United States Court of Appeals for the Federal Circuit

GILEAD SCIENCES, INC.,
Plaintiff-Cross-Appellant

v.

MERCK & CO., INC., MERCK SHARP & DOHME CORP., IONIS PHARMACEUTICALS, INC.,
Defendants-Appellants

2016-2302, 2016-2615

Appeals from the United States District Court for the Northern District of California in No. 5:13-cv-04057-BLF, Judge Beth Labson Freeman.

Decided: April 25, 2018

JUANITA ROSE BROOKS, Fish & Richardson, PC, San Diego, CA, argued for plaintiff-cross-appellant. Also represented by CRAIG E. COUNTRYMAN, JONATHAN ELLIOT SINGER; ELIZABETH M. FLANAGAN, DEANNA JEAN REICHEL, Minneapolis, MN; ROBERT M. OAKES, Wilmington, DE; EDMUND HIRSCHFELD, E. JOSHUA ROSENKRANZ, Orrick, Herrington & Sutcliffe LLP, New York, NY.

JEFFREY A. LAMKEN, MoloLamken LLP, Washington, DC, argued for defendants-appellants. Also represented by JAMES A. BARTA, SARAH JUSTINE NEWMAN, MICHAEL

GREGORY PATTILLO, JR.; SARA MARGOLIS, New York, NY; JESSAMYN SHELI BERNIKER, STANLEY E. FISHER, BRUCE GENDERSON, JESSICA PALMER RYEN, Williams & Connolly LLP, Washington, DC; MITCHELL EPNER, STEPHEN S. RABINOWITZ, Hughes Hubbard & Reed LLP, New York, NY.

Before TARANTO, CLEVENGER, and CHEN, *Circuit Judges*.

TARANTO, *Circuit Judge*.

This case involves two patents relating to treatments for Hepatitis C. Merck & Co., Inc. and Ionis Pharmaceuticals, Inc. (formerly Isis Pharmaceuticals, Inc.) collaborated on research in the area and eventually obtained U.S. Patent Nos. 7,105,499 and 8,481,712. The patents, whose specifications are materially the same for present purposes, describe and claim classes of compounds, identified by structural formulas, and the administration of therapeutically effective amounts of such compounds. Gilead Sciences, Inc., developed its own Hepatitis C treatments—marketed now as Solvadi® and Harvoni®, both based on the compound sofosbuvir.

Gilead filed this action against Merck & Co., its subsidiary Merck Sharp & Dohme Corp., and Ionis (collectively, "Merck" unless the context indicates reference just to Merck & Co. and/or Merck Sharp). Gilead sought a declaratory judgment that Merck's '499 and '712 patents are invalid and that Gilead is not infringing by its activities involving its sofosbuvir products. Merck counterclaimed for infringement.

Gilead eventually stipulated to infringement based on the district court's claim construction, which is not challenged on appeal. A jury trial was held on Gilead's challenges to the patents as invalid for lack of both an adequate written description and enablement of the asserted claims (claims 1–2 of the '499 patent and claims

1–3, 5, 7, and 9-11 of the '712 patent) as well as Gilead's closely related defense that Merck did not actually invent the subject matter but derived it from another inventor, employed by Gilead's predecessor. The jury ruled for Merck and awarded damages.

The district court then held a bench trial on Gilead's equitable defenses, including unenforceability against Gilead based on the allegation that Merck had unclean hands regarding the patents. The district court ruled for Gilead, finding both pre-litigation business misconduct and litigation misconduct attributable to Merck, and it barred Merck from asserting the patents against Gilead. *Gilead Scis., Inc. v. Merck & Co.*, No. 13-cv-04057-BLF, 2016 WL 3143943, at *39 (N.D. Cal. June 6, 2016). Having so concluded, the district court subsequently deemed moot Gilead's motion for judgment as a matter of law of invalidity for lack of adequate written description and enablement. The court also awarded attorney's fees, relying on the finding of unclean hands.

Merck appeals the unenforceability judgment based on unclean hands. Gilead cross-appeals the denial of judgment as a matter of law of invalidity, but it asks us to reach that issue only if we set aside the unenforceability judgment. We have jurisdiction under 28 U.S.C. § 1295(a)(1). We affirm the judgment based on unclean hands, concluding that it is sufficiently supported by findings that withstand review for clear error. We therefore do not reach the issues raised by Gilead's conditional cross-appeal.

