IN THE SUPREME COURT OF THE UNITED STATES

17A ____

MERCK & CO., INC., MERCK SHARP & DOHME CORP., AND ISIS PHARMACEUTICALS, INC.,

Petitioners,

v.

GILEAD SCIENCES, INC.,

Respondent.

APPLICATION FOR AN EXTENSION OF TIME IN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the Federal Circuit:

Merck & Co., Inc., Merck Sharp & Dohme Corp., and Isis (now Ionis) Pharmaceuticals, Inc. (collectively "Merck") respectfully request a 59-day extension of time (the 60th day being a Saturday), to and including September 21, 2018, within which to file a petition for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the Federal Circuit in this case, *Gilead Sciences, Inc.* v. *Merck & Co., Inc.*, Nos. 2016-2302, 2016-2615 (Fed. Cir.). The court of appeals entered judgment on April 25, 2018. Unless extended, the time for filing a petition

for a writ of certiorari will expire on July 24, 2018. Pursuant to this Court's Rule 13.5, this application is being filed at least 10 days before that date. This Court has jurisdiction under 28 U.S.C. § 1254(1). A copy of the court of appeals' opinion is attached as Exhibit 1.

As explained below, the extension is necessary to permit counsel of record to determine whether to file a petition for a writ of certiorari, and, if one is to be filed, to see to its preparation and submission. Counsel of record also has been heavily engaged with the press of other matters.

1. The patents at issue in this case—U.S. Patent Nos. 7,105,499 and 8,481,712—disclose Merck's invention of a class of compounds for treating the life-threatening effects of the hepatitis C virus ("HCV"). Ex. 1, Op. at 2. That invention arose from a partnership, formed in 1998, between Merck and Isis Pharmaceuticals. *Id.* at 3. They discovered molecules (modified nucleosides) that would act as "chain terminators" that stop viral replication mid-stream. See *id.* at 3-4. An enzyme involved in the virus's RNA assembly would mistake the modified nucleoside for a building block of its own RNA, and add it to the virus's growing chain when replicating strains of its RNA. *Id.* at 4. But the nucleoside would prevent the strand from being completed—stopping replication—by preventing additional molecules from being added to the chain. *Ibid.*

Recognizing it had discovered an important class of molecules, Merck sought to protect its invention. Dr. Philippe Durette, a Merck patent prosecutor, was as-

signed to handle patent prosecution. Ex. 1, Op. at 4. Two separate applications that Merck filed in January 2002 eventually became the patents at issue in this case. *Ibid.* Those applications described and claimed families of compounds using chemical formulas that list different atoms that might be attached at different positions on the nucleoside. *Ibid.* The shared specification of the two applications also included a number of example compounds illustrating possible modifications. *Ibid.*

A pharmaceutical company called Pharmasset, which respondent Gilead Sciences, Inc., later acquired, had also been researching HCV treatments. Ex. 1, Op. at 8. Shortly after the Merck applications published, Pharmasset challenged its chemists to find "'loopholes'" in the applications. *Ibid.* Pharmasset chemist Jeremy Clark proposed making a compound now known as PSI-6130. *Ibid.* Pharmasset made and tested PSI-6130 by May 2003. *Ibid.*

In early 2004, Pharmasset approached Merck about partnering to develop PSI-6130 as a clinical candidate. Ex. 1, Op. at 17. Pharmasset proposed to reveal the structure of PSI-6130 to Merck during a due-diligence call on March 17, 2004. *Ibid.* Durette and another employee participated in the call on Merck's behalf. *Id.* at 17-18. Durette's participation in the call would later become a focal point of this case: Pharmasset's successor, Gilead, urged that Durette should not have been on the call; that Durette improperly used confidential information from the call in prosecuting the '499 patent; and that other misconduct infected the '712 patent as well. See *id.* at 16-19, 28-30. The negotiations between Merck and Pharmasset ultimate-

ly failed because Merck recognized that PSI-6130 was already covered by its '499 patent application.

