IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXTER HEALTHCARE CORPORATION,	)	
Plaintiff,	)	
	)	C.A. No. 18- _____
v.	)	
HOSPIRA, INC. and ORION CORP.,	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Baxter Healthcare Corporation ("Baxter"), through counsel, hereby brings its Complaint for Declaratory Judgment against Hospira, Inc. ("Hospira") and Orion Corp. ("Orion"), and alleges as follows:

NATURE OF THE SUIT

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent Nos. 6,716,867 (the "'867 Patent"), 8,242,158 (the "'158 Patent"), 8,338,470 (the "'470 Patent"), and 8,455,527 (the "'527 Patent") (collectively, "the Patents-in-Suit") to enable Baxter to bring its generic dexmedetomidine hydrochloride in 0.9% sodium chloride injection 200 mcg/50 mL and 400 mcg/100mL (the "Baxter ANDA Product") to market at the earliest possible date under the applicable statutory and Food and Drug Administration ("FDA") regulatory provisions, and to allow the public to enjoy the benefits of generic competition for these products.

THE PARTIES

2. Baxter Healthcare Corporation is a corporation incorporated in Delaware with its principal place of business at One Baxter Parkway, Deerfield, IL 60015.

3. Upon information and belief, Hospira, Inc. is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

4. Upon information and belief, Orion Corp. is a corporation organized under the laws of Finland with its principal place of business at Orionintie 1, FIN-02200 Espoo, Finland.

JURISDICTION, VENUE AND JOINDER

5. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984 (codified as amended at 21 U.S.C. § 355)) (the "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) (the "MMA"), based upon an actual controversy between the parties to declare that Baxter is free, upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import its proposed product as described in Abbreviated New Drug Application ("ANDA") No. 208532.

6. This Court has original jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 1400(b), at least because Hospira resides in this District within the meaning of 28 U.S.C. § 1400(b).

8. This Court has personal jurisdiction over Hospira because, among other things, Hospira is a Delaware corporation, that, having availed itself of Delaware's corporate laws, is subject to personal jurisdiction in Delaware.

9. This Court has personal jurisdiction over Orion because, among other things, on information and belief, Orion does business in this District by co-owning a patent covering

Precedex® (*i.e.*, the ’867 Patent), exclusively licensing in the United States its ownership interest in said patent to Hospira—a Delaware corporation—and receiving royalty payments from Hospira for the sale of Precedex®, which is sold in Delaware.

10. This Court also has personal jurisdiction over Orion because Orion has regularly and purposefully availed itself of the privileges and benefits of this forum, having brought multiple suits in this District, including suits specifically alleging infringement of the ’867 Patent at issue in this suit: *Hospira Inc. and Orion Corp v. Sandoz International GmbH, et al.*, Civ. No. 09-00665 (D. Del.); *Hospira, Inc. and Orion Corp. v. Aurobindo Pharma Ltd., at al.*, Civ. No. 14-00486 (D. Del.); *Hospira, Inc. and Orion Corp. v. Ben Venue Labs, Inc.*, Civ. No. 14-00487 (D. Del.); *Hospira, Inc. and Orion Corp. v. Actavis LLC et. Al.*, Civ. No. 14-00488 (D. Del.); *Hospira, Inc. and Orion Corp. v. Ben Venue Labs., Inc., et al*., Civ. No. 14-1008 (D. Del.).

11. Upon information and belief, the license agreement between Orion and Hospira imposes an obligation on Orion to participate in the enforcement or defense of the ’867 patent with Hospira, which is engaged in exploiting the patent rights in Delaware through its sale of Precedex®.

12. By virtue of its repeated assertion of infringement of the ’867 Patent in this District, Orion has waived any argument that it is not subject to specific personal jurisdiction in this District for actions relating to the infringement thereof.

13. Venue is proper in this district for Orion pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Orion is a corporation organized and existing under the laws of Finland and is subject to personal jurisdiction in this judicial district.