I

A

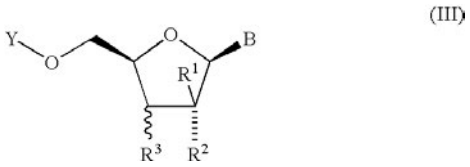
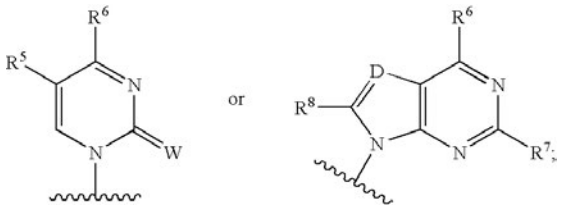
In 1998, Merck and Isis began collaborating on finding a way to block propagation of the Hepatitis C virus (HCV) by impeding the synthesis of its RNA. J.A. 20291. The collaborators sought a molecule that would have two

properties. First, an enzyme involved in RNA assembly (NS5B polymerase) would recognize the molecule as a building block and add it to the growing RNA chain during replication of the virus's RNA. Second, the addition of this molecule would effectively stop further RNA assembly before completion and, hence, end RNA replication and prevent viral propagation.

Starting in 2001, the two collaborators filed a series of patent applications related to antiviral agents for Hepatitis C. Dr. Phillipe Durette, a Merck chemist who had become a patent attorney, was central to their initial patenting efforts. J.A. 20301. A provisional patent application dated January 22, 2001, summarizes the invention as "a method for inhibiting hepatitis C virus (HCV) NS5B polymerase, a method for inhibiting HCV replication, and/or a method for treating HIV infection" by administering a "therapeutically effective amount of a compound of structural formula I." J.A. 25808. It sets forth and claims large families of possible structures in Markush format: it displays a number of configurations of nucleic acid derivatives and shows variables at a number of locations in the structures (*e.g.*, different bases, different molecules attached to the sugar ring), the variables each stated to represent any of a substantial number of possible constituents. J.A. 25803–980.

The same is true of Merck's two January 2002 applications under the Patent Cooperation Treaty (PCT applications). J.A. 24832, 26913. One of those became Merck's July 2003 U.S. application 10/250,873, which issued as the '499 patent. J.A. 150, 27227. A non-provisional U.S. application filed in January 2002 led to the 2007 application that issued as the '712 patent. J.A. 223. The number of possible combinations within the Markush groups is very large.

One instance of the formulas in the written description, from the 2003 application that issued as the '499 patent, is:

> structural formula III which is of the stereochemical configuration:
>
> 
>
>
> wherein B is
>
> 
>
>
> D is N, CH, C—CN, C—NO2, C—C_{1-3} alkyl, C—$NHCONH_2$, C—$CONR^{11}R^{11}$, C—$CSNR^{11}R^{11}$, C—$COOR^{11}$, C-hydroxy, C—C_{1-3} alkoxy, C-amino, C—C_{1-4} alkylamino, C-di(C_{1-4} alkyl)amino, C-halogen, C-(1,3-6oxazol-2-yl), C-(1,3-thiazol-2-yl), or C-(imidazol-2-yl); wherein alkyl is unsubstituted or substituted with one to three groups independently selected from halogen, amino, hydroxy, carboxy, and
>
> C_{1-3} alkoxy;
>
> W is O or S;
>
> Y is H, C_{1-10} alkylcarbonyl, $P_3O_9H_4$, $P_2O_6H_3$, or $P(O)R^9R^{10}$;
>
> R^1 is hydrogen, CF_3, or ***C_{1-4} alkyl*** and one of R^2 and R^3 is OH or C_{1-4} alkoxy and the other of R^2 and R^3 is selected from the group consisting of

hydrogen,

hydroxy,

fluoro,

C_{1-3} alkyl,

trifluoromethyl,

C_{1-8} alkylcarbonyloxy,

C_{1-3} alkoxy, and

amino; or

R^2 is hydrogen, CF_3, or C_{1-4} alkyl and one of R^1 and R^3 is OH or C_{1-4} alkoxy and the other of R^1 and R^3 is selected from the group consisting of

hydrogen,

hydroxy,

fluoro,

C_{1-3} alkyl,

trifluoromethyl,

C_{1-8} alkylcarbonyloxy,

C_{1-3} alkoxy, and

amino; or

R^1 and R^2 together with the carbon atom to which they are attached form a 3- to 6-membered saturated monocyclic ring system optionally containing a heteroatom selected from O, S, and NC_{0-4} alkyl;

R^6 is H, OH, SH, NH_2, C_{1-4} alkylamino, di(C_{1-4} alkyl)amino, C_{3-6} cycloalkylamino, halogen, C_{1-4} alkyl, C_{1-4} alkoxy, or CF_3;

R^5 is H, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-4} alkylamino, CF_3, or halogen;

R^7 is hydrogen, amino, C_{1-4} alkylamino, C_{3-6} cycloalkylamino, or di(C_{1-4} alkyl)amino;

each R^{11} is independently H or C_{1-6} alkyl;