2. After acquiring Pharmasset, Gilead obtained FDA approval of Sovaldi® and Harvoni® for treating HCV. Ex. 1, Op. at 2. Both products are based on the compound "sofosbuvir" and the compound Clark invented, PSI-6130. *Id.* at 2, 8. Before launching its products, Gilead filed a complaint seeking declaratory judgments of non-infringement and invalidity of Merck's '499 and '712 patents. *Id.* at 2. Merck counterclaimed for infringement. *Ibid.* Gilead eventually stipulated that sofosbuvir (like PSI-6130) infringes both patents. *Id.* at 2, 13.

Gilead pursued invalidity defenses. Ex. 1, Op. at 2-3. Gilead also claimed that Merck did not actually invent the subject matter and instead derived the invention from Pharmasset through the failed business discussions in 2004. *Id.* at 3. Gilead asserted the equitable defense of unclean hands based on the same theory. *Ibid.* The jury returned a verdict finding Merck's patents not invalid and awarding Merck $200 million as damages for infringement. *Ibid.*

The district court, however, ruled against Merck on Gilead's equitable defense of unclean hands. Ex. 1, Op. at 3. The district court cited supposed "business" and "litigation" misconduct to foreclose the patents' enforcement. *Id.* at 3, 13. The "business misconduct," the court asserted, consisted of Durette learning the confidential structure of Pharmasset compound PSI-6130 during the March 2004 due-diligence call and pursuing patent claims to cover that compound in viola-

tion of the parties' agreement. *Id.* at 16-20. The court accused Durette of improperly using information learned on the call to inform his conduct in amending the '499 patent. *Id.* at 20-22.

The district court also found "litigation misconduct" involving Durette as a witness both at his deposition and at trial. Ex. 1, Op. at 22. At his deposition, Durette had testified inconsistently about whether he had participated in the March 2004 call. See *id.* at 22, 24. He initially testified that he did not recall participating in the call. *Id.* at 24. He later stated that he did not participate. *Ibid.* Still later, he said he might have participated on the call, but he did not remember. *Ibid.* Merck admitted that Durette had attended the call; at trial, Durette acknowledged his participation as well. *Ibid.* The district court found that Durette's denial of participation was intentionally false, and it charged Merck with the consequences of that testimony. *Id.* at 24, 27. The court also disbelieved Durette's explanation for why he had amended the '499 patent in 2005. *Id.* at 25-26. Finally, the court found that the misconduct "'infect[ed] the entire lawsuit, including the enforceability of the '712 Patent.'" *Id.* at 29.

Having concluded that the equitable defense of unclean hands was established, the district court barred Merck from enforcing its patents against Gilead and overturned the jury's verdict and award of damages for Merck. Ex. 1, Op. at 3. Relying on the unclean-hands finding, the court later awarded Gilead attorneys' fees. *Ibid.*

3. Merck appealed, and the Federal Circuit affirmed. Ex. 1, Op. at 1-30.

The court of appeals rejected Merck's argument that the district court had erred in holding that unclean hands does not require that the "connection between" the alleged "misconduct and the litigation" at issue be "'material.'" Ex. 1, Op. at 14. It noted that the district court had recited the "governing legal standard" for unclean hands from this Court's decision in *Keystone Driller Co.* v. *General Excavator Co.*, 290 U.S. 240 (1933). Ex. 1, Op. at 13. "For purposes of this case, which involves clear misconduct in breaching commitments to a third party and clear misconduct in litigation," the court stated, *Keystone*'s "'immediate and necessary relation' standard" sufficiently captures the doctrine's requirements. *Id.* at 14.

