UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Merck KGaA, Merck Serono SA, and Ares Trading SA v. Hopewell Pharma Ventures, Inc., et al.

Merck v. Hopewell · No. C.A. No. 22-1365-GBW-CJB · Decided December 4, 2025

OPINION

Merck KGaA, Merck Serono SA, and Ares Trading SA v. Hopewell Pharma Ventures, Inc., et al.
PER CURIAM.
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
MERCK KGaA, MERCK SERONO SA, and
ARES TRADING SA,
Plaintiffs,
C.A. No. 22-1365-GBW-CJB
v. CONSOLIDATED
HOPEWELL PHARMA VENTURES, INC.,
et al., Defendants. Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNEL LLP, Wilmington, DE; David B. Bassett, Mary Pheng, Gillian T. Farrell, WILMER CUTLER PICKERING HALE & DORR LLP, New York, NY; Vinita Ferrera, Emily R. Whelan, Deric X. Geng, Wenli Gu, Asher S. McGuffin, WILMER CUTLER PICKERING HALE & DORR LLP, Boston, MA; H. Rachael Million-Perez, WILMER CUTLER PICKERING HALE & DORR LLP, Denver, CO; Reid M. Whitaker, Nora N. Xu, WILMER CUTLER PICKERING HALE & DORR LLP, Washington, D.C. Counsel for Plaintiffs Karen E. Keller, Nate R. Hoeschen, SHAW KELLER LLP, Wilmington, DE; J.C. Rozendaal, Chandrika Vira, Christina Dashe, STERNE KESSLER GOLDSTEIN & FOX P.L.L.C., Washington, D.C. Counsel for Defendant Hopewell Kenneth L. Dorsney, Cortlan S. Hitch, MORRIS JAMES LLP, Wilmington, DE; Stephen R. Auten, Jaimin Shah, Luke T. Shannon, Ian Scott, TAFT STETTINIUS & HOLLISTER LLP, Chicago, IL; Deepro R. Mukerjee, Lance A. Soderstrom, KATTEN MUCHIN ROSENMAN LLP, New York, NY; Joseph M. Janusz, KATTEN MUNCHIN ROSENMAN LLP, Charlotte, NC. Counsel for Defendant Apotex
MEMORANDUM OPINION
December 4, 2025 Wilmington, Delaware
GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE
Plaintiffs Merck KGaA, Merck Serono SA, and Ares Trading SA (collectively, “Plaintiffs” or “Merck”) filed suit against Defendants Hopewell Pharma Ventures, Inc. (“Hopewell”), Aurobindo

Pharma USA Inc., Aurobindo Pharma Limited, Apotex Inc., and Apotex Corp. (collectively, “Defendants”), alleging infringement of U.S. Patent Nos. 7,713,947 and 8,377,903 (together, “the Asserted Patents”).' On December 23, 2024, the Court granted Hopewell’s Emergency Motion to Stay the Case Pending Resolution of any Appeal of IPR2023-00480 and IPR2023-00481 (‘the IPR Appeals”)” (D.1. 196) (“the Emergency Motion to Stay the Case”), and tolled the 30-month “statutory stay of FDA[*] approval of Hopewell’s ANDAJ"*] product” (“the Regulatory Stay”). (D.I. 223 at 1). On January 16, 2025, the Court stayed Merck’s action against the remaining Defendants. (See D.I. 236 at 2).° Pending before the Court is Hopewell’s Emergency Motion to Lift the Regulatory Stay (D.I. 252) (“Hopewell’s Motion’), which has been fully briefed (D.I. 252; D.I. 258; D.I. 261). For the following reasons, the Court denies Hopewell’s Motion. Merck’s individual actions against the Defendants were consolidated. See Merck KGaA v. Hopewell Pharma Ventures, Inc., C.A. No. 22-1365-GBW-CJB, 2024 WL 2973034, at *1 n.l (D. Del. June 13, 2024), report and recommendation adopted, C.A. No. 22-1365- GBW-CIJB, 2024 WL 3967463 (D. Del. Aug. 28, 2024). IPR2023-00480 and IPR2023-00481 invalidated the claims of the Asserted Patents that Merck asserts in this action. The “FDA” refers to the United States Food and Drug Administration. “ANDA” refers to an Abbreviated New Drug Application. ° The Court will refer to this stay as “the Hopewell Stay.” ie,