R^8 is H, halogen, CN, carboxy, C_{1-4} alkyloxycarbonyl, N_3, amino, C_{1-4} alkylamino, di(C_{1-4} alkyl)amino, hydroxy, C_{1-6} alkoxy, C_{1-6} alkylthio, C_{1-6} alkylsulfonyl, or (C_{1-4} alkyl)$_{0-2}$ aminomethyl; and

R^9 and R^{10} are each independently hydroxy, $OCH_2CH_2SC(=O)$t-butyl, or $OCH_2O(C=O)$iPr;

with the provisos that (a) when R^1 is hydrogen and R^2 is fluoro, then R^3 is not hydrogen, trifluoromethyl, fluoro, C_{1-3} alkyl, amino, or C_{1-3} alkoxy; (b) when R^1 is hydrogen and R^2 is fluoro, hydroxy, or C_{1-3} alkoxy, then R^3 is not hydrogen or fluoro; and (c) when R^1 is hydrogen and R^2 is hydroxy, then R^3 is not ß-hydroxy.

'499 Patent, col. 13, line 5 through col. 14, line 17 (emphases added to highlight terms of particular interest for this case); J.A. 27245–47.[1]

Various claims appeared in Merck's patent applications based on that structural formula or related ones, including claims 6 and 8 of the January 2001 provisional, J.A. 25954–56, claims 6 and 8 of the PCT application that

---

[1] The top figure shows the key elements of the nucleoside. B is the base, shown in the next two figures in single-ring (pyrimidine) and double-ring (purine) versions. R^1 and R^2 are located at the 2′ (carbon) position on the ring, with R^1 at the 2′ "up" location and R^2 at the 2′ "down" location. R^3 is at the 3′ position.

issued as the '499 patent, J.A. 25036–38, and claim 44 of that same application, which was added, substituting for earlier claims, immediately upon filing the U.S. version in July 2003, J.A. 27482–83. The 2003-added claim 44 of the 2003 application, for example, recites the above structural formula but is limited to the single-ring bases shown above (pyrimidine bases, such as cytosine and uracil). It therefore omits the above-quoted language concerning D, R^7, and R^8, which appear only on the double-ring bases shown above (purine bases, such as adenine and guanine). *Id.*

Claim 44 of the 2003 application and its PCT counterpart, like the structural formula III, encompasses, among the large number of possible combinations of values of the variables, structures having (i) a single-ring base, (ii) a methyl (C_1 alkyl) in the R^1 position, and (iii) a fluoro in the R^2 or R^3 position. J.A. 25036–38, 27482–83. A subgenus with those characteristics—which embraces both a metabolite of Gilead's sofosbuvir and an earlier identified compound that was modified to arrive at sofosbuvir, and which Merck eventually focused on in new claims in 2005—is central in this case.

B

In 2002, a pharmaceutical company called Pharmasset, which was later acquired by Gilead, was researching Hepatitis C treatments. When one of Merck's early applications was published that year, Pharmasset reviewed the application, looking for "loopholes." J.A. 20048 (533). After reviewing Merck's application, Jeremy Clark, a chemist at Pharmasset, proposed the compound PSI-6130 (the compound that led to sofosbuvir). *Id.* (533–534). PSI-6130 had a single-ring base (cytosine), a methyl in the 2′ up position, and a fluoro in the 2′ down position. J.A. 24619, 24826. Pharmasset synthesized and tested PSI-6130 by May 2003. J.A. 20040 (504). It was the first compound made by Pharmasset that was active against

Hepatitis C. J.A. 20050–51 (544–45). PSI-6130 led to sofosbuvir, which has the same methyl and fluoro substituents as PSI-6130 but contains uracil, rather than cytosine, as its base. J.A. 19913–17, 19951 (401).

Pharmasset filed a patent application for Mr. Clark's invention in May 2003. J.A. 20042 (511–12). The application was published in January 2005. The published application, the "Clark Application," described and claimed (in 129 claims) a range of structures, including both single-ring (pyrimidine) and double-ring (purine) bases, and methods of using them for treatment of various conditions, including Hepatitis C. J.A. 23709–86. Among the many specifically described and claimed structures was PSI-6130. J.A. 23727 (application ¶ 168), 23756 (claim 26). The application issued in September 2008 as U.S. Patent No. 7,429,572, with only 19 claims, which cover PSI-6130. J.A. 29947–87.

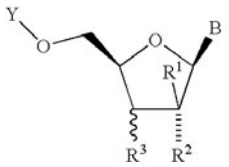
C

In February 2005, the month after the January 2005 publication of the Clark Application, Merck, through Dr. Durette, filed a narrowing amendment in the 2003 application that eventually issued as the '499 patent. J.A. 28318–21. Merck canceled all pending claims and substituted two narrower claims (claims 53 and 54). The claims issued as claims 1 and 2 of the '499 patent on September 12, 2006.