Applying the "immediate and necessary relation" standard, the Federal Circuit "[did] not find a sufficient basis to set aside the district court's determination of unclean hands under the applicable deferential" abuse-of-discretion "standard of review." Ex. 1, Op. at 16. Although the court of appeals did not agree with all of the district court's findings, see, *e.g.*, *id.* at 19 n.4, 21 n.5, it found "adequate evidentiary support" for the district court's findings that Merck had engaged in "two related forms of pre-litigation business misconduct," *id.* at 16. It faulted Durette for participating in the March 2004 due-diligence call in violation of a "'firewall' understanding between Pharmasset and Merck that call participants not be involved in related Merck patent prosecutions." *Ibid.* It also faulted Merck for "continu[ing]

to use Dr. Durette in the related patent prosecutions even after the call." *Ibid.* The Federal Circuit also found that the evidence supported the district court's conclusion of litigation misconduct. According to the court of appeals, the district court did not clearly err in finding that Durette gave "false testimony" that "bore on the origin story of the February 2005 amendment" to the '499 patent, "which was relevant to the invalidity issues in the litigation and hence immediately and necessarily related to the equity of the patent-enforcement relief Merck seeks in this case." *Id.* at 23.

The Federal Circuit thus concluded that "the district court did not abuse its discretion in applying the doctrine of unclean hands." Ex. 1, Op. at 30. In a separate appeal decided on July 6, 2018, the Federal Circuit summarily affirmed the district court's award of attorneys' fees in light of its earlier affirmance of the unclean-hands finding. See *Gilead Scis., Inc.* v. *Merck & Co., Inc.*, No. 2018-1017 (Fed. Cir.) (attached as Exhibit 2).

4. Merck respectfully requests that an extension of time be granted. The additional time is needed to determine whether to file a petition for a writ of certiorari and, if one is to be filed, to see to its preparation and submission. Counsel also requires additional time given the complex issues involved and the lengthy record; the trial transcript exceeds 2,600 pages. The additional time will also allow Merck to address, in a single petition, any issues arising out of the Federal Circuit's July 6, 2018 affirmance of the attorneys'-fees award in No. 2018-1017

(Fed. Cir.) (Exhibit 2); otherwise, counsel would have only 18 days between the issuance of the Federal Circuit's summary order and the deadline to file a consolidated petition. Counsel of record also has been heavily engaged with the press of other matters.[1] Accordingly, Merck respectfully requests a 59-day extension of time (the 60th day being a Saturday), to and including September 21, 2018, within which to file a petition for a writ of certiorari.

[1] These include a reply brief in *Continental Circuits LLC* v. *Intel Corp.*, No. 18-1076, filed in the Federal Circuit on June 8, 2018; an opening brief in *TCL Communication Technology Holdings Ltd.* v. *Telefonaktiebolaget LM Ericsson, Ericsson Inc.*, Nos. 18-1363, -1380, -1382, -1732, filed in the Federal Circuit on June 11, 2018; an amicus brief in *Lacaze* v. *Louisiana*, No. 17-1566, filed in this Court on June 18, 2018; an opening brief in *Idenix Pharmaceuticals LLC* v. *Gilead Sciences, Inc.*, No. 18-1691, filed in the Federal Circuit on June 28, 2018; a reply brief in support of a petition for a writ of certiorari in *World Programming Ltd.* v. *SAS Institute, Inc.*, No. 17-1459, filed in this Court on July 9, 2018; a petition for a writ of certiorari due in this Court on July 23, 2018; a reply brief in support of a petition for a writ of certiorari in *Bank Markazi* v. *Peterson*, No. 17-1534, due in this Court on July 25, 2018; a reply brief in *Idenix Pharmaceuticals LLC* v. *Gilead Sciences, Inc.*, No. 18-1691, due in the Federal Circuit on August 21, 2018; a response brief in *Green Mountain Glass, LLC* v. *Saint-Gobain Containers, Inc.*, No. 18-1725, due in the Federal Circuit on August 22, 2018; a respondents' brief in *Frank* v. *Gaos*, No. 17-961, due in this Court on August 29, 2018; and opening briefs due in *Merck Sharp & Dohme Corp.* v. *Wyeth LLC*, No. 18-2133, and *Merck Sharp & Dohme Corp.* v. *Wyeth LLC*, No. 18-2134, due in the Federal Circuit on September 7, 2018.

Respectfully submitted.

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