I. BACKGROUND

“Plaintiffs allege that Defendants have infringed [various patent] claims .. . by submitting their respective Abbreviated New Drug Applications seeking approval to market generic versions of Plaintiffs’ MAVENCLAD® product.” (2024 WL 2973034, at *1 (citing D.I. 67 at 1, 7 n.5); see also D.I. 1 ¥ 1). Hopewell filed successful inter partes review (“IPR”) challenges against Merck’s asserted patent claims. See Hopewell Pharma Ventures, Inc. v. Merck Serono S.A., No. IPR2023-00480, Paper 62, 2024 Pat. App. LEXIS 3751 (P.T.A.B. Sept. 18, 2024); Hopewell Pharma Ventures, Inc. v, Merck Serono S.A., No. IPR2023-00481, Paper 62, 2024 Pat. App. LEXIS 3752 (P.T.A.B. Sept. 18, 2024); (see also D.I. 233 at 5; D.I. 197 at 1; D.I. 195 at 1).° As noted below, the Court stayed Merck’s actions in light of Hopewell’s successful IPR challenges. A. Hopewell’s Emergency Motion to Stay On November 27, 2024, Hopewell filed its Emergency Motion to Stay the Case. (D.I. 196). Therein, Hopewell “move[d] to stay this matter pending the resolution of any appeal of IPR2023- ° 00480 and IPR2023-00481, in which the PTAB[’] [held that] the asserted claims [of] U.S. Patent Nos. 7,713,947 and 8,377,903 [are] invalid as obvious.” (D.I. 196 at 1). In its accompanying opening brief, Hopewell contended that “[t]he Court should grant a stay so that the parties and the Court can stop devoting resources to a case in which no trial is necessary.” (D.I. 197 at 1; see also 6 “The Leahy-Smith America Invents Act, 35 U.S.C. § 100 et seq., establishes a process called ‘inter partes review.’ Under that process, the United States Patent and Trademark Office (PTO) is authorized to reconsider and to cancel an issued patent claim in limited circumstances.” Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC, 584 US. 325, 328-29 (2018); see also SNIPR Techs. Lid. v. Rockefeller Univ., 72 F 4th 1372, 1381- 82 (Fed. Cir.