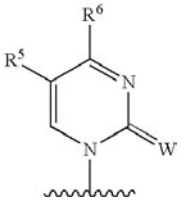
Claim 1 of the '499 patent is representative. It states:

> 1. A method of treating hepatitis C virus (HCV) infection comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of structural formula III, or a pharmaceutically acceptable salt or acyl derivatives thereof,

(III)



wherein B is



W is O or S;

Y is H, C_1-10 alkylcarbonyl, $P_3O_9H_4$, $P_2O_6H_3$, or $P(O)R^9R^{10}$;

R^1 is CF_3, or C_{1-4} alkyl and one of R^2 and R^3 is OH or C_{1-4} alkoxy and the other of R^2 and R^3 is fluoro;

R^6 is H, OH, SH, NH_2, C_{1-4} alkylamino, di(C_{1-4} alkyl)amino, C_{3-6} cycloalkylamino, halogen, C_{1-4} alkyl, C_{1-4} alkoxy, or CF_3;

R^5 is H, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-4} alkylamino, CF_3, or halogen; and

R^9 and R^{10} are each independently hydroxy, $OCH_2CH_2SC(=O)$t-butyl, or $OCH_2O(C=O)$iPr.

'499 Patent, col. 137, line 2 through col. 138, line 16. Merck seems to accept that the '499 patent claims include PSI-6130. Merck Br. 18. Gilead characterizes the claim as "target[ing]" PSI-6130. Gilead Br. 16, 18.

We will elaborate below on the connection of Pharmasset's work on PSI-6130 with Dr. Durette, Merck, and Merck's 2005 claim amendments for what became the '499 patent. Those connections, together with Dr. Durette's eventual testimony about those connections, came to be the basis of the district court's ultimate determination

that Merck had unclean hands, precluding patent enforcement against Gilead.

D

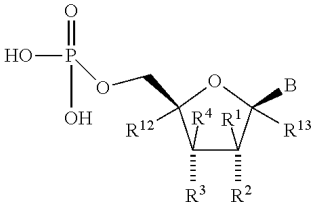
In February 2007, a few months after the '499 patent issued, Merck's Dr. Durette filed the application that ultimately issued as the '712 patent. J.A. 24147. The original claims of that application were quite different from PSI-6130, J.A. 24336–41, and Dr. Durette immediately substituted two claims that were closer, but that the parties here do not contend covered PSI-6130, J.A. 24150–53. It appears undisputed that after April 2007 Dr. Durette did not participate in prosecuting the '712 application. Merck Br. 18; *see e.g.*, J.A. 24369–70 (April 2007 filing by the attorney who took over responsibility for prosecuting the application from Dr. Durette).

In 2010, Pharmasset published an article in the Journal of Medicinal Chemistry describing "sofosbuvir" (PSI-7977) to treat HCV. J.A. 31990–2007. In 2011, attorney Jeffrey Bergman took over prosecuting the '712 application for Merck. J.A. 32383. Merck amended the '712 application to include new claims. J.A. 24394–410. The '712 patent issued on July 9, 2013.

Claim 1 of the '712 patent is representative. It states:

1. A compound having the formula:

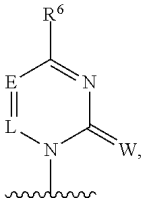
(VIII)



or a pharmaceutically acceptable salt thereof,

wherein:

B is:



L is CH or N;

E is N or CR^5;

W is O or S;

R^1 is C_{2-4} alkenyl, C_{2-4} alkynyl, or C_{1-4} alkyl optionally substituted with amino, hydroxy, or 1 to 3 fluorine atoms; R^3 is hydroxy or C_{1-4} alkoxy; and R^2 is selected from the group consisting of

halogen,

C_{1-4} alkyl, optionally substituted with 1 to 3 fluorine atoms,

C_{1-10} alkoxy, optionally substituted with C_{1-3} alkoxy or 1 to 3 fluorine atoms,

C_{2-6} alkenyloxy,

C_{1-4} alkylthio,

C_{1-8} alkylcarbonyloxy,

aryloxycarbonyl,

azido,

amino,

C_{1-4} alkylamino, and

di(C_{1-4} alkyl)amino;

R^4 and R^6 are each independently H, OH, SH, NH_2, C_{1-4} alkylamino, di(C_{1-4} alkyl)amino, C_{3-6} cycloalkylamino, halogen, C_{1-4} alkyl, C_{1-4} alkoxy, or CF_3;

> R^5 is H, $C_{1\text{-}6}$ alkyl, $C_{2\text{-}6}$ alkenyl, $C_{2\text{-}6}$ alkynyl, $C_{1\text{-}4}$ alkylamino, CF_3, or halogen;
>
> R^{12} and R^{13} are each independently hydrogen or methyl.

