

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MALLINCKRODT IP UNLIMITED	:	
COMPANY, MALLINCKRODT	:	
HOSPITAL PRODUCTS INC., and SCR	:	
PHARMATOP	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 17-365-LPS
	:	
B. BRAUN MEDICAL INC.,	:	
	:	
Defendant.	:	

MALLINCKRODT IP UNLIMITED	:	
COMPANY AND MALLINCKRODT	:	
HOSPITAL PRODUCTS INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 17-660-LPS
	:	
B. BRAUN MEDICAL INC.,	:	
	:	
Defendant.	:	

MEMORANDUM ORDER

Having reviewed various motions filed by the parties in these matters, and all associated filings, IT IS HEREBY ORDERED that:

1. New Pharmatop L.P.’s (“New Pharmatop”) Motion to Substitute Party (C.A. No. 17-365 D.I. 46) is GRANTED. The relief requested is entirely consistent with Federal Rule of Civil Procedure 25(c). No substantive rights are affected: if original plaintiff “SCR Pharmatop” properly “enjoyed” an automatic 30-month stay of FDA approval, then New Pharmatop, as a proper transferee, does as well; if SCR Pharmatop did not enjoy such a stay, then neither does New Pharmatop. This decision is without prejudice to B. Braun Medical Inc.’s (“Braun”) ability to seek

discovery from SCR Pharmatop and/or to amend its pleadings to add SCR Pharmatop as a party, if necessary. To the extent New Pharmatop (or any other party) has suggested that Braun does not need any discovery from SCR Pharmatop or the inventors on the patents-in-suit, the Court disagrees.

2. Braun's Motion to Dismiss for Lack of Jurisdiction Over the Subject Matter (C.A. No. 17-365 D.I. 49) is DENIED. The "Mallinckrodt Parties" (i.e., Mallinckrodt IP Unlimited Co. and Mallinckrodt Hospital Prods. Inc.), and SCR Pharmatop (with the Mallinckrodt Parties hereinafter "Plaintiffs") have met their burden to establish, at this stage of the proceedings, that "SCR Pharmatop," "Pharmatop SCR," "S.C. Pharmatop," "Pharmatop SC," and "Pharmatop" are one and the same entity. Therefore, based on the evidence of record at this point, SCR Pharmatop had standing at the time of the filing of the original and amended complaints. To the extent they have not done so already, Plaintiffs shall produce evidence responsive to Braun's requests relating to standing, including unredacted versions of the Patent Assignment Agreement and the Asset Purchase Agreement. Any disputes in this regard should be brought to the Court through the Discovery Matters Procedures. As the Court has an ongoing obligation to examine its subject matter jurisdiction, today's ruling is without prejudice to Braun renewing a challenge to standing or subject matter jurisdiction if/when it believes it has a meritorious basis to do so.

3. Braun's Motion to Dismiss for Failure to State a Claim (C.A. No. 17-365 D.I. 62), which seeks dismissal of Plaintiffs' claims for infringement of U.S. Patent Nos. 6,992,218 (the "'218 patent") and 9,399,012 (the "'012 patent"), is DENIED. Taking, as the Court must, the well-pleaded factual allegations of the complaint as true, Plaintiffs have stated a plausible claim for patent infringement. Among other things, the Court agrees with Plaintiffs that it must credit as true the allegations about the "scientific" fact of what manufacturing processes must be followed in order to end up with a stable product of the type claimed in the patent. Braun's motion essentially asks the Court to take its contrary allegations as true and to resolve claim construction disputes, as well as

issues of prosecution history estoppel and disclaimers, and infringement, on a motion filed pursuant to Federal Rule of Civil Procedure 12. This the Court cannot do.

