

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

GALDERMA LABORATORIES INC., :
GALDERMA LABORATORIES, L.P., and :
SUPERNUS PHARMACEUTICALS, INC., :

Plaintiffs, :

v. :

C.A. No. 11-1106-LPS

AMNEAL PHARMACEUTICALS, LLC :
and AMNEAL PHARMACEUTICALS CO. :
(I) PVT. LTD., :

Defendants. :

MEMORANDUM ORDER

At Wilmington this 7th day of September, 2012:

IT IS HEREBY ORDERED that Defendants' motion for partial judgment on the pleadings based on collateral estoppel (D.I. 52) (hereinafter, "Motion" or "Mot.") is GRANTED for the following reasons:

In this Abbreviated New Drug Application ("ANDA") patent litigation, Defendants, Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals Co. (I) Pvt. Ltd. (collectively, "Amneal"), move for judgment on the pleadings that their proposed 40 mg doxycycline product does not infringe the "Ashley patents."¹ Amneal's Motion is based on collateral estoppel (issue preclusion). Specifically, Amneal relies on this Court's finding in a related ANDA action² (hereinafter, "the Mylan Action") that a proposed generic product containing 40 mg doxycycline

¹The Ashley patents are U.S. Patent Nos. 7,232,572 and 7,211,267. An additional patent, U.S. Patent No. 7,749,532 (the "Chang patent"), is also asserted against Amneal in this action. (D.I. 1 Exhs. A-C)

²See *Research Found. of State Univ. of New York v. Mylan Pharms. Inc.*, 809 F. Supp. 2d 896 (D. Del. 2011) (hereinafter, "Mylan").

administered once daily does not infringe the Ashley patents, because such products do not contain the required “sub-antibacterial amounts” of doxycycline but, rather, significantly inhibit the growth of microorganisms. *See Mylan*, 809 F. Supp. 2d at 317 & n.12.

Plaintiffs, Galderma Laboratories Inc., Galderma Laboratories, L.P., and Supernus Pharmaceuticals, Inc. (collectively, “Galderma”), who assert the Ashley patents against Amneal, oppose the Motion. (D.I. 59) Galderma contends that collateral estoppel does not apply because the instant action does not present the “identical issue” as the Mylan Action. In Galderma’s view, the Motion must be denied because this case involves Amneal’s proposed product, while the Mylan Action involved Mylan’s different proposed product. Galderma also insists that the Motion is premature because Galderma has not yet taken discovery on Amneal’s proposed product. Galderma further asserts that granting the Motion will undermine judicial efficiency, given the potential outcome of its pending appeal in the Mylan Action.

Pursuant to Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings, “[a]fter pleadings are closed – but early enough not to delay trial.” As the Third Circuit has explained, in authority on which Galderma relies (D.I. 59 at 3):

“Under Rule 12(c), judgment will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law. In reviewing the grant of a Rule 12(c) motion, we must view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party.”

Domino’s Pizza LLC v. Deak, 383 Fed. Appx. 155, 158 (3d Cir. 2010) (quoting *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008)). “[J]udgment will not be granted unless the movant clearly establishes there are no material issues of fact, and he is entitled to judgment as a matter of law.” *Sikirica v. Nationwide Ins. Co.*, 416 F.3d 214, 220 (3d Cir. 2005). A Rule 12(c)

motion is subject to the same standard as a Rule 12(b)(6) motion to dismiss. *See Citisteel USA, Inc. v. Gen. Elec. Co.*, 78 Fed. Appx. 832, 835 n.3 (3d Cir. 2003).

A party asserting collateral estoppel must prove the following elements: (1) the previous determination was necessary to the decision; (2) the identical issue was previously litigated; (3) the issue was actually decided on the merits and the decision was final and valid; and (4) the party being precluded from re-litigating the issue was adequately represented in the previous action. *See Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006); *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1333 (Fed. Cir. 2004).

Galderma essentially concedes all but the second of the four elements of collateral estoppel. With respect to element (1), Galderma, in its opposition, does not contest (and, of course, it cannot) that the Court's finding of non-infringement of the Ashley patents was necessary to the Court's decision in the Mylan Action, given that Galderma asserted there that Mylan infringed the Ashley patents. With respect to element (3), Galderma does not challenge Amneal's contention that the issue of infringement of the Ashley patents was actually decided in the Mylan Action, and that decision (although currently on appeal) is presently embodied in a final and valid judgment. With respect to element (4), Galderma concedes by its silence that it was adequately represented in the Mylan Action (in which, not incidentally, it was represented by the same able counsel as represents it in the instant action), an action in which it had a full and fair opportunity – culminating in a four-day bench trial followed by substantial post-trial briefing – to litigate infringement of the Ashley patents.³

³Galderma Laboratories Inc. and Galderma Laboratories LP, both of whom are plaintiffs here, were also parties to the *Mylan* action. *See* C.A. No. 09-184-LPS (D. Del.); C.A. No. 10-892-LPS (D. Del.).

