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.	)	

BAXTER'S MOTION FOR REARGUMENT OF THE SCHEDULING ORDER

I. INTRODUCTION

Plaintiff Baxter Healthcare Corporation ("Baxter"), by counsel, submits this Motion for Reargument of the Scheduling Order pursuant to Local Rule 7.1.5. Baxter requests that the Court reconsider its prohibition on dispositive motions and its summary denial of Baxter's Motion for Judgment on the Pleadings ("Judgment Motion"). (D.I. 21, ¶ 12.) This case presents a unique situation where litigating all four patents-in-suit through trial would be unjust to Baxter, and result in an inefficient allocation of the parties' and Court's resources.

For three of the four patents-in-suit, Baxter seeks a declaration of noninfringement, and Hospira, Inc. ("Hospira") and Orion Corp. (collectively, "Defendants") have NOT counterclaimed for infringement. With respect to these patents, Defendants' admissions in their answer are sufficient for the Court to grant judgment as a matter of law to Baxter and streamline the issues for discovery, claim construction, and trial. Moreover, through respective litigation counsel, Defendants have signaled their agreement that Baxter does not infringe these patents.

The sole remaining patent claims a method of use that Baxter's Abbreviated New Drug Application ("ANDA") No. 208532 carves out. Notably, Defendants have not asserted this patent

against any other ANDA filer that carved out this use. Baxter's carve out makes this issue amenable to judgment on the pleadings.

Defendants declined to sue Baxter for infringement when Baxter served its Paragraph IV Certification notices. However, the Food and Drug Administration ("FDA") unexpectedly only tentatively approved Baxter's ANDA, and Baxter now needs a declaration of noninfringement on all patents-in-suit to obtain final FDA approval. Despite lacking a colorable case of infringement, Defendants seek to prolong this case to preserve the status quo monopoly. Accordingly, Baxter respectfully requests that the Court reconsider the Judgment Motion to avoid injustice.

Alternatively, Baxter requests revision of the Scheduling Order to provide for trial in late 2018.[1] A 2018 trial is feasible and appropriate given the lack of disputed facts, limited need for discovery and claim construction, and preclusion of dispositive motions. Baxter appreciates the Court's adoption of a May 3, 2019 trial date, but the ban on dispositive motions forecloses any opportunity for Baxter to obtain a final judgment of noninfringement before expiry of the only contested patent in this case. Without final judgment, FDA is effectively precluded from finally approving Baxter's ANDA until at least late 2019 and perhaps considerably longer. Thus, a 2018 trial date is necessary to avoid manifest injustice.

II. NATURE OF THE CASE & PROCEDURAL POSTURE

Baxter is the holder of 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 Baxter ANDA Product is a generic form of Precedex®, Hospira's dexmedetomidine hydrochloride product. Hospira listed four patents relevant to this case in FDA's Orange Book: U.S. Patent Nos. 6,716,867 ("'867 Patent"), 8,242,158

[1] A Proposed Revised Scheduling Order is attached at Exhibit A for the Court's consideration.

("'158 Patent"), 8,338,470 ("'470 Patent"), and 8,455,527 ("'527 Patent") (collectively, "the Patents-in-Suit"). The '867 Patent expires on March 31, 2019, and the '158 Patent, '470 Patent, and '527 Patent (collectively, the "Glass Patents") expire on January 4, 2032. Each patent is subject to a six-month pediatric exclusivity period following expiration.

FDA tentatively approved Baxter's ANDA on January 22, 2018, but withheld final approval because of a first applicant's eligibility for 180-day generic drug exclusivity. Unless the first applicant triggers the running of its exclusivity period, FDA is presently prohibited from finally approving Baxter's ANDA Product until 2032, when the last of the Patents-in-Suit and any pediatric exclusivity expire. Baxter can avoid this result only by obtaining a final judgment of noninfringement on *all* patents asserted in the first applicant's ANDA.

Baxter filed this lawsuit seeking declaratory judgment of noninfringement on February 22, 2018, exactly one month after FDA tentatively approved Baxter's ANDA. (D.I. 1.) Defendants admitted in their answer and subsequent submissions to this Court that the Baxter ANDA Product does not infringe the Glass Patents. (D.I. 10, ¶¶ 33, 46, 58, 87-89, 95-96, 102-103; D.I. 18; D.I. 19.) The parties are discussing entry of a consent judgment on these patents, but no agreement has yet been reached.

On April 24, 2018, Baxter filed its Judgment Motion. (D.I. 16.) Before Defendants' opposition to the Judgment Motion was due, the Court entered a Scheduling Order prohibiting dispositive motions. (D.I. 21, ¶ 12.) In the Scheduling Order, the Court wrote that Baxter's "Motion for Judgment on the Pleadings (D.I. 16) is DENIED." (*Id.*) Trial is set for May 3, 2019 (*id.*, ¶ 14), which is over a month *after* the key patent in this case expires.

III. LEGAL STANDARD

Reargument is appropriate where the Court has "patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension." *Brambles USA, Inc. v. Blocker*, 735 F. Supp. 1239, 1241 (D. Del. 1990). The Court should grant a motion for reargument without hesitation when "compelled to prevent manifest injustice or to correct clear error." *Id.*; *see Max's Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999); Fed. R. Civ. P. 59(e).

IV. ARGUMENT

Reconsideration of the Scheduling Order is necessary to avoid manifest injustice for at least two reasons. First, the ban on dispositive motions forces Baxter to litigate three patents in which Defendants admit there is no infringement. Such an outcome unjustly delays Baxter's relief, and results in an inefficient allocation of time and resources to litigate uncontested allegations of noninfringement that can be appropriately resolved through dispositive motions.

Second, summary denial of the Judgment Motion, coupled with the prohibition of dispositive motions, denies Baxter any chance of obtaining a final judgment of noninfringement before the '867 Patent expires. Expiry of the '867 Patent prior to final judgment forces Baxter to delay marketing the Baxter ANDA Product until late 2019 or longer. This is contrary to the legislative purpose of the Hatch-Waxman Amendments—a key element of which is to make non-infringing generic products available to the American public as quickly as possible. For these reasons, Baxter requests that the Court consider its Judgment Motion on the merits. In the alternative, Baxter requests a 2018 trial date to resolve its case before the '867 Patent expires.

A. Judgment as a Matter of Law is Warranted on at Least the Glass Patents.

Dispositive motions are appropriate where there are no material issues of fact and judgment can be granted as a matter of law. *See* Fed. R. Civ. P. 12(c), 56. The purpose of a dispositive motion is not only to enable early case resolution, but also to dispose of meritless claims and streamline issues for discovery and trial. These are the precise purposes for which Baxter filed its Judgment Motion, and underscore why judgment as a matter of law is warranted.

Defendants expressly and repeatedly acknowledge in their answer and subsequent submissions to this Court that Baxter does not infringe the Glass Patents (D.I. 10, ¶¶ 33, 46, 58, 87-89, 95-96, 102-103; D.I. 18; D.I. 19), and have indicated the same to Baxter through the parties' respective litigation counsel. Defendants further have not counterclaimed for infringement of these patents. The prohibition on dispositive motions, however, forces Baxter to litigate the Glass Patents through trial, including serving noninfringement contentions, hiring experts, briefing claim construction, and preparing a Markman presentation, despite Defendants' admission that there is no infringement. These are the exact circumstances that dispositive motions—and, in particular, motions for judgment on the pleadings—were created to avoid. Thus, because Defendants have admitted that Baxter does not infringe the Glass Patents, the Court should reconsider Baxter's Judgment Motion—at least with respect to the Glass Patents—to avoid manifest injustice.

B. The Ban on Dispositive Motions Precludes Judgment Before the '867 Patent Expires.

The impending expiry of the '867 Patent makes it crucial that Baxter receive a final non-appealable judgment of noninfringement before pediatric exclusivity for the '867 Patent begins on April 1, 2019. Practically speaking, this means Baxter needs a final non-appealable judgment by January 11, 2019, because the first applicant has 75 days to either market its product or forfeit its exclusivity upon entry of final judgment, and Baxter must still obtain final FDA approval if the

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