THE PATENTS-IN-SUIT

The ’867 Patent

14. On its face the ’867 Patent, entitled “Use of Dexmedetomidine for ICU Sedation,” indicates it was issued by the U.S. Patent and Trademark Office on April 6, 2004. A copy of the ’867 Patent is attached as Exhibit A.

15. According to records at the U.S. Patent and Trademark Office, Hospira and Orion are co-assignees of the ’867 Patent.

16. On information and belief, Hospira is the exclusive licensee in the United States of Orion’s interest in the ’867 Patent.

17. The ’867 Patent contains twelve claims.

18. The ’867 Patent contains two independent claims.

19. Each independent claim of the ’867 Patent recites “[a] method of sedating a patient in an intensive care unit.”

20. The ’867 Patent’s ten dependent claims incorporate the limitations of the claims from which they depend. Thus, all claims of the ’867 Patent require “[a] method of sedating a patient in an intensive care unit.”

The ’158 Patent

21. On its face the ’158 Patent, entitled “Dexmedetomidine Premix Formulation,” indicates it was issued by the U.S. Patent and Trademark Office on August 14, 2012. A copy of the ’158 Patent is attached as Exhibit B.

22. The ’158 Patent issued from application number 13/343,672 (the “’672 Application”).

23. According to records at the U.S. Patent and Trademark Office, Hospira is the

assignee of the ’158 Patent.

24. The ’158 Patent contains four claims.

25. The ’158 Patent contains one independent claim.

26. The independent claim of the ’158 Patent recites “[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container.”

27. The ’158 Patent’s three dependent claims incorporate the limitations of the claims from which they depend. Thus, all claims of the ’158 Patent require “[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container.”

28. When the ’672 Application was initially filed, its claims did not require that the sealed container be made of glass.

29. On March 13, 2012, in response to an office action rejecting the originally-filed claims of the ’672 Application, Hospira amended the sole pending independent claim to include the present requirement that the sealed container be “a sealed glass container.”

30. In its March 13, 2012 filing with the U.S. Patent and Trademark Office, Hospira argued that it discovered that using glass containers resulted in unexpectedly superior stability compared to using plastic containers. Response to Office Action, at 7-8 (Mar. 13, 2012) (arguing it was surprising that “a 4µg/mL premixture formulation stored in glass vials and ampoules maintained a higher level of potency after a 5 month storage period compared to storage in plastic, CR3, or PVC containers”).

31. On April 18, 2012, the U.S. Patent and Trademark Office issued a notice of allowance for the ’672 Application. In this notice, the examiner stated that “requiring the composition to be disposed within a sealed glass container[] was effective to overcome the previous rejection under 35 U.S.C[. §] 102(b).” Notice of Allowance, ¶ 3 (Apr. 18, 2012)

32. The specification of the ’158 Patent discloses plastic as an alternative material for the container:

> In certain non-limiting embodiments, the container or vessel includes, but is not limited to glass vials (for example, but not limited to, flint glass vials), ampoules, plastic flexible containers, for example, but not limited to, PVC (polyvinyl chloride) containers, VisIV™ plastic containers (Hospira, Inc., Lake Forest, Ill.) and CR3 elastomer copolyester ether containers (Hospira, Inc., Lake Forest, Ill.), CZ resin containers, poly propylene containers and syringes.

’158 Patent at 9:17-24.

33. No claims of the ’158 Patent cover a ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 μg/mL disposed within a sealed plastic container.

34. On February 6, 2018, the Honorable Richard G. Andrews of the United States District Court for the District of Delaware entered a final judgment in the action *Hospira, Inc. v. Amneal Pharmaceuticals LLC*, Civ. No. 1:15-cv-00697-RGA (the “Amneal Judgment”), invalidating claims 3 and 4 of the ’158 Patent for obviousness. Because claims 3 and 4 depend from claims 1 and/or 2, a Court would likewise properly find claims 1 and 2 also invalid.

The ’470 Patent

35. On its face the ’470 Patent, entitled “Dexmedetomidine Premix Formulation,” indicates it was issued by the U.S. Patent and Trademark Office on December 25, 2012. A copy of the ’470 Patent is attached as Exhibit C.