The dispute, then, is whether Galderma's claim that Amneal infringes the Ashley patents presents the "identical issue" that was previously litigated and decided against Galderma in the Mylan Action. On this question, the Court agrees with Amneal.

In the Mylan Action, the Court decided whether a product containing 40 mg of doxycycline, administered once daily, infringes the Ashley patents. *See Mylan*, 809 F. Supp. 2d at 317-22. It is undisputed that Amneal's ANDA, like Mylan's ANDA, seeks FDA approval to market a product containing 40 mg of doxycycline to be administered once daily. (D.I. 1 ¶ 27) Hence, in order to prevail against Amneal on its claim for infringement of the Ashley patents, Galderma would have to prevail on the "identical issue" it previously litigated – and lost – in the Mylan Action.

In response to this simple logic, Galderma argues that no identical issue is presented here, because the Mylan Action involved Mylan's proposed product while the instant action involves Amneal's different proposed product. Galderma even suggests that Amneal has somehow been inconsistent, claiming that Amneal has, over the course of this litigation, argued "that its generic product has a distinct formulation from Mylan's generic product." (D.I. 59 at 2) Galderma's argument lacks merit. Galderma identifies no actual inconsistency in Amneal's position. Instead, the two citations on which Galderma relies – a portion of Amneal's brief opposing Galderma's motion to stay (which the Court denied, *see* D.I. 56), and a statement Amneal made during a scheduling conference (*see* D.I. 59 at 4, 6) (citing D.I. 21 at 10; D.I. 34 at 10) – show that Amneal has consistently argued its proposed product differs from Mylan's proposed product

in terms of their overall formulations, a matter having nothing to do with the Ashley patents.⁴

Galderma's remaining arguments are likewise flawed. Galderma places heavy emphasis on the fact that its appeal of the Court's ruling in the Mylan Action is pending, presenting the possibility that the Federal Circuit will reverse or vacate the Court's finding of non-infringement on the Ashley patents. It may be, as Galderma expects, that "the Federal Circuit will address claim construction of the term 'sub-antibacterial amount' and related terms in the Mylan Appeal, and that the Federal Circuit's ruling on this issue will guide or possibly control the issue of Ashley patent infringement in this action." (D.I. 59 at 8) Yet, unless or until such a ruling is handed down by the Federal Circuit, this Court's judgment in the *Mylan* Action has effect – including, here, collateral estoppel effect. The pendency of an appeal does not diminish either the finality or binding effect of a trial court's holding. *See Pharmacia & UpJohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1381 (Fed. Cir. 1999).

On this point, the Court adheres to the reasoning it articulated at the June 2012 hearing, in denying Galderma's motion to stay this action pending appeal:

By no means am I saying that I have any idea or any confidence or lack of confidence that what the Court ruled in the Galderma v Mylan case will be affirmed in part or in whole, but that ruling is the status quo at the moment and unless and until the Federal Circuit does something to change it, this Court, in an exercise of its discretion, is going to act on that status quo.

(D.I. 67 at 49)

Relatedly, Galderma contends that if this Court's decision in the Mylan Action is reversed or vacated, judicial economy will have been undermined by today's ruling, as it will

⁴Instead, this is the subject of the parties' dispute relating to the Chang patent, which the Court found to be infringed by Mylan. *See* 809 F. Supp. 2d at 329-31.

then be necessary to revive the claims relating to the Ashley patents. Galderma's unstated assumption that matters of judicial economy may preclude application of collateral estoppel may be incorrect. *See generally Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1979) ("Collateral estoppel . . . has the dual purpose of protecting litigants from the burden of relitigating an identical issue with the same party or his privy and of promoting judicial economy by preventing needless litigation."). Assuming, without deciding, that concerns of judicial economy may trump proper application of collateral estoppel, Galderma's reasoning is unpersuasive in the instant case. The Court does not perceive any efficiencies to be gained by permitting litigation of the Ashley patents to proceed at this time, nor any likely inefficiencies that will result from its decision today. Indeed, Amneal has largely mooted Galderma's concerns by conceding that "[s]hould the Federal Circuit conclude in any *Mylan* appeal that 40 mg of doxycycline does infringe the Ashley patents, Amneal will *not* seek to re-litigate this issue." (D.I. 66 at 9 (emphasis added); *see also* D.I. 53 at 11 ("[I]f Galderma prevails on appeal and the Federal Circuit reverses this Court's non-infringement decision as to the Ashley patents, then Galderma may move to modify this Court's judgment against Amneal just as this Court's judgment in the prior *Mylan* action will be modified."))