'712 Patent, col. 143, lines 2–54. The parties characterize these claims, which embrace a single-ring base with methyl up and fluoro down at the 2′ position in the sugar, as covering metabolites of sofosbuvir, produced in the body after administration of sofosbuvir. Merck Br. 18; Gilead Br. 19. As noted above, in this case Gilead ultimately stipulated to infringement of the asserted claims of the '712 and '499 patents based on the district court's claim construction.

II

After a bench trial on Gilead's equitable defenses, the district court held that Merck could not enforce the two patents at issue here against Gilead because its conduct gave it unclean hands. *Gilead*, 2016 WL 3143943, at *39. The court rested that determination on its findings of both pre-litigation business misconduct and litigation misconduct attributable to Merck. *Id.* at *27. The court balanced the equities and applied its determination to both patents. *Id.* at *37–39.

The Supreme Court has articulated the governing legal standard. In *Keystone Driller Co. v. General Excavator Co.*, the Court explained that a determination of unclean hands may be reached when "misconduct" of a party seeking relief "has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation," *i.e.*, "for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court." 290 U.S. 240, 245 (1933). In *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, the Court stated that the doctrine "closes the doors of a

court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant," and requires that claimants "have acted fairly and without fraud or deceit as to the controversy in issue." 324 U.S. 806, 814–15 (1945). The Court added that the doctrine "necessarily gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant." *Id.* at 815; *see also Northbay Wellness Grp., Inc. v. Beyries*, 789 F.3d 956, 960 (9th Cir. 2015) (explaining need for equitable balancing).[2]

Merck invokes the term "material" to describe the kind of connection between misconduct and the litigation that the Supreme Court's formulations require. But Merck has not identified how that term helpfully refines the Supreme Court's standard in a way that is relevant to this case. *See* Merck Br. 39–43. For purposes of this case, which involves clear misconduct in breaching commitments to a third party and clear misconduct in litigation, the "immediate and necessary relation" standard, in its natural meaning, generally must be met if the conduct normally would enhance the claimant's position regarding legal rights that are important to the litigation if the impropriety is not discovered and corrected. Merck cites no authority holding such misconduct to be outside *Keystone*'s scope. Nor does Merck deny that the standard can cover at least some misconduct that ultimately fails to affect the litigation, as when it is discovered before it

---

[2] The doctrine of unclean hands is not patent-specific, but its application to patents has some distinctive features affecting the patent system. We need not choose between Ninth Circuit and Federal Circuit law on the subject here. The parties have identified no differences pertinent to this case, and they have not identified what law they contend controls in this appeal.

bears fruit, as long as its objective potential to have done so is sufficient.

Significantly, this is not a case in which it is clear that the identified misconduct could not reasonably have enhanced the claimant's legal position as to either the creation or the enforcement of the legal rights at issue. Nor is this a case involving alleged deficiencies in communications with the PTO during patent prosecution, for which this court's inequitable-conduct decisions, *e.g.*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), set important limits on conclusions of unenforceability through that doctrine.[3] In the circumstances present in this case, we see no genuine issue about the governing legal standard, but only its application.

We conclude that the district court made findings that have adequate support in the evidence and that, taken together, justify the equitable determination of unclean hands as a defense to enforcement in this case. In so concluding, we apply deferential standards of review, as Merck itself urges. We review the district court's ruling for abuse of discretion, which means that we review factual findings only for clear error. *See* Merck Br. 37 (citing *Northbay*, 789 F.3d at 959).

Our decision rests only on the totality of the evidence-supported misconduct we summarize, not individual elements alone and not every finding of the district court. We are conscious, as any court presented with a defense

---

[3] We therefore have no occasion in this case to consider issues that may arise in seeking to ensure that the unclean-hands doctrine operates in harmony with, and does not override, this court's inequitable-conduct standards governing unenforceability challenges based on prosecution communications with the PTO.

of unclean hands must be, both of the judicial system's vital commitment to the standards of probity protected by the doctrine and, also, of the potential for misuse of this necessarily flexible doctrine by parties who would prefer to divert attention away from dry, technical, and complex merits issues toward allegations of misconduct based on relatively commonplace disputes over credibility. Having those considerations in mind, we do not find a sufficient basis to set aside the district court's determination of unclean hands under the applicable deferential standard of review.

A

The district court found, with adequate evidentiary support, two related forms of pre-litigation business misconduct attributable to Merck. First, Dr. Durette learned of Pharmasset's PSI-6130 structure by participating, at Merck's behest, in a conference call with Pharmasset representatives, violating a clear "firewall" understanding between Pharmasset and Merck that call participants not be involved in related Merck patent prosecutions. Second, Merck continued to use Dr. Durette in the related patent prosecutions even after the call. The district court also found, with adequate evidentiary support, a direct connection to the ultimate patent litigation involving sofosbuvir. Thus, Dr. Durette's knowledge of PSI-6130, acquired improperly, influenced Merck's filing of narrowed claims, a filing that held the potential for expediting patent issuance and for lowering certain invalidity risks. Those findings establish serious misconduct, violating clear standards of probity in the circumstances, that led to the acquisition of the less risky '499 patent and, thus, was immediately and necessarily related to the equity of giving Merck the relief of patent enforcement it seeks in this litigation.