2023). “[O]nce a claim is already and finally held unpatentable as a result of an IPR, the claim is subject to a wholly ministerial, inevitable, unreversible cancellation.” Kroy IP Holdings, LLC v. Groupon, Inc., 127 F.4th 1376, 1381 (Fed. Cir. 2025). 7 “PTAB” refers to the Patent Trial and Appeal Board. id. at 2 (“[A] stay is appropriate despite the late stage of the litigation because there are no issues left to litigate.”)). Merck opposed Hopewell’s Emergency Motion to Stay the Case. (See D.I. 205 at 2). Merck alternatively requested that, “if the Court were to stay the trial, it should at a minimum toll Hopewell’s statutory 30-month stay under 21 U.S.C. § 355G)(5)(B)Gii) for the pendency of the litigation stay.” (/d.). According to Merck, Hopewell’s Emergency Motion to Stay was “‘itself a failure to cooperate in the expeditious resolution of this litigation and thus sufficient reason to toll the statutory stay.” (/d. at 4). This was so, according to Merck, because “Hopewell simply cannot simultaneously cooperate in the expeditious resolution of this litigation and request a stay of the same litigation.” (Ud. at 5). Merck also contended that “a tolling of the statutory stay period comports with the statutory scheme of the Hatch-Waxman Act.” (/d.). Hopewell disagreed. Hopewell responded that there was no “basis for extending the 30-month stay of FDA approval of Hopewell’s ANDA.” (D.L. 207 at 2). According to Hopewell, its “request for a stay to avoid the burden and expense of an unnecessary trial cannot be fairly characterized as a ‘failure to cooperate in the expeditious resolution of th[e] litigation.’” (/d. (alteration in original) (quoting D.I. 205 at 4)). Hopewell also contended that it “will certainly be prejudiced if the FDA determines [that] Hopewell’s ANDA is in condition for approval, but the agency is not free to grant final approval because of an injunction based on invalid patent claims.” (/d.). On December 23, 2024, the Court granted Hopewell’s Emergency Motion to Stay the Case. (D.I. 223 at 1). The Court also granted Merck’s alternative request for tolling. (See id. (“[P]ursuant to 21 U.S.C. § 355q)(S)(B)(Giii), the thirty (30) month statutory stay of FDA approval of Hopewell’s ANDA product is tolled during the pendency of the litigation stay.”)). B. The Global Stay Considering the overlap between Merck’s actions against the Defendants, on January 10, 2025, the Court informed the parties that, “unless good cause is shown, the Court w[ould], for purposes of judicial efficiency, impose a global stay that includes Plaintiffs’ actions against the other Defendants until the conclusion of any appeal in IPR2023-00480 and IPR2023-00481.” □□□□□ 232). Merck responded that “[flor the purposes of judicial efficiency, Plaintiffs do not oppose a global stay.” (D.I. 233 at 1). Apotex Inc. and Apotex Corp. (collectively, “Apotex”) opposed a global stay, at least without additional provisos. (/d. at 1, 5). Apotex responded that, “if Apotex can approach the [C]Jourt following a favorable decision in the IPR [A]ppeals and request that its 30-month stay be lifted, without waiting for a mandate, Apotex would be amenable to a global stay.” (Ud. at 5). Apotex also responded that, “[s]hould the Court determine a stay is appropriate, Apotex’s 30-month stay should not be tolled or otherwise extended.” (/d. at 5 n.5 (“Unlike Hopewell, Apotex has not requested a litigation stay, and there is therefore no basis to toll or extend its 30-month stay.”)). On January 16, 2025, the Court sua sponte ordered a global stay. (See D.1. 236 at 2). “By entering th[e] global stay ... the Court [did] not toll[] the Apotex Defendants’ thirty (30) month

statutory stay from receiving FDA approval of their ANDA product." (/d.). C. The Federal Circuit's Decision On October 30, 2025, the Federal Circuit issued an opinion affirming the PTAB's decision invalidating all the asserted claims. Merck Serono S.A. v. Hopewell Pharma Ventures, Inc., No. 25-1210, 2025 WL 3030020 (Fed. Cir. Oct. 30, 2025). However, the Federal Circuit has yet to issue a mandate in the appeal. See generally Merck, No. 25-1210 (Fed. Cir.); see also Fed. R. App. P. 41(b) ("The court's mandate must issue 7 days after the time to file a petition for rehearing expires, or 7 days after entry of an order denying a timely petition for panel rehearing, petition for rehearing en banc, or motion for stay of mandate, whichever is later.").