Galderma observes that a claim of patent infringement will not often be defeated by an assertion of collateral estoppel. It is undeniable, however, that collateral estoppel may *sometimes* defeat a claim of patent infringement. *See Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 348 (1971) ("[T]he accused infringer should have available an estoppel defense that can be pleaded affirmatively and determined on a pretrial motion for judgment on the pleadings or summary judgment."); *Molinaro v. Fannon/Courier Corp.*, 745

F.2d 651, 655 (Fed. Cir. 1984) (“[W]here a determination of the scope of patent claims was made in a prior case, and the determination was essential to the judgment there on the issue of infringement, there is collateral estoppel in a later case on the scope of such claims, *i.e.*, the determined scope cannot be changed.”). Here, application of collateral estoppel is compelled because precisely the issue on which Galderma’s assertion of the Ashley patents against Amneal is based – the anti-bacterial effect of 40 mg of doxycycline administered once daily – was previously litigated and decided against Galderma. How frequently similar circumstances arise is immaterial.

Galderma further argues that the Motion is premature, as discovery on Amneal’s proposed product is not yet completed. But, as is plain from what the Court has already stated, the pertinent issue is not “fact-laden,” as Galderma unpersuasively contends. (D.I. 59 at 4) To the contrary, the Court’s finding of non-infringement of the Ashley patents in the *Mylan* Action was in no meaningful sense tied to anything unique about Mylan’s proposed product. This conclusion is inescapable from the fact that the Court relied on scientific publications discussing the antibacterial effect *in vivo* of 40 mg doxycycline administered once daily. *See Mylan*, 809 F. Supp. 2d at 317. This same conclusion is further confirmed by the Court’s express statement that ***Galderma’s product*** was itself ***not*** an embodiment of the Ashley patents. *See id.* at 321-22. As Amneal states, “no amount of discovery will change the fact that ‘40 mg doxycycline administered once-daily ***does*** significantly inhibit the growth of some microorganisms in some locations of some humans at some times.’” (D.I. 66 at 6) (quoting *Mylan*, 809 F. Supp. 2d at 317).

Galderma argues that Amneal’s Motion is premature for the additional reason that, at the

time it was filed, the pleadings were not “closed,” because Amneal’s (unopposed) request to amend its counterclaim to add the affirmative defense of collateral estoppel (following the Court’s entry of judgment in the *Mylan* Action) had not yet been granted. (D.I. 59 at 4 n.1) But, as Amneal points out, the pleadings were closed at the time it filed the Motion, even though they were subsequently amended. (See D.I. 66 at 5-6 n.2) (citing *Novo Nordisk, Inc. v. Paddock Labs., Inc.*, 797 F. Supp. 2d 926, 929 (D. Minn. 2011)) Proceeding as Galderma implies the Court should do – denying the Motion without prejudice, requiring Amneal to renew its Motion, then granting the renewed Motion – would not promote the “just, speedy, and inexpensive determination” of this action. Fed. R. Civ. Proc. 1.

In sum, after viewing the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to Galderma, the Court concludes that Amneal has clearly established that no material issue of fact remains as to collateral estoppel and Amneal is entitled to judgment as a matter of law.

Accordingly, Defendants’ motion for partial judgment on the pleadings based on collateral estoppel (D.I. 52) is GRANTED. Specifically, judgment is entered FOR Amneal and AGAINST Galderma on: (1) Counts II and III of Galderma’s Complaint (D.I. 1), which assert infringement of the Ashley patents; (2) Amneal’s First Affirmative Defense (D.I. 57 ¶¶ 50-51), asserting non-infringement of the Ashley patents; (3) Amneal’s Sixth Affirmative Defense (*id.* ¶ 59), asserting collateral estoppel; and (4) Count I of Amneal’s counterclaim (*id.* at pp. 14-15) to the extent that it asserts non-infringement of the Ashley patents.


UNITED STATES DISTRICT JUDGE