1

The business misconduct found in this case grows out of Merck's dealings with Pharmasset. In the early 2000s, the two companies discussed possible business arrangements that would include work on "discovery and development of antiviral agents against . . . hepatitis C virus." *Gilead*, 2016 WL 3143943, at * 6. They entered into a non-disclosure agreement in January 2001. *Id.*

In September 2003, Pharmasset gave Merck certain information about Pharmasset's NS5B Nucleoside Inhibitor, *i.e.*, PSI-6130. *Id.*; J.A. 32161–81. In October 2003, the companies signed a Material Transfer Agreement under which Pharmasset would give Merck the "Pharmasset HCV NS5B Nucleoside Inhibitor" for Merck to evaluate. *Gilead*, 2016 WL 3143943, at *7; J.A. 30077–83. The Agreement allowed Merck to test PSI-6130 as long as it did not try to discern the compound's chemical structure. *Gilead*, 2016 WL 3143943, at *7; J.A. 30078 ¶ 3.1.

In January 2004, Merck asked Pharmasset to furnish more information to a "firewalled" Merck medicinal chemist—meaning that the chemist was "firewalled" from Merck's own Hepatitis C program. *Gilead*, 2016 WL 3143943, at *7–8; J.A. 32183–86. Pharmasset agreed to provide information to Merck's chemist, Dr. Ashton, on the conditions that the information was subject to the 2001 non-disclosure agreement and, what is critical here, that it was to be shared only on a "'fire walled' basis." J.A. 22921–22; *Gilead*, 2016 WL 3143943, at *7–8. In February 2004, Merck's "firewalled" chemist determined that "PSI6130 and its relatives represent a potentially good fit with Merck's existing anti-HCV portfolio arising from the Isis collaboration." J.A. 22918–19.

Merck and Pharmasset then scheduled, for March 17, 2004, a conference call during which Pharmasset would disclose the structure of PSI-6130. J.A. 23706–07; *see Gilead*, 2016 WL 3143943, at *8. Merck planned to have

Dr. Durette, Merck's patent prosecutor for what became the '499 patent, "view the structure" during the call. J.A. 23706–07; *Gilead*, 2016 WL 3143943, at *8; *see also* J.A. 19945 (375) (Dr. Durette's supervisor asked him to participate in the call). The district court found that Dr. Durette knew before the call "that any information he learned about Pharmasset's PSI-6130 nucleoside analog compound would overlap with the subject matter of his patent prosecution docket for Merck, thereby creating a conflict." *Gilead*, 2016 WL 3143943, at *9.

On the March 17, 2004 call, before disclosing the compound's structure, Pharmasset confirmed the importance of the firewall to it by asking whether the two participating Merck employees (Dr. Durette and Dr. Pon) were within the firewall separating Merck call participants from related Merck HCV patenting efforts. *Id.*; J.A. 31544–45; J.A. 19947 (382). At some point in the call, the Merck participants said that they were within the firewall. *Gilead*, 2016 WL 3143943, at *9–10; J.A. 31544–45; J.A. 19960 (435). Pharmasset's notes from the call, however, also indicate some disclosure by Dr. Durette of a conflict issue for him: "It's a problem for Phil Durette; he needs to have a conversation with his supervisor; 'seems quite related to things that I'm involved with.' . . . [H]e is personally conflicted; not the company." J.A. 31545; *see Gilead*, 2016 WL 3143943, at *9–10. The PSI-6130 structure was disclosed during the call. *Id.* at *9.

After the March 17, 2004 call, Dr. Durette stopped participating in the work of the Merck team dealing with Pharmasset. J.A. 19944 (373). But Merck kept him working as the prosecuting attorney for its patent applications related to nucleosides that inhibit Hepatitis C virus replication. *Gilead*, 2016 WL 3143943, at *10 ("Instead of withdrawing from prosecution, Dr. Durette continued to prosecute Merck's HCV patent applications and write new claims that targeted Pharmasset's work."). The court found that neither Merck nor Dr. Durette

provided any explanation as to why he was not removed from further prosecution of the Merck patent applications. *Id.*