Il. LEGAL STANDARDS

A. 30-Month Regulatory Stay "The Hatch-Waxman Act strikes a balance between the sometimes-competing policy interests of inducing pioneering research and development of new drugs and enabling production of low-cost, generic copies of those drugs." Eli Lilly & Co. v. Teva Pharms. USA, Inc., 557 F.3d 1346, 1348 (Fed. Cir. 2009). "Under the Hatch-Waxman Amendments, a manufacturer that seeks to market a generic drug may submit an ANDA for approval by the FDA, rather than submitting a full New Drug Application ("NDA') concerning the safety and efficacy of the generic drug, and it may rely on safety and efficacy studies previously submitted by the pioneer manufacturer by submitting information showing the generic drug's bioequivalence with the previously approved drug product." Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002) (citing 21 U.S.C. § 355(j)(2)(A)). "{A]n ANDA submitted to the FDA must address any patents covering the approved reference drug; these patents are listed by the NDA holder in the FDA's 'Orange Book.'" Actavis Lab'ys FL, Inc. v. United States, 131 F.4th 1345, 1349 (Fed. Cir. 2025) (citing 21 U.S.C. § 355(b)(1)(A)(viii)). "If a generic drug company seeks to market a generic version of a listed drug before the expiration of Orange-Book-listed patents covering that drug, it must file a certification under 21 U.S.C. § 355G)(2)(A)(vii)(IV), ie. a 'Paragraph IV certification.'" Caraco Pharm. Lab'ys, Ltd. v. Forest Lab'ys, Inc., 527 F.3d 1278, 1283 (Fed. Cir. 2008) (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 677 (1990)). "A generic drug manufacturer who files an ANDA containing a Paragraph IV certification must notify the owner of the unexpired patent that is the subject of the certification." Allergan, Inc. v. Alcon Lab'ys, Inc., 324 F.3d 1322, 1326 (Fed. Cir. 2003) (citing 21 U.S.C. § 355q)(2)(B)G) & (ii). "After the generic applicant sends the patent owner a [P]aragraph IV notice, the patent owner has forty-five days to decide whether to file an infringement suit." Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC, 124 F.4th 898, 905 (Fed. Cir. 2024) (citing 21 U.S.C. § 355G)(5)(B) iii). "A brand-drug sponsor that sues within 45 days of receiving notice of a generic's [P]aragraph IV certification is entitled to an automatic thirty-month stay of FDA approval so the infringement and validity questions can be worked out in court." Celgene Corp. v. Mylan Pharms. Inc., 17 F Ath 1111, 1118 (Fed. Cir. 2021) (citing 21 U.S.C. § 355G)(5)(B) (iii); FTC v. Actavis, Inc., 570 U.S. 136, 143 (2013)). "The court entertaining the suit has discretion under the statute to order a shorter or longer stay if 'either party to the action fail[s] to reasonably

cooperate in expediting the action."" Eli Lilly, 557 F.3d at 1348 (alteration in original) (quoting 21 U.S.C. § 355q)(5)(B)qii)). il. DISCUSSION Hopewell asks the Court to lift the Regulatory Stay, which currently precludes the FDA from granting final approval of Hopewell's ANDA No. 215547. (See generally D.I. 252). Hopewell asserts that it is entitled to have the Regulatory Stay lifted on two bases: (1) not lifting the Regulatory Stay would cause irreparable competitive harm; and (2) Merck failed to reasonably cooperate in expediting this action on appeal to the Federal Circuit. (See generally id.; see also D.J. 261). For the reasons set forth below, neither of the proffered bases are persuasive. Hopewell's Motion is therefore DENIED. A. The Court Cannot Lift the Regulatory Stay to Prevent Injustice Hopewell first claims that maintaining the Regulatory Stay "needlessly warps the competitive environment." (D.I. 252 at 2). Because the Regulatory Stay was tolled for Hopewell, but Apotex's 30-month stay has since expired, once the FDA approves Apotex's ANDA, Apotex will be able to launch at-risk, while Hopewell would face a "potentially months-long delay in reaching the market." (/d. at 4). Hopewell therefore contends that, "[d]espite filing later and playing no part in invalidating the [asserted claims,] Apotex stands to gain an unfair commercial advantage over Hopewell due to the continuation of Hopewell's regulatory stay." (/d. at 4). This outcome, according to Hopewell, cannot "be squared with the goals of the Hatch-Waxman Act." (id. at 5). Merck responds by claiming that "the continued tolling of the statutory stay is consistent with the purpose of the Hatch-Waxman Act." (D.I. 256 at 5). According to Merck, that Hopewell decided to undertake an IPR and "requested a delay of this proceeding" requires that Hopewell face "consequences for how its actions affected the timely resolution of the instant litigation." (/d. at 6). Ultimately, the Court concludes that it lacks the power to lift the regulatory stay to prevent an alleged injustice. The Regulatory Stay is a product of the Hatch- Waxman Act, which requires 8 Merck, in the "Legal Standard" section of its answering brief, claims that "[a] [cJourt has the inherent power and discretion to lift a stay only when 'circumstances have changed such that the court's reasons for imposing that stay no longer exist or are inappropriate.'"" (D.I. 256 at 2 (quoting Dermafocus LLC v. Ulthera, Inc., C.A. No. 15-654 (MN), 2018 WL 5113960, at *2 (D. Del. Oct. 19, 2018))). This standard, however, and the cases Merck cites in support, concern lifting a /itigation stay (e.g., the Hopewell Stay), not the 30-month statutory stay under the Hatch-Waxman Act (e.g., the Regulatory Stay). See, □□□□□ Dermafocus, 2018 WL 5113960, at *1 ("DermaFocus and Ulthera entered into a stipulation to stay the instant litigation . . . ." (emphasis added)); Rohm & Haas Co. v. Brotech Corp., No. 90-109 (RRM), 1992 WL 313099, at *2 (D. Del. July 16, 1992) ("In December of 1991, Brotech moved to stay this litigation. . . . [T]he Judge previously assigned to this case granted that motion . . . ." (emphasis added)). 9 To be clear, the Court does not reach whether the present ruling results in an injustice against Hopewell. In fact, given that Hopewell asked the Court to stay the present action, knowing when Apotex's statutory stay expired, the Court is skeptical that there is an injustice created here. However, the Court need not decide whether Hopewell's potential delay in entering the market constitutes an injustice, because even if the Court accepts Hopewell's arguments, the

Court lacks the authority to lift the Regulatory Stay under the present circumstances. a 30-month stay if an infringement action is filed by an NDA holder within 45-days after receiving a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)Gii). The relevant text of the Hatch- Waxman Act provides that: If the applicant made a certification described in subclause (IV) of paragraph (2)(A){vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B){i) 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 .... 21 U.S.C. § 3559)(5)(B)(ii) (emphasis added). The following subsections change the duration of the statutory stay when the district court decides that the patent is either: (1) invalid or not infringed; or (2) infringed. 21 U.S.C. § □□□□□□□□□□□□□□□□□□□□□□□□□□ Hopewell has not provided, nor could the Court identify, any case where the duration of the statutory stay was changed to prevent a perceived injustice. Therefore, the Court holds that, to change the duration of the statutory stay, it must decide that: (1) the patent-in-suit is invalid or not infringed; (2) the patent-in-suit is infringed; or (3) either party to the action failed to reasonably cooperate in expediting the action. See 21 U.S.C. § 355G)(5)(B)Gii). Despite Hopewell's claim that maintaining the Regulatory Stay does not square "with the goals of the Hatch-Waxman Act," (D.I. 252 at 5), the Court finds that Congress has made its policy choices clear in the text of the statute. See Romag Fasteners, Inc v. Fossil, Inc., 590 U.S. 212, 215 (2020) (Courts should not "read into statutes words that aren't there"); see also Newman vy. Corrado, 897 F.2d 1579, 1583 (Fed. Cir. 1990) (The "court cannot impose requirements not grounded in the statute solely because they may represent sound public policy."), The Federal Circuit has yet to issue a mandate in the IPR Appeals, so the Court declines to decide that the asserted claims are invalid at this time. See generally Merck, No. 25-1210 (Fed. Cir.). For all the foregoing reasons, the Court holds that it cannot lift the Regulatory Stay to prevent the risk of Apotex from receiving final FDA approval to launch its generic product before Hopewell, however "unfair" Hopewell claims such a launch would be. B. Merck's Actions in the IPR Appeals Are Insufficient to Shorten the Regulatory Stay Hopewell next asserts that "Merck's recent failure to 'reasonably cooperate in expediting th[is] action' itself warrants lifting the [R]egulatory [S]tay." (D.I. 252 at 5 (quoting 21 U.S.C. § 355G)(5)(B)(iii)) (first alteration in original)). According to Hopewell, "Merck did its utmost to drag out the proceedings on appeal," and therefore the statutory criteria of 21 U.S.C. § 355(j)(5)(B)(iii) are met. (/d.). The problem for Hopewell, however, is that any unreasonable failure of Merck to cooperate in expediting the IPR