36. The ’470 Patent issued from application number 13/541,524 (the “’524 Application”).

37. According to records at the U.S. Patent and Trademark Office, Hospira is the assignee of the ’470 Patent.

38. The ’470 Patent contains seven claims.

39. The ’470 Patent contains one independent claim.

40. The independent claim of the ’470 patent recites “[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container.”

41. The ’470 Patent’s six dependent claims incorporate the limitations of the claims from which they depend. *See* 35 U.S.C. § 112(d). Thus, all claims of the ’470 Patent require “[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container.”

42. On August 17, 2012, the U.S. Patent and Trademark Office issued an office action rejecting all pending claims of the ’524 Application as obvious.

43. On September 17, 2012, Hospira responded to the rejection, arguing that using glass containers resulted in unexpectedly superior stability compared to using plastic containers. Response to Office Action, at 6 (Sept. 17, 2012) (arguing it was surprising that “a 4µg/mL premixture formulation stored in glass vials and ampoules maintained a higher level of potency after a 5 month storage period compared to storage in plastic, CR3, or PVC containers”); Decl. of Huailiang Wu, Ph.D., ¶ 13 (Sept. 17, 2012) (“[S]toring a ready to use formulation of dexmedetomidine at concentrations recited by the claims of the ’524 application in glass containers resulted in an unexpected reduction in potency loss of the composition compared to storage in plastic PVC containers.”).

44. On October 22, 2012, the U.S. Patent and Trademark Office issued a notice of allowance for the ’524 Application. In this notice, the examiner credits Hospira’s arguments that dexmedetomidine formulations stored in glass containers exhibit unexpectedly better stability than those stored in plastic. Notice of Allowance, ¶ 3 (Oct. 22, 2012) (crediting Hospira’s

argument that "the Specification demonstrates that a dexmedetomidine 4µg/mL formulation 'stored in glass vials and ampoules maintained a higher level of potency after a 5 month storage period compared to storage in plastic, CR3 or PVC containers,'" as well as "the Declaration of Huailang Wu provided by Applicants [which] provides further evidence of the surprising increase in stability of dexmedetomidine compositions (1, 10, 15 and 50 µg/ml) stored in sealed glass containers compared to storage in PVC bags.").

45. The specification of the '470 Patent discloses plastic as an alternative material for the container:

> In certain non-limiting embodiments, the container or vessel includes, but is not limited to glass vials (for example, but not limited to, flint glass vials), ampoules, plastic flexible containers, for example, but not limited to, PVC (polyvinyl chloride) containers, VisIV™ plastic containers (Hospira, Inc., Lake Forest, Ill.) and CR3 elastomer copolyester ether containers (Hospira, Inc., Lake Forest, Ill.), CZ resin containers, poly propylene containers and syringes.

'470 Patent at 9:22-29.

46. No claims of the '470 Patent cover a ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 µg/mL disposed within a sealed plastic container.

47. On February 6, 2018, the Honorable Richard G. Andrews of the United States District Court for the District of Delaware entered the Amneal Judgment, invalidating claim 4 of the '470 Patent for obviousness. Because claim 4 depends from claim 1, a Court would likewise properly find at least claim 1 also invalid.

The ’527 Patent

48. On its face the ’527 Patent, entitled “Methods of Treatment Using a Dexmedetomidine Premix Formulation,” indicates it was issued by the U.S. Patent and Trademark Office on June 4, 2013. A copy of the ’527 Patent is attached as Exhibit D.

49. The ’527 Patent issued from application number 13/678,148 (the “’148 Application”).

50. According to records at the U.S. Patent and Trademark Office, Hospira is the assignee of the ’527 Patent.

51. The ’527 Patent contains fifteen claims.

52. The ’527 Patent contains one independent claim.

53. The independent claim of the ’527 Patent recites a method of using “a ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container.”

54. The ’527 Patent’s fourteen dependent claims incorporate the limitations of the claims from which they depend. Thus, all claims of the ’527 Patent require “a ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container.”

55. In the November 15, 2012 Accelerated Examination Support Document, filed concomitantly with the ’148 Application, Hospira argues that using glass containers resulted in unexpectedly superior stability compared to using plastic containers. Accelerated Examination Support Document, at 46 (Nov. 15, 2012) (arguing that it was unexpected that “when stored in glass vials or ampoules, the ready to use liquid pharmaceutical composition maintained over 98% potency after 5 months,” but “when stored in plastic or PVC containers, which include plastic syringes and plastic bags, the potency was reduced by as much as 20% after only a two-week storage period.”).

56. On January 11, 2013, the U.S. Patent and Trademark Office issued a notice of allowance for the '148 Application. In this notice, the examiner "concur[red] with [Hospira's] detailed explanation of patentability as set forth at pages 44-73 of the Examination Support Document filed by [Hospira] on 11/15/2008 [*sic*, 2012]." Notice of Allowance, *supra*, ¶ 3.

57. The specification of the '527 Patent discloses plastic as an alternative material for the container:

> In certain non-limiting embodiments, the container or vessel includes, but is not limited to glass vials (for example, but not limited to, flint glass vials), ampoules, plastic flexible containers, for example, but not limited to, PVC (polyvinyl chloride) containers, VisIV™ plastic containers (Hospira, Inc., Lake Forest, Ill.) and CR3 elastomer copolyester ether containers (Hospira, Inc., Lake Forest, Ill.), CZ resin containers, poly propylene containers and syringes.

'527 Patent at 9:22-29.

58. No claims of the '527 Patent cover methods of using a ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 μg/mL disposed within a sealed plastic container.

59. On February 6, 2018, the Honorable Richard G. Andrews of the United States District Court for the District of Delaware entered the Amneal Judgment, invalidating claim 5 of the '527 Patent. Because claim 5 depends from claims 1, a Court would likewise properly find at least claim 1 also invalid.

BACKGROUND

60. In December 2003, Congress passed the Medicare Modernization Act of 2003 (the "MMA"). Title XI of that Act, entitled "Access to Affordable Pharmaceuticals," included a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of a patent listed in FDA's *Approved Drug Products with Therapeutic*

Equivalence Evaluations (commonly referred to as the Orange Book) if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

61. The MMA also added provisions for the forfeiture of eligibility for the 180-day exclusivity to which an ANDA "first applicant," as defined in 21 U.S.C. § 355(j)(5)(B)((iv)(II)(bb), might otherwise be entitled pursuant to the Hatch Waxman Act. *Id.* § 355 (j)(5)(D). The forfeiture provision at issue here requires, *inter alia*, the entry of a judgment of non-infringement, unenforceability or invalidity with respect to the patents to which a first applicant has filed a Paragraph IV certification, regardless of whether those patents are asserted against subsequent ANDA applicants. *Id.* § 355(j)(5)(D)(i)(I)(bb).

62. Upon information and belief, Hospira, Inc. is the current holder of approved New Drug Application ("NDA") No. 21-038 for Precedex® Injection (dexmedetomidine HCl), 200 mcg base/50 mL and 400 mcg base/100 mL.

63. Hospira identified the Patents-in-Suit to the FDA for listing in the Orange Book, as patents to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" products containing dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL ("Dexmedetomidine Product").

64. The Patents-in-Suit remain listed in the Orange Book with respect to NDA No. 21-038 and Hospira maintains and continues to represent to the public that the Patents-in-Suit claim the drug approved in NDA 21-038 or a method of using that drug, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant who attempts to market a generic version of the drug prior to the delisting of the Patents-in-Suit. The FDA Orange Book also lists a six-month pediatric exclusivity for each of the Patents-in-Suit,

which upon information and belief will prevent ANDA applicants from obtaining final FDA marketing approval for their generic dexmedetomidine products until six months after the expiration of the Patents-in-Suit.

65. According to Orange Book listings, Precedex®, or treatments using Precedex® are claimed in the Patents-in-Suit.

66. Celerity Pharmaceuticals, LLC ("Celerity") submitted and later transferred to Baxter ANDA No. 208532 for a proposed drug product containing dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL. Baxter's ANDA seeks FDA approval for the commercial manufacture, use, importation, offer for sale and sale of generic dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL.

67. In ANDA No. 208532 Baxter/Celerity filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") certifying that the '158 Patent, the '470 Patent, and the '527 Patent (collectively, the "Paragraph IV Patents") will not be infringed by the manufacture, use, or sale of the Baxter's ANDA Product.

68. In ANDA No. 208532 Baxter/Celerity included a statement pursuant to 21 U.S.C. § 505(j)(2)(A)(viii) and 21 C.F.R. § 314.94(a)(12)(iii)(A) ("Section viii Carve-out") that the method of use recited in the '867 patent does not claim any indication for which Baxter's ANDA seeks approval. Under 21 U.S.C. § 505(j)(2)(A)(viii), a statement pursuant to that section—in lieu of a certification—is appropriate if the listed method of use patent "does not claim a use for which the [ANDA] applicant is seeking approval. . . ." *Id.*

69. In accordance with 35 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Baxter/Celerity, on or about June 6, 2016, served Hospira with a Notice Letter informing Hospira of Baxter's ANDA seeking approval to engage in the commercial manufacture, use,

importation, offer for sale, or sale of Baxter's ANDA Product before the expiration of the Patents-in-Suit. Celerity's Notice Letter included a Paragraph IV certification that the Paragraph IV Patents would not be infringed by the manufacture, use, or sale of the product covered by the ANDA because Baxter's ANDA Product is provided in a plastic container rather than a "sealed glass container," as claimed in the Paragraph IV Patents.

70. Celerity's June 6, 2016 notice letter further informed Hospira that Baxter's ANDA Product does not infringe the '867 Patent because of the Section viii Carve-out.

71. Baxter desires to bring its generic dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL to market and to allow the public to enjoy the benefits of generic competition for these products at the earliest possible date under the applicable statutory and FDA regulatory provisions.

72. On January 25, 2018, FDA issued a letter tentatively approving Baxter's ANDA No. 208532. As stated in that letter, FDA's approval of ANDA No. 208532 was tentative rather than final on the basis of a first applicant's continued eligibility for 180-day exclusivity. But for a first applicant's continued eligibility for 180-day exclusivity, FDA would have finally approved ANDA No. 208532, thus permitting the immediate marketing of the Baxter ANDA Product.

73. On information and belief, the earliest possible date that Baxter can currently obtain final FDA marketing approval for the Baxter ANDA Product is upon the expiration of the Paragraph IV Patents and any applicable pediatric exclusivity. Unless a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the Patents-in-Suit are invalid or not infringed, Baxter

may not be able to begin marketing the Baxter ANDA Product until the expiration of the Paragraph IV Patents and any applicable pediatric exclusivity.

74. Prior to Baxter/Celerity filing ANDA No. 208532, other ANDA applicants filed ANDAs for dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL containing Paragraph IV certifications to the Patents-in-Suit challenging, *inter alia*, the validity of the Patents-in-Suit. For example, Hospira filed a patent infringement suit in this District against Amneal Pharmaceuticals, Inc.—one of the generic manufacturers to have filed Paragraph IV statements before Baxter/Celerity in this District for patent infringement—alleging that Amneal infringed the Paragraph IV Patents. Hospira did not assert the ’867 Patent against Amneal in that lawsuit. Amneal failed in its Paragraph IV challenge to noninfringement of the ’106 Patent.

75. Because Amneal failed in its attempt to have all claims of the Patents-in-Suit held invalid or otherwise prevail, Amneal’s Paragraph IV certification with respect to the ’106 patent should convert to a Paragraph III certification, which requires Amneal to wait until 2032, when the ’106 patent and any applicable pediatric exclusivity expire, before it can market its generic dexmedetomidine HCl products.

76. On the basis of FDA’s tentative approval letter of January 25, 2018, a first applicant retains eligibility for 180-day generic exclusivity for dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL by virtue of a first applicant’s Paragraph IV certification to one or more of the Patents-in-Suit. Presently, unless a first applicant triggers the running of the 180-day exclusivity period by obtaining approval and initiating marketing, the FDA will be statutorily prohibited from granting final approval of Baxter’s ANDA Product until the expiration of the Patents-in-Suit and any applicable pediatric exclusivity in 2032. Such a scenario can be prevented if a court enters a final decision from which no appeal (other than a

petition to the Supreme Court for a writ of certiorari) has been or can be taken that the Patents-in-Suit are invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

77. Unless the Court declares the Patents-in-Suit invalid, unenforceable or not infringed by Baxter's ANDA Product, Baxter will be prohibited from selling its product until a first applicant eventually obtains approval of its ANDA, initiates marketing, and 180 days have expired thereby injuring Baxter by depriving it of sales revenue for that period of time and injuring the public by depriving the public of the benefit of the generic competition that would otherwise be provided by Baxter's ANDA product. If a first applicant fails to obtain approval of its ANDA, or for some other reason fails to initiate marketing, Baxter may be forced to wait until 2032 to market its product, thereby greatly prolonging the period of injury to Baxter and the public.

78. On information and belief, no court has entered the "final decision" identified in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) with respect to the Patents-in-Suit. Upon information and belief, no court has entered a final decision from which an appeal has been or can be taken that all claims of the Patents-in-Suit are invalid or not infringed. However, the Amneal Judgment invalidated claims 3 and 4 of the '158 Patent, claim 4 of the '470 Patent, and claim 5 of the '527 Patent. Because the issues of invalidity of each of those claims are substantially identical to issues of invalidity of the remaining claims in each of those patents, Hospira is collaterally estopped from arguing that all claims of the '158, '470, and '527 Patents are not invalid.

79. On information and belief, no court has signed a "settlement order or consent decree" identified in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) that enters final judgment which includes a finding that the Patents-in-Suit are invalid or not infringed.

COUNT ONE:
Declaratory Judgment of Noninfringement of the '867 Patent

80. Baxter repeats and realleges each and every allegation set forth in the foregoing paragraphs, as though fully set forth herein.

81. Because every claim of the '867 Patent requires practicing "[a] method of sedating a patient in an intensive care unit," and the tentatively approved label for the Baxter ANDA Product does not contain an indication for such use, the claims of the '867 Patent will not be infringed by Baxter's manufacture, marketing, use, offer for sale, sale and/or importation of the Baxter ANDA Product.

82. There is a substantial and continuing controversy between Baxter on the one hand and Hospira and Orion on the other, and a declaration of rights is both necessary and appropriate to establish that Baxter does not infringe any valid or enforceable claim of the '867 Patent and allow Baxter to bring the Baxter ANDA Product to market.

83. But for Hospira's decision to list the Patents-in-Suit in the Orange Book, FDA approval of Baxter's ANDA No. 208352 would not have been delayed by those patents. Baxter is being injured by Hospira's actions of requesting the FDA to list the Patents-in-Suit in the Orange Book and continuing said listing in the Orange Book.

84. Baxter's injury can be redressed by the requested relief: declaratory judgment of non-infringement of the Patents-in-Suit would necessitate a first applicant initiating marketing within 75 days or risk forfeiting its eligibility for 180-day exclusivity, which currently blocks final FDA marketing approval of Baxter's ANDA. Because approval of Baxter's ANDA No. 208532 is blocked by a first applicant's eligibility for 180-day exclusivity, Baxter will be monetarily harmed, as it will lose sales of the Baxter ANDA Product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory

provisions, and will be deprived of an economic opportunity to compete in the market for dexmedetomidine hydrochloride in 0.9% sodium chloride injection, 200 mcg/50 mL and 400 mcg/100 mL single-dose containers.

COUNT TWO:
Declaratory Judgment of Noninfringement of the ’158 Patent

85. Baxter repeats and realleges each and every allegation set forth in the foregoing paragraphs, as though fully set forth herein.

86. Because every claim of the ’158 Patent requires “[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container” and the tentatively approved Baxter ANDA Product is not disposed within a sealed glass container, the claims of the ’158 Patent will not be infringed by the manufacture, marketing, use, offer for sale, sale and/or importation of the Baxter ANDA Product.

87. Because Hospira amended its claims by adding the limitation that the sealed container be made of glass to overcome a rejection made during the prosecution of the ’158 Patent, the doctrine of prosecution history estoppel prevents Hospira from asserting that the Baxter ANDA Product infringes the ’158 Patent’s claims under the doctrine of equivalents.

88. Because Hospira argued during the prosecution of the ’158 Patent that disposing the composition in a glass container provided surprising and unexpected results over plastic containers, the doctrine of prosecution history estoppel prevents Hospira from asserting that the Baxter ANDA Product infringes the ’158 Patent’s claims under the doctrine of equivalents.

89. Because the ’158 Patent discloses plastic as an alternate material for the container but only claims glass containers, the Baxter ANDA Product cannot infringe the ’158 Patent’s claims under the doctrine of equivalents pursuant to the disclosure-dedication rule.

90. There is a substantial and continuing controversy between Baxter and Hospira and

a declaration of rights is both necessary and appropriate to establish that Baxter does not infringe any valid or enforceable claim of the ’158 Patent and allow Baxter to bring the Baxter ANDA Product to market.

91. But for Hospira’s decision to list the Patents-in-Suit in the Orange Book, FDA approval of Baxter’s ANDA would not have been delayed by those patents. Baxter is being injured by Hospira’s actions of requesting the FDA to list the Patents-in-Suit in the Orange Book and continuing said listing in the Orange Book.

92. Baxter’s injury can be redressed by the requested relief: a declaratory judgment of non-infringement of the Patents-in-Suit would necessitate a first applicant initiating marketing within 75 days or risk forfeiting its eligibility for 180-day exclusivity, which currently blocks final FDA marketing approval of Baxter’s ANDA. Because approval of Baxter’s ANDA No. 208532 is blocked by a first applicant’s eligibility for 180-day exclusivity, Baxter will be monetarily harmed, as it will lose sales of the Baxter ANDA Product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and will be deprived of an economic opportunity to compete in the market for dexmedetomidine hydrochloride in 0.9% sodium chloride injection, 200 mcg/50 mL and 400 mcg/100 mL single-dose containers.

COUNT THREE:
Declaratory Judgment of Noninfringement of the ’470 Patent

93. Baxter repeats and realleges each and every allegation set forth in the foregoing paragraphs, as though fully set forth herein.

94. Because every claim of the ’470 Patent requires “[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container” and the tentatively approved Baxter ANDA Product is not disposed within a sealed glass container, the claims of the

’470 Patent will not be infringed by the manufacture, marketing, use, offer for sale, sale and/or importation of the Baxter ANDA Product.

95. Because Hospira argued during the prosecution of the ’470 Patent that disposing the composition in a glass container provided surprising and unexpected results over plastic containers, the doctrine of prosecution history estoppel prevents Hospira from asserting that the Baxter ANDA Product infringes the ’470 Patent’s claims under the doctrine of equivalents.

96. Because the ’470 Patent discloses plastic as an alternate material for the container but only claims glass containers, the Baxter ANDA Product cannot infringe the ’470 Patent’s claims under the doctrine of equivalents pursuant to the disclosure-dedication rule.

97. There is a substantial and continuing controversy between Baxter and Hospira and a declaration of rights is both necessary and appropriate to establish that Baxter does not infringe any valid or enforceable claim of the ’470 Patent and allow Baxter to bring the Baxter ANDA Product to market.

98. But for Hospira’s decision to list the Patents-in-Suit in the Orange Book, FDA approval of Baxter’s ANDA would not have been delayed by those patents. Baxter is being injured by Hospira’s actions of requesting the FDA to list the Patents-in-Suit in the Orange Book and continuing said listing in the Orange Book.