Those facts support the district court's findings of serious business misconduct. Merck sent Dr. Durette to participate in the March 2004 call despite the clear firewall and the fact that "Merck . . . knew that Pharmasset's compound was an NS5B polymerase inhibitor just like its own compounds from the Merck-Isis collaboration." *Id.* at *28. "Dr. Durette's involvement with Merck's HCV patents violated the understanding the parties had about their firewall obligations, which excluded anyone involved with Merck's internal HCV program." *Id.* And after the call, it was "wrong for Merck to allow Dr. Durette to continue to prosecute" the Merck applications: he continued prosecution of the application that became the '499 patent, and in 2007 he filed (and immediately amended) the application that became the '712 patent. *Id.*[4]

---

[4] The court added that Merck's own "corporate policy forb[ade] Merck's patent prosecutors from participating in licensing discussions in an area related to their prosecution work." *Id.* at *9 (citing J.A. 22341 (38–39)); *see id.* at *28; J.A. 22374 (170–71). That policy, as we note below, confirms the connection between (a) Merck's patent prosecutor learning the structure of PSI-6130 during the March 2004 call and (b) Merck's patenting and the resulting litigation. To the extent that the district court suggested that the violation of Merck's internal policy was an independent basis for finding wrongful conduct, even apart from the violation of the firewall understanding, we see no basis for such a suggestion. A patent-obtaining firm may legitimately have such a policy simply to avoid having its later litigation position weakened by exposure to information gained from licensing discussions. Violation of such a policy would be a wrong to the firm but not

2

The district court found, with sufficient basis, that the wrongful business conduct had the required connection to this patent litigation. *Id.* at *29. As laid out above, in February 2005, a month after the publication of Pharmasset's Clark Application, Dr. Durette amended the Merck application that ultimately issued as the '499 patent by canceling the broad genus claims and substituting claims that narrowed the scope to a subgenus focused on the key features of PSI-6130. *Id.* at *11. The district court found that "Dr. Durette would not have written new claims to cover PSI-6130 in February 2005 but for his improper participation on the March 17, 2004 patent due diligence call and learning the structure of PSI-6130 ahead of the structure being published." *Id.*

Given that Dr. Durette learned of the PSI-6130 structure in March 2004 (as is now conceded), the district court could readily find that his knowledge from the call played a significant role in his actual process of decision-making that led him to file claims focusing on that and similar structures. Dr. Durette admitted during his deposition that participation in the March 2004 call, which he at the time denied, "would have tainted [his] judgment as to what claims to pursue in the Merck/Isis collaboration." J.A. 22341 (38). The timing of Merck's February 2005 amendment, which occurred just one month after the structure of PSI-6130 was published in January 2005, supports the inference, as the district court put it, that Merck was deliberately "wait[ing]." *Gilead*, 2016 WL 3143943, at *11 ("Dr. Durette waited to amend the claims . . . until Clark application was published"). Dr. Durette provided support for the inference of a taint when

---

to the potential licensee, or the judicial system, in the absence of other understandings, such as the firewall understanding here.

he stated in his deposition that failing to keep participants in the March 2004 call separate from the patent prosecutors "could raise issues down the road on the patent that would issue based on the attorneys prosecuting of those patents." J.A. 22374 (171).[5]

The additional finding that Dr. Durette would not otherwise have made the February 2005 amendment is not clearly erroneous. Dr. Durette's testimony at his deposition greatly downplayed the role of the sole prominent candidate for an independent cause of the February 2005 amendment, namely, the January 2005 Clark Application. In doing so, Dr. Durette gave testimony that is capable of being read as suggesting that the Clark Application alone would not have led him to amend the claims. J.A. 22344–46. Significantly, Merck did not present evidence that would compel a finding, or even meaningfully argue for a finding, that even if Dr. Durette personally had not made the February 2005 amendment, others at Merck lacking the earlier knowledge of PSI-6130 would have done something equivalent so as to break any causal connection between the business misconduct and the patent-rights benefits associated with the amendment. *See* Defs.' [Proposed] Findings of Fact and Conclusions of Law Regarding Gilead's Equitable Defenses, *Gilead Scis., Inc. v. Merck & Co., Inc., et al.*, Case No. 5:13-cv-04057-

---

[5] The timing of the amendment undermines a different, but ultimately immaterial, finding of the district court—that Merck violated the non-disclosure agreement with Pharmasset. *E.g.*, *Gilead*, 2016 WL 3143943, at *10, *27, *29. The only identified forbidden use of information covered by the agreement—Dr. Durette's February 2005 claim amendment focusing on PSI-6130—did not occur until the information was publicly disclosed in the Clark Application. The disclosure ended the information's protection by the agreement. J.A. 32152 ¶ 3(ii).

BLF, D.I. 407 at 27–28 (¶¶ 113–15) (N.D. Cal. Apr. 22, 2016) (brackets in document name in original).