Appeals is ot a failure of Merck to reasonably cooperate in expediting the 10 The Court believes the result reached today comports with the policy behind the Hatch- Waxman Act, which is that "generic manufacturing of a drug should be allowed as soon as it is determined that it does not violate patent rights." Minnesota Mining And Mfg. Co. v. Barr Lab'ys, Inc., 289 F.3d 775, 786 (Fed. Cir. 2002) (Gajarsa, J., concurring). Until the Federal Circuit issues its mandate, it has not been determined that Defendants' potential launch of their generic products would not violate Plaintiffs' patent rights. Given the policy behind the Hatch-Waxman Act, and the present circumstances of the instant case, Apotex having the ability to launch at-risk, while Hopewell is forced to wait for the Federal Circuit's mandate, is not a nonsensical result. See id. ("[T]he [Hatch-Waxman Act's] provisions on the exclusivity period should not be read to reach nonsensical results."). 10 present infringement action. The Federal Circuit addressed a similar distinction in Andrx Pharmaceuticals, Inc. v. Biovail Corp., 276 F.3d 1368 (Fed. Cir. 2002), which Hopewell does not address, (see D.I. 252; D.I. 261). In Andrx, the Federal Circuit held that an NDA holder's "allegedly improper conduct before the FDA" did not grant it the authority to shorten the 30-month statutory stay, finding that the Hatch-Waxman Act addresses only the "delay related to the particular infringement action." 276 F.3d at 1376. Just as in Andrx, the alleged delay here is not the result of a delay in the present infringement action, but of a delay in an IPR appeal. (See D.I. 252 at 5 ("Merck did its utmost to drag out the proceedings on appeal'')); Andrx, 276 F.3d at 1376. Although the Court recognizes that any delay in the IPR Appeals will functionally result in a delay of the present infringement action, the Federal Circuit expressly rejected such reasoning. Andrx, 276 F.3d at 1376 ("[T]he district court appeared to conclude that it could shorten the period because of delay in the resolution of the overall patent dispute between Biovail and Andrx. We find no such authority in the statute ...."). Thus, the Court holds that it lacks the authority to shorten the Regulatory Stay based on an unreasonable failure to cooperate in expediting the JPR Appeals. Even if the Court had the authority to shorten the Regulatory Stay based on an unreasonable failure to cooperate in expediting the IPR Appeals, it would decline to do so under the circumstances. Hopewell appears to assert that Merck behaved unreasonably when it waited "until the last permissible moment to file its notice of appeal... ." (D.I. 252 at 5). However, Hopewell does not provide, nor can the Court identify, any instance where a court has held that a party failed to reasonably cooperate in expediting an action, when said party filed a required document on a 11 deadline rather than before a deadline." (See generally D.I. 252; D.I. 261 (failing to provide any such cases)). Although Hopewell did move for a 60-day extension of time to file its opening brief in the IPR Appeals, the Federal Circuit "denied Merck's motion . . . and ordered that no extensions of time would be allowed." (D.I. 252 at 6 (citing Order, D.I. 28, Merck Serono, S.A. v. Hopewell Pharma Ventures, Inc., No, 2025-1210 (Fed. Cir. Dec. 27, 2024))). The Court does not believe a failed attempt at obtaining an extension of time qualifies as failing to reasonably cooperate in expediting an action, and Hopewell does not provide a case holding otherwise. Importantly, it was Hopewell that requested the case be stayed pending the IPR

Appeals, which the Court granted over Merck's objections. (See D.I. 252 at 3-4 ("Hopewell moved to stay this litigation for the pendency of the IPR [A]ppeals .... Merck Opposed ... ."); see also D.I. 196 (Hopewell's Motion to Stay the Case); D.I. 205 (Merck's Opposition to Hopewell's Motion to Stay the Case); D.I. 223 (The Court's order granting a stay of the present case)). At least one other court has held that a request to stay a pending infringement action necessitates a finding that the party requesting the stay is not reasonably cooperating in expediting said action. Novartis Corp. v. Dr. Reddy's Lab'ys, Ltd., No. 04-0757, 2004 WL 2368007, at *3 (S.D.N.Y. Oct. 21, 2004) ('DRL cannot feasibly argue that it is reasonably cooperating in expediting the action when it has asked the court to stay the proceedings."). Thus, it appears that it was Hopewell that was not reasonably cooperating in expediting the action, not the other way around. Therefore, even if the Court had the authority to shorten to statutory stay, it would decline to do so under the present circumstances. i The Court can envision a scenario where a party may not be reasonably cooperating in expediting the action, while simultaneously meeting all deadlines (such as unreasonably delaying discovery responses). See Eli Lilly, 557 F.3d at 1350 (citing Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1337 n. 5 (Fed. Cir. 2003) (Schall, J., concurring)) ("Trial courts ... may shorten or extend the thirty-month statutory period based on the parties' uncooperative discovery practices before the court."). However, complying with a set briefing schedule is not such a scenario. 12 The only instance in the present case that Hopewell identifies as an example of Merck failing to reasonably cooperate in expediting the action is Merck's purported delay in supplying the Court with its portion of the joint status report that the Court ordered be submitted "within thirty (30) days of any decision by the Federal Circuit in the IPR Appeals," (D.I. 236 at 2). (D.I. 252 at 6-7). As previously discussed, however, filing a document on a deadline, rather than before a deadline, does not qualify as a failure to reasonably cooperate in expediting the action. This is especially true when the action is stayed (at Hopewell's request) pending the conclusion of the IPR Appeals. (See D.I. 236 at 1). Because the IPR Appeals have not concluded (as no mandate has been issued), Merck's alleged delay in supplying the Court with its portion of the joint status report does not warrant lifting the Regulatory Stay before the Federal Circuit issues a mandate in the IPR Appeals.

IV. CONCLUSION

The Court is sensitive to the predicament that Hopewell finds itself in: being the first to file an ANDA on a generic version of MAVENCLAD®, but facing the potential of being the later-launched generic product. However, this is a situation of Hopewell's own making, having asked this Court to stay the present action pending the IPR Appeals, against Merck's objections and with full knowledge of the expiration date of Apotex's 30-month stay. It was also feasible, at the time Hopewell moved to stay the case, that the Court would subsequently toll Hopewell's 30-month stay, given that at least one other court had tolled a generic manufacturer's 30-month stay in a similar situation. See Novartis, 2004 WL 2368007, at *3. Ultimately, the Court concludes that, under the present circumstances, it lacks the authority to lift the Regulatory Stay. Moreover, even

if lifting the Regulatory Stay was within the Court's discretion, it would decline to do so under the circumstances. Hopewell's Motion (D.I. 252) is therefore DENIED. 13 However, given that both Hopewell and Merck are in agreement that the Regulatory Stay should be lifted once the Federal Circuit issues its mandate (See D.I. 257 at 1 n.1 ("Merck Serono is not asking the Court to maintain the stay beyond entry of the Federal Circuit Mandate")), the Court will order the parties to file a joint status report, with a proposed final judgment Gf applicable), within one (1) day of the date that the Federal Circuit issues its mandate in the IPR Appeals. 12 Apotex believes final judgment should be entered immediately after the Federal Circuit issues its mandate. (D.I. 259 at 2). 14