Moreover, pursuant to 35 U.S.C. § 271(e): “It shall be an act of infringement to submit . . . an application under section . . . 505(b)(2) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.” Braun is alleged to have made such a filing and to have given the required notice (i.e., “paragraph IV certification”) to Plaintiffs. (See C.A. No. 17-365 D.I. 14 ¶¶ 15, 29-33) Further, the Amended Complaint identifies additional factual allegations that Braun likely infringes the ’218 and ’012 patents because, *inter alia*, numerous pharmaceutical companies have failed to design around the ’218 patent’s claims (*id.* ¶ 40) and Braun’s proposed labeling will promote a method of administering certain dosages of the proposed products infringing at least claim 1 of the ’012 patent (*id.* ¶¶ 38, 42). This is sufficient to create a justiciable controversy and, at least in the context of the complaints filed here, to state a plausible claim for relief. See generally *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003); see also *Insys Therapeutics v. Alkem Labs., Ltd.*, C.A. No. 17-1419-LPS (D. Del.) D.I. 24 at 37-38.

The concerns raised by Braun as to the purported lack of merit of Plaintiffs’ allegations are more properly raised (if at all) on a motion for sanctions pursuant to Fed. R. Civ. Proc. 11 or (if Braun prevails on the merits) in connection with a request that this case be deemed “exceptional” and attorney fees be awarded pursuant to 35 U.S.C. § 285. This is particularly so given that Plaintiffs had only 45 days after receiving paragraph IV certifications to decide whether (and where, and on what patents, and against whom, etc.) to sue if they wished to obtain the benefit of the automatic stay of regulatory approval, and because the Court and the parties are operating under a

statutory mandate to attempt to “expedite” the resolution of this case. *See* 21 U.S.C. § 355(c)(3)(C) (providing “approval [of an application] may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice . . . or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action”).

4. New Phartatop’s Motion to Defer B. Braun’s Motion to Dismiss Pending Decision on New Phartatop’s Motion to Substitute and Extend the Case Schedule (C.A. No. 17-365 D.I. 75) is DENIED AS MOOT. The Court has today granted the motion to substitute. Should New Phartatop believe any modifications of the schedule are required, it may (after meeting and conferring with the other parties) make a renewed request.

5. Plaintiffs’ Motion for Leave to File Sur-Reply (C.A. No. 17-365 D.I. 93) is DENIED AS MOOT, as the Court has today denied the motion to dismiss with respect to which the sur-reply is offered.

6. New Phartatop’s Motion for Leave to File Answering Brief to Defendant’s Motion to Dismiss (C.A. No. 17-365 D.I. 145) is DENIED AS MOOT, as the Court has today denied the motion to dismiss with respect to which the brief is offered.

7. Braun’s Motion for Leave to File Motion for Summary Judgment (C.A. No. 17-365 D.I. 157) is DENIED WITHOUT PREJUDICE. Braun may renew its motion for leave (which the Court is likely to grant, for reasons including those suggested during the April 17, 2018 teleconference (*see* C.A. No. 17-365 D.I. 143 at 45, 57-59)) after the Court issues its claim construction decision, which the Court anticipates doing within 60 days after the hearing tomorrow.


8. Braun’s Motion to Dismiss for Failure to State a Claim (C.A. No. 17-660 D.I. 47), which seeks dismissal of Plaintiffs’ claims for infringement of the ’012 patent and U.S. Patent No. 9,610,265 (the “’265 patent”), is DENIED, for the reasons stated in paragraph 3 above with respect

to the similar motion to dismiss filed in C.A. No. 17-365. (*See, e.g.*, C.A. No. 17-660 D.I. 11 at ¶¶ 52-53)

9. The Mallinckrodt Parties' Motion for Leave to File Sur-Reply in Further Opposition to B. Braun Medical Inc.'s Motion to Dismiss (C.A. No. 17-660 D.I. 66) is DENIED AS MOOT, as the Court has today denied the motion to dismiss with respect to which the brief is offered.

10. All requests for fees made in any of the foregoing motions are DENIED.

11. Given that the Court has now resolved the motions that were scheduled for argument, each side will be allocated just forty-five (45) minutes for its presentation on claim construction.



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT COURT