Although Merck stresses that even the pre-February 2005 claims *included* PSI-6130 and similar structures, Dr. Durette explained the benefits to a patentee's legal position from a narrowing amendment of this sort. "It would expedite prosecution." J.A. 22347 (62); *see* J.A. 19945 (376) ("the Examiner would have less subject matter to . . . search"). Relatedly, "limiting the scope" of the claims would mean "fewer opportunities for prior art to . . . present an issue of patentability" under 35 U.S.C. §§ 102 and 103. J.A. 22347 (62). That would be so during prosecution and also in a litigation challenge. And a narrowing amendment can reduce a patentee's risk on other invalidity issues, such as the risk that breadth can create under the requirement that the "full scope" of a claim be enabled. *See*, *e.g.*, *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1375 (Fed. Cir. 2017). Such risks can be reduced even if, as here, the resulting claim still covers a large, though less large, number of compounds.

In these circumstances, we see no error in the district court's determination that the pre-litigation business misconduct we have summarized was immediately and necessarily related to the equity of Merck's obtaining enforcement of its patent in this litigation.

B

The district court also found, with adequate evidentiary support, essentially two forms of litigation misconduct involving Dr. Durette as a witness and attributable to Merck. First, in his deposition, where he appeared partly as Merck's corporate witness on issues to which the March 2004 call was relevant, Dr. Durette gave testimony that he did not participate in the March 2004 call—testimony that was later conceded to be false and that the court found to be intentionally so. Second, both in the deposition and then at trial, Dr. Durette, in support of

Merck's validity positions, gave testimony about the role the January 2005 Clark Application played in Dr. Durette's filing of the February 2005 amendment that the court found so incredible as to be intentionally false. The intentional testimonial falsehoods qualify as the kind of misconduct that can, in these circumstances, support a determination of unclean hands. The court also found, with adequate evidentiary support, that the false testimony, in both respects, bore on the origin story of the February 2005 amendment, 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.

1

In 2015, during the discovery phase of this case, Merck designated Dr. Durette as its corporate witness under Fed. R. Civ. P. 30(b)(6) on certain issues, even though he had retired from Merck in 2010. *Gilead*, 2016 WL 3143943, at *12; J.A. 22335 (15–16), 22377 (181–84); J.A. 22214. In particular, Merck designated him to represent the corporation regarding the prosecution of the application that issued as the '499 patent. *Gilead*, 2016 WL 3143943, at *12; J.A. 22214–16 (¶¶ 15–21). Dr. Durette was not Merck's representative regarding the 2007 application that issued as the '712 patent, *id.* (¶¶ 20–21), though he filed that application.

On May 8, 2015, Gilead deposed Dr. Durette in both his personal and his representative capacities. J.A. 22331–83. Near the end of the deposition, Dr. Durette stated that his answers regarding the '499 patent would not differ according to the capacity in which he was testifying. J.A. 22377 (183–84). Merck's counsel represented both Merck and Dr. Durette at the deposition. *Gilead*, 2016 WL 3143943, at *12; J.A. 22333 (7). Dr. Durette testified that, in preparation for his deposition, he met with Merck's outside counsel for six to seven hours on

each of two days and spent eight to ten additional hours on his own. *Gilead*, 2016 WL 3143943, at *12; J.A. 22334 (10–11).

Dr. Durette gave two different answers about whether he participated in the March 17, 2004 call with Pharmasset. Near the start of the deposition, J.A. 22336 (19), and toward the end of the deposition, J.A. 22374–75 (172–73), he repeatedly said that he did not recall participating. But during a portion of the deposition not long after it started (corresponding to about nine pages of the transcript), Dr. Durette repeatedly stated, definitively, that he did not participate. J.A. 22339–41 (30–38); *see*, *e.g.*, J.A. 22339 (31) ("sure" that he was not involved in any discussion with Pharmasset in March 2004 where he was told of PSI-6130's structure); J.A. 22341 (37) ("I never participated in a due diligence meeting on March 17 . . . . I did not participate in any meeting of due diligence on March 17"). One reason that he was so sure, he said, was that it would have violated Merck policy to allow his participation and to keep him on the related patent prosecutions. J.A. 22341 (38–39), 22373–74 (168–72); 22382 (202). On the basis of those definitive denials, the district court found that "[w]hen asked about the March 17, 2004, call at the deposition, Dr. Durette denied ever having been on such a call. When asked whether he was sure that he was not on the March 17, 2004, call, Dr. Durette unequivocally answered yes." *Gilead*, 2016 WL 3143943, at *12.

That denial of participation was false, as came to be undisputed by Merck, and acknowledged by Dr. Durette, at trial. *See id.* at *14; J.A. 19937–38 (344–47). The district court found the falsity of the deposition denial of participation to be intentional. *Gilead*, 2016 WL 3143943, at *29–31. We cannot deem that state-of-mind finding to be clearly erