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

SUMMARY

The United States District Court for the District of Delaware denied Hopewell Pharma Ventures, Inc.'s motion to lift the 30-month FDA approval stay associated with its ANDA for a generic version of MAVENCLAD®. The court held that it lacked authority to lift or shorten the statutory stay based on alleged competitive unfairness or alleged delays in related inter partes review appeals, and concluded that Hopewell's own request for a litigation stay weighed against its position. The court ordered the parties to file a joint status report within one day after the Federal Circuit issues its mandate.

CASE DETAILS

COURT	United States District Court for the District of Delaware
WRITING FOR THE COURT	Gregory B. Williams
JURISDICTION	United States District Court for the District of Delaware
DECIDED	December 4, 2025
DOCKET	C.A. No. 22-1365-GBW-CJB
DISPOSITION	other
PROCEDURAL POSTURE	Hopewell moved to lift the 30-month statutory FDA approval stay imposed under the Hatch-Waxman Act while the related inter partes review appeals were pending. The District of Delaware denied the emergency motion.
STANDARD OF REVIEW	Statutory interpretation and review of the court's authority under the Hatch-Waxman Act; the court also stated that, even if it had discretion to shorten the regulatory stay, it would decline to exercise that discretion under the circumstances.
PRECEDENTIAL VALUE	unpublished district court opinion

TOPICS

patent infringement · patent law · fda regulation · statutory interpretation · civil procedure

PRACTICE AREAS

patent law | patent infringement | pharmaceutical regulation | civil procedure | appellate procedure

QUESTIONS PRESENTED

1. Whether the district court had authority under the Hatch-Waxman Act to lift or shorten Hopewell's 30-month regulatory stay merely to prevent an alleged competitive injustice.
2. Whether Merck's alleged delays in the IPR appeals and in submitting a joint status report constituted a failure to reasonably cooperate in expediting the infringement action under 21 U.S.C. § 355(j)(5)(B)(iii).
3. Whether the court could determine that the asserted patent claims were invalid before the Federal Circuit issued its mandate affirming the PTAB decisions.

HOLDINGS

1. The district court lacks authority under the Hatch-Waxman Act to change the duration of the 30-month regulatory stay solely to prevent a perceived injustice or competitive disadvantage.
2. The court lacked authority to shorten the regulatory stay based on an alleged failure to reasonably cooperate in expediting the IPR appeals because the statutory provision concerns cooperation in expediting the particular infringement action, not a related administrative appeal.
3. Merck's filing of documents at the applicable deadline, its unsuccessful request for an extension in the IPR appeal, and its alleged delay in providing its portion of a joint status report did not warrant shortening the regulatory stay.

KEY QUOTATIONS

> *"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."* (at 9)

> *"Thus, the Court holds that it lacks the authority to shorten the Regulatory Stay based on an unreasonable failure to cooperate in expediting the IPR Appeals."* (at 10)

> *"Ultimately, the Court concludes that, under the present circumstances, it lacks the authority to lift the Regulatory Stay."* (at 13)

FACTUAL BACKGROUND

Merck alleged that the defendants infringed U.S. Patent Nos. 7,713,947 and 8,377,903 by submitting ANDAs seeking approval to market generic versions of Merck's MAVENCLAD product. Hopewell successfully challenged the asserted claims in inter partes review proceedings, and the Federal Circuit affirmed those decisions, but its mandate had not issued. Because Hopewell requested a stay of the infringement action pending the IPR appeals, the district court tolled Hopewell's 30-month regulatory stay while Apotex's comparable stay later expired, creating the competitive disparity that Hopewell argued justified lifting its stay.

PROCEDURAL HISTORY

Merck sued Hopewell, Aurobindo, and Apotex for infringement of two patents based on their ANDA filings. The court consolidated the actions, granted Hopewell's request to stay the litigation pending appeals from PTAB decisions invalidating the asserted claims, and tolled Hopewell's regulatory stay during the litigation stay. The Federal Circuit affirmed the PTAB decisions but had not issued its mandate when Hopewell moved to lift the regulatory stay. The court denied the motion and ordered a joint status report within one day after issuance of the Federal Circuit's mandate.

DISPOSITION

other

CASES CITED

- Merck KGaA v. Hopewell Pharma Ventures, Inc., C.A. No. 22-1365-GBW-CJB, 2024 WL 2973034, at *1 n.1 (D. Del. June 13, 2024), report and recommendation adopted, 2024 WL 3967463 (D. Del. Aug. 28, 2024)
- 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)
- Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 584 U.S. 325, 328-29 (2018)
- SNIPR Technologies Ltd. v. Rockefeller University, 72 F.4th 1372, 1381-82 (Fed. Cir. 2023)
- Kroy IP Holdings, LLC v. Groupon, Inc., 127 F.4th 1376, 1381 (Fed. Cir. 2025)
- Merck Serono S.A. v. Hopewell Pharma Ventures, Inc., No. 25-1210, 2025 WL 3030020 (Fed. Cir. Oct. 30, 2025)
- Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc., 557 F.3d 1346, 1348, 1350 (Fed. Cir. 2009)
- Andrx Pharmaceuticals, Inc. v. Biovail Corp., 276 F.3d 1368, 1371, 1376 (Fed. Cir. 2002)
- Actavis Laboratories FL, Inc. v. United States, 131 F.4th 1345, 1349 (Fed. Cir. 2025)
- Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc., 527 F.3d 1278, 1283 (Fed. Cir. 2008)
- Allergan, Inc. v. Alcon Laboratories, Inc., 324 F.3d 1322, 1326, 1337 n.5 (Fed. Cir. 2003)
- Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC, 124 F.4th 898, 905 (Fed. Cir. 2024)
- Celgene Corp. v. Mylan Pharmaceuticals Inc., 17 F.4th 1111, 1118 (Fed. Cir. 2021)
- Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 677 (1990)
- FTC v. Actavis, Inc., 570 U.S. 136, 143 (2013)
- Dermafocus LLC v. Ulthera, Inc., C.A. No. 15-654 (MN), 2018 WL 5113960, at *1-2 (D. Del. Oct. 19, 2018)
- Rohm & Haas Co. v. Brotech Corp., No. 90-109 (RRM), 1992 WL 313099, at *2 (D. Del. July 16, 1992)
- Romag Fasteners, Inc. v. Fossil, Inc., 590 U.S. 212, 215 (2020)
- Newman v. Corrado, 897 F.2d 1579, 1583 (Fed. Cir. 1990)
- Minnesota Mining and Manufacturing Co. v. Barr Laboratories, Inc., 289 F.3d 775, 786 (Fed. Cir. 2002) (Gajarsa, J., concurring)

- Novartis Corp. v. Dr. Reddy's Laboratories, Ltd., No. 04-0757, 2004 WL 2368007, at *3 (S.D.N.Y. Oct. 21, 2004)