IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXTER HEALTHCARE CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-303-RGA
	)	
HOSPIRA, INC. and ORION CORP.,	)	
	)	
Defendants.	)	

OPPOSITION TO MOTION FOR EXTENSION OF TIME

Plaintiff Baxter Healthcare Corporation ("Baxter"), by counsel, submits this Opposition to Motion for a Fourteen (14) Day Extension of Time to Answer, Move or Otherwise Respond to Complaint ("Extension Motion") filed by Hospira, Inc. ("Hospira"). While normally Baxter would readily consent to reasonable extensions of time, the circumstances of this case are unique, and a denial of Hospira's Extension Motion is warranted for three reasons. First, Hospira has been aware of the facts and legal principles surrounding this dispute for nearly two years. Second, Hospira has litigated similar disputes against other parties in numerous courts. Third, Baxter's case for noninfringement is exceptionally strong, and this case implicates a failure of the Hatch-Waxman regime that only prompt judicial relief can correct. Accordingly, Baxter respectfully requests that the Court deny Hospira's Extension Motion.

NATURE OF THE CASE & PROCEDURAL HISTORY

This case raises a unique and time-sensitive issue, the resolution of which is crucial for mitigating harm to both Baxter and the public. Hospira is the assignee or co-assignee of four United States patents at issue in this case: 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"). The '867 Patent requires "[a] method of sedating a patient in an intensive

care unit . . . wherein the patient remains orientated and arousable," while the '158 Patent, '470 Patent, and '527 Patent each require "[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed glass container."

Hospira identified the Patents-in-Suit to the Food and Drug Administration ("FDA") for listing in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). By doing so, Hospira stated that the Patents-in-Suit were ones in 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. The Patents-in-Suit remain listed in the Orange Book with respect to Hospira's New Drug Application ("NDA") No. 21-038 for Precedex® Injection (dexmedetomidine HCl), 200 mcg base/50 mL and 400 mcg base/100 mL.

In April 2016, Celerity Pharmaceuticals, LLC submitted and later transferred to Baxter Abbreviated New Drug Application ("ANDA") No. 208532 for a proposed drug product containing dexmedetomidine HCl, 200 mcg base/50 mL and 400 mcg base/100 mL (the "Baxter ANDA Product"). Baxter's ANDA seeks FDA approval for the commercial manufacture, use, importation, offer for sale and sale of the Baxter ANDA Product. Baxter seeks to bring its product to market at the earliest possible date under the applicable statutes and FDA regulations to allow the public to enjoy the benefits of generic competition for these products.[1]

In accordance with Title XI of the Medicare Modernization Act of 2003, Baxter 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

[1] In addition, the Baxter ANDA Product provides greatly improved convenience of use for clinicians because it is packaged in a flexible plastic IV container rather than a glass vial.

Patents") will not be infringed by the manufacture, use, or sale of the Baxter's ANDA Product. In particular, Baxter's ANDA Product does not use a sealed glass container. Similarly, Baxter 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. Baxter's ANDA does not seek approval of a label including a method of sedating a patient in an intensive care unit wherein the patient remains orientated and arousable.

On June 6, 2016, Baxter served Hospira with a Notice Letter informing Hospira of Baxter's ANDA seeking approval to manufacture and market Baxter's ANDA Product before the expiration of the Patents-in-Suit. As required by statute, this letter explained the basis for Baxter's Paragraph IV Certification and Section viii Carve-out. Hospira had 45 days to sue Baxter for infringement upon receipt of the letter, but elected not to file suit.[2]

On January 25, 2018, the FDA tentatively approved Baxter's ANDA No. 208532. As stated in the FDA's tentative approval letter, the approval of ANDA No. 208532 was tentative rather than final because of a first applicant's continued eligibility for 180-day exclusivity. But for that eligibility, the FDA would have finally approved Baxter's ANDA, permitting the immediate marketing of the Baxter ANDA Product. 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 finally approving Baxter's ANDA Product until 2032, when the Patents-in-Suit and any applicable pediatric exclusivity expire. This delay can be prevented if a court enters a final decision from which no appeal (other than a petition to the Supreme Court for

[2] Baxter has also timely amended its ANDA and provided notice to Hospira as additional, newly issued patents were added to the Orange Book while the ANDA has been pending.

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). No court has yet entered final judgment that includes a finding that the Patents-in-Suit are invalid or not infringed.

On February 22, 2018, Baxter filed its Complaint for Declaratory Judgment seeking a declaration of noninfringement of the Patents-in-Suit. (D.I. 1.) Hospira was served with the Complaint on February 23, 2018. (D.I. 5.) Accordingly, Hospira's responsive pleading is currently due on or before March 16, 2018. Fed. R. Civ. P. 12(a)(i).

On March 16, 2018, Hospira filed a Motion for Extension of Time (D.I. 7.), requesting this Court to extend Hospira's time for filing a responsive pleading to the Complaint by 14 days, until April 2, 2018.

ARGUMENT

Baxter opposes the extension of time for three primary reasons: (1) Hospira has been on notice of the issues in this case since it received multiple notice letters from Baxter beginning in June 2016; (2) Hospira has engaged in extensive litigation with similar plaintiffs regarding infringement of the Patents-in-Suit; and (3) Baxter and the public are suffering irreparable harm from Baxter's inability to bring the Baxter ANDA Product to market. Therefore, there is no good cause under Federal Rule of Civil Procedure 6(b)(1)(A) to delay the responsive pleading deadline.

First, this lawsuit should come as no surprise to Hospira, which has been on notice of Baxter's position regarding noninfringement since June 2016. In accordance with Title XI of the Medicare Modernization Act of 2003, Baxter, as an ANDA applicant, is permitted to bring a declaratory judgment action for noninfringement of a patent listed in 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). Baxter provided Hospira with its Paragraph IV Certification and Section viii Carve-out notice on June 6, 2016. Hospira had 45 days to file suit and challenge Baxter's ANDA for infringement. During this time period, Hospira had an opportunity to examine the Patents-in-Suit and Baxter's ANDA Product in-depth. Hospira gained familiarity with the underlying law and facts of this suit and, following its review, elected not to sue Baxter. Accordingly, Hospira has been on notice of the core facts and legal arguments in this case since June 2016, and should not require any additional time to respond.

Second, none of Baxter's noninfringement positions are novel or surprising in view of Hospira's prior litigation experience involving alleged infringement of the '867 Patent and dexmedetomidine premix products packaged in plastic containers. *See, e.g., Hospira, Inc. et al. v. Eurohealth S.A.R.L. et al.*, C.A. No. 14-1008 (D. Del.); *Hospira Inc. & Orion Corp. v. Sandoz Int'l GmbH, et al.*, Civ. No. 09-00665 (D. Del.); *Hospira, Inc. & Orion Corp. v. Aurobindo Pharma Ltd., et al.*, Civ. No. 14-00486 (D. Del.); *Hospira, Inc. & Orion Corp. v. Ben Venue Labs, Inc.*, Civ. No. 14-00487 (D. Del.); *Hospira & Orion Corp. v. Actavis LLC et al.*, Civ. No. 14-00488 (D. Del.); *Hospira, Inc. & Orion Corp. v. Ben Venue Labs, Inc., et al.*, Civ. No. 14-1008 (D. Del.); *Hospira, Inc. & Orion Corp. v. Sandoz Int'l GmbH & Sandoz, Inc.*, C.A. No. 09-4591-MLC (D.N.J.). Hospira is extremely familiar with the Patents-in-Suit – more so than Baxter – and should be able to timely respond to a lawsuit that is substantively similar to its past and current litigation.

Third, Baxter has a strong case for noninfringement, and will suffer irreparable harm unless the Court provides prompt judicial relief. Specifically, with respect to the '158 Patent, '470 Patent, and '527 Patent, the Baxter ANDA Product does not infringe because these Patents each require "[a] ready to use liquid pharmaceutical composition . . . disposed within a sealed

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