99. Baxter’s injury can be redressed by the requested relief: declaratory judgment of non-infringement of the Patents-in-Suit would necessitate a first applicant initiating marketing within 75 days or risk forfeiting its eligibility for 180-day exclusivity, which currently blocks final FDA marketing approval of Baxter’s ANDA. Because approval of Baxter’s ANDA No. 208532 is blocked by a first applicant’s eligibility for 180-day exclusivity, Baxter will be monetarily harmed, as it will lose sales of the Baxter ANDA Product by virtue of not being able

to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and will be deprived of an economic opportunity to compete in the market for dexmedetomidine hydrochloride in 0.9% sodium chloride injection, 200 mcg/50 mL and 400 mcg/100 mL single-dose containers.

COUNT FOUR:
Declaratory Judgment of Noninfringement of the '527 Patent

100. Baxter repeats and realleges each and every allegation set forth in the foregoing paragraphs, as though fully set forth herein.

101. Because every claim of the '527 Patent requires "[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container" and the tentatively approved Baxter ANDA Product is not disposed within a sealed glass container, the claims of the '527 Patent will not be infringed by the manufacture, marketing, use, offer for sale, sale and/or importation of the Baxter ANDA Product.

102. Because Hospira argued during the prosecution of the '527 Patent that disposing the composition in a glass container provided surprising and unexpected results over plastic containers, the doctrine of prosecution history estoppel prevents Hospira from asserting that Baxter's ANDA Product infringes the '527 Patent's claims under the doctrine of equivalents.

103. Because the '527 Patent discloses plastic as an alternate material for the container but only claims glass containers, the Baxter ANDA Product cannot infringe the '527 Patent's claims under the doctrine of equivalents pursuant to the disclosure-dedication rule.

104. There is a substantial and continuing controversy between Baxter and Hospira and a declaration of rights is both necessary and appropriate to establish that Baxter does not infringe any valid or enforceable claim of the '527 Patent and allow Baxter to bring the Baxter ANDA Product to market.

105. But for Hospira's decision to list the Patents-in-Suit in the Orange Book, FDA approval of Baxter's ANDA would not have been delayed by those patents. Baxter is being injured by Hospira's actions of requesting the FDA to list the Patents-in-Suit in the Orange Book and continuing said listing in the Orange Book.

106. Baxter's injury can be redressed by the requested relief: a declaratory judgment of non-infringement of the Patents-in-Suit would necessitate a first applicant initiating marketing within 75 days or risk forfeiting its eligibility for 180-day exclusivity, which currently blocks final FDA marketing approval of Baxter's ANDA. Because approval of Baxter's ANDA No. 208532 is blocked by a first applicant's eligibility for 180-day exclusivity, Baxter will be monetarily harmed, as it will lose sales of the Baxter ANDA Product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and will be deprived of an economic opportunity to compete in the market for dexmedetomidine hydrochloride in 0.9% sodium chloride injection, 200 mcg/50 mL and 400 mcg/100 mL single-dose containers.

PRAYER FOR RELIEF

WHEREFORE, Baxter Healthcare Corporation respectfully requests that this Court enter judgment as follows:

1. Declaring that the manufacture, marketing, use, offer for sale, sale, and/or importation of the Baxter ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe or induce or contribute to the infringement by others of any claims of the Patents-in-Suit;

2. Declaring that the U.S. Food and Drug Administration may approve Baxter's Abbreviated New Drug Application (No. 208532) concerning dexmedetomidine hydrochloride in

0.9% sodium chloride injection, 200 mcg/50 mL and 400 mcg/100 mL single-dose, without awaiting any further order, judgment, or decree of this Court; and that the judgment entered in this case is a judgment reflecting a decision that the Patents-in-Suit are not infringed pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii)(I)(aa);

3. Awarding Baxter its costs, expenses, and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

4. Awarding Baxter such other and further relief as the Court may deem just and proper.

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Dated: February 22, 2018
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