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 14-Day Extension of Time to File Response to Plaintiff's Motion for Judgment on the Pleadings ("Extension Motion") filed by Hospira, Inc. and Orion Corp. (collectively, "Hospira"). The Court should deny Hospira's Extension Motion for two reasons. First, Baxter would be prejudiced by any extension because time is of the essence due to the expiry of United States Patent No. 6,716,867 on March 31, 2019. Second, Baxter's Motion for Judgment on the Pleadings does not raise complex issues of fact or law that require extensive analysis, and Hospira is already familiar with the applicable legal standards given its extensive litigation of this patent in other cases. Accordingly, Baxter respectfully requests that the Court deny Hospira's Extension Motion.

NATURE OF THE CASE & PROCEDURAL POSTURE

This case raises a time-sensitive issue, the resolution of which is crucial for mitigating harm to Baxter. Baxter is the current holder of Abbreviated New Drug Application ("ANDA") No. 208532 for a proposed drug product containing dexmedetomidine hydrochloride in 0.9% sodium chloride injection, 200 mcg/50 mL and 400 mcg/100 mL (the "Baxter ANDA Product"). The Food and Drug Administration ("FDA") tentatively approved ANDA No. 208532 on

January 25, 2018, but withheld final approval because of a first applicant's continued eligibility for 180-day exclusivity. Unless the first applicant either forfeits its exclusivity or makes use of the 180-day exclusivity period by obtaining approval and initiating marketing, the FDA will be prohibited from finally approving Baxter's ANDA Product until 2032, when the last of the relevant patents owned by Hospira and applicable pediatric exclusivity expire. This delay can be prevented if a court enters final judgment of noninfringement from which no appeal, other than a petition for writ of certiorari to the Supreme Court, is or can be taken on all four of the patents at issue in this case: 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").

Baxter filed this declaratory judgment lawsuit on February 22, 2018, less than a month after the FDA tentatively approved ANDA No. 208532. (D.I. 1.) After requesting a 14-day extension of time to answer the complaint (D.I. 7), only four days of which this Court granted (D.I. 9), Hospira filed its answer on March 20, 2018 (D.I. 10). In its answer, Hospira admitted that Baxter did not infringe any claim of the '158 Patent, '470 Patent, and '527 Patent that requires a "sealed glass container" because the Baxter ANDA Product is disposed in a plastic container. (D.I. 10, ¶¶ 33, 46, 58, 87-89, 95-96, 102-103.) Hospira further represented to the Court in the jointly filed Proposed Scheduling Order (D.I. 18) and its Extension Motion (D.I. 19, ¶ 6) that it is not asserting the '158 Patent, '470 Patent, and '527 Patent. As such, three of the four patents are not at issue, and the Court can easily—and should—grant judgment as a matter of law with respect to those patents.

In conjunction with its answer, Hospira filed a counterclaim against Baxter for infringement of the '867 Patent.[1] (D.I. 10.) Baxter answered the counterclaim on April 10, 2018. (D.I. 14.) On April 24, 2018, Baxter filed its Motion for Judgment on the Pleadings. (D.I. 16.) Hospira's answering brief is currently due on May 8, 2018. *See* Local Rule 7.1.2(b).

On April 30, 2018, Hospira filed a Motion for Extension for Time (D.I. 19), requesting that this Court extend its time for filing the answering brief by 14 days, until May 22, 2018.

ARGUMENT

Baxter opposes the requested extension of time for two primary reasons: (1) an extension of time prejudices Baxter because time is of the essence due to expiry of the '867 Patent on March 31, 2019; and (2) Baxter's Motion for Judgment on the Pleadings does not raise novel or complex issues of fact or law, and Hospira is familiar with the relevant legal standards given its litigation of this patent in other cases. Therefore, good cause under Federal Rule of Civil Procedure 6(b)(1)(A) does not exist in this case.

A. Time is of the Essence because the '867 Patent Expires on March 31, 2019.

First, granting an extension of time would prejudice Baxter because Baxter must obtain a final non-appealable judgment of non-infringement of the '867 Patent before January 11, 2019. Otherwise, even with a favorable decision on the other three patents, FDA may be precluded from approving Baxter's ANDA until 2020.

After the '867 Patent expires on March 31, 2019, a six-month pediatric exclusivity period extends until October 1, 2019, during which FDA may not approve ANDAs for generic dexmedetomidine hydrochloride without a waiver from Hospira. Upon patent expiry, this Court

[1] The '867 Patent expires on March 31, 2019, with a pediatric exclusivity period starting upon patent expiry and extending until October 1, 2019.

will no longer be able to issue a judgment of noninfringement, while at the same time, the pediatric exclusivity period starts. Thus, absent a final non-appealable judgment before the '867 patent expires, Baxter must endure the six-month pediatric exclusivity period without means for judicial relief. Moreover, to the extent the first applicant finally markets its product, possibly starting at the very end of the pediatric exclusivity period, Baxter will be subject to an additional 180-day delay while the first applicant exercises its exclusive marketing right.

To avoid this delay, Baxter must obtain a judgment of noninfringement not only from this Court but also from the U.S. Court of Appeals for the Federal Circuit before expiry of the '867 Patent. Only a final judgment from which *no appeal* (other than a petition to the Supreme Court for a writ of certiorari) is or can be taken will enable FDA to grant final approval of Baxter's ANDA. As a practical matter, such judgment must be rendered no later than January 11, 2019, because a first applicant has 75 days after final judgment to launch or forfeit its exclusivity, and Baxter must still obtain final approval from FDA. Thus, Baxter has less than eight months to obtain a final judgment of noninfringement. This underscores why Baxter submitted expedited dates in its Proposed Scheduling Order.

Indeed, Baxter has litigated this case expeditiously from its inception. Contrary to Hospira's assertion (D.I. 19, ¶ 3), Baxter did not delay in bringing its declaratory judgment action. Baxter's ANDA was not tentatively approved by FDA until January 25, 2018. On that date Baxter expected to receive full FDA approval of its ANDA, because of the first applicant's apparent forfeiture of exclusivity for failure to obtain tentative approval within 30 months after submitting its ANDA. As such, there was no apparent need for this suit until January 25, 2018. Moreover, filing suit against Hospira before receiving tentative approval would likely have raised ripeness concerns (or at least a protest from Hospira). Baxter filed this declaratory

judgment lawsuit on February 22, 2018, less than one month after it received tentative approval. (D.I. 1.) On April 24, 2018, Baxter moved for judgment on the pleadings.[2] Thus, Baxter's actions have not been dilatory, and indeed Baxter has prosecuted this case with a sense of urgency while Hospira has now sought extensions for both of its responsive filings. (*See* D.I. 7 (requesting a 14-day extension of time to answer the complaint); D.I. 19 (requesting a 14-day extension of time to file a responsive brief to Baxter's Motion for Judgment on the Pleadings).)

Therefore, the Court should deny Hospira's Extension Motion because any delay would prejudice Baxter and thwart the purposes of the Hatch-Waxman provisions of the Food, Drug, and Cosmetic Act, one of which is that a section viii statement regarding a method-of-use patent should not delay approval of a generic drug because a section viii statement, with corresponding carved-out labeling, is plain and satisfactory evidence that there is no intent to infringe that patent. While Hospira asserts that the '867 Patent does not affect whether Baxter can receive final FDA approval to launch its product (D.I. 19, ¶ 6), this argument misses the point. FDA cannot finally approve Baxter's ANDA because a first applicant included a Paragraph IV certification as to the '867 Patent in its application. Therefore, without a final judgment that Baxter does not infringe the '867 Patent, FDA cannot approve Baxter's ANDA because a first filer has not triggered its period of exclusivity. Only after a final judgment of noninfringement on *all* the Patents-in-Suit forces the first applicant to either market its product or forfeit its exclusivity can FDA approve Baxter's ANDA.

[2] Hospira asserts that Baxter took over five weeks to respond to the counterclaim and file its motion. (D.I. 19, ¶ 4.) This wording is deceptive. Hospira filed its answer and counterclaim on March 20, 2018, and Baxter filed its answer to the counterclaim on April 10, 2018—within the prescribed 21-day response time. Baxter then filed its Motion for Judgment on the Pleadings on April 24, 2018—14 days later. Thus, Baxter filed its actual motion only two weeks after the pleadings closed.

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