered this effort by

making inconsistent and contradictory statements to FDA, the District of Maryland, and the District of New Jersey regarding the scope of the '867 patent with respect to the surgical indication.

109. Hospira has stated that generic manufacturers seeking to market dexmedetomidine hydrochloride, such as Par Sterile, must first establish that they do not infringe Hospira's rights under the '867 patent before the FDA can allow generic versions of Precedex™ on the market. This unjustified and unsupported attempt to extend the scope and validity of the patent permitted Hospira to monopolize the market for eight months longer than it otherwise would have.

110. There is no business necessity or other pro-competitive justification for Hospira's conduct.

111. Hospira's actions have delayed Par Sterile's entry into the market for dexmedetomidine hydrochloride injections for use in surgical settings. As a result, Par Sterile has been injured in its business and property.

112. Consumers have been injured as well, because Hospira's actions deprived them, and will continue to deprive them, of the benefits of competition, including lower prices and choice.

COUNT EIGHT

Tortious Interference by Hospira

113. Par Sterile realleges Paragraphs 1-112 of the Amended Complaint as if fully set forth herein.

114. Hospira's conduct gives rise to common law liability for tortious interference with prospective business relations and economic advantage.

115. Par Sterile had a prospective economic or contractual relationship with multiple customers. Upon information and belief, Hospira was aware of this prospective economic or contractual relationship and acted with malice in abusing the regulatory and court systems to prevent Par Sterile from fulfilling these contracts, and acted with no justification or intent other than to protect its unwarranted monopoly. Par Sterile was unable to complete any of these contracts due to Hospira's conduct, and therefore suffered damages in the form of lost sales.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Par Sterile respectfully requests a trial by jury on all issues properly triable to a jury.

PRAYER FOR RELIEF

WHEREFORE, Par Sterile respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. Declare that the claims of the '867 patent are invalid;

B. Declare that the filing of Par Sterile's ANDA seeking marketing approval of Par Sterile's ANDA Product did not infringe any valid claim of the '867 patent;

C. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Par Sterile's approved ANDA Product would not infringe any valid claim of the '867 patent;

D. Declare that Defendants are collaterally estopped from asserting claims of the '867 patent against Par Sterile;

E. Award Par Sterile damages sufficient to compensate it for the injuries it has sustained on account of Hospira's state and federal antitrust violations, including lost profits, to be trebled, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15;

F. Award Par Sterile damages sufficient to compensate it for the injuries it suffered due to Hospira's tortious interference;

E. Award Par Sterile its costs and reasonable attorney fees to the extent permitted by law, including under 15 U.S.C. § 15; and

F. Award Par Sterile such other and further relief as the Court deems just and proper.

Dated: October 3, 2014

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify pursuant to Local Civil Rule 11.2 that this matter in controversy is not the subject of any other action pending in any court, arbitration or administrative proceeding.

Dated: October 3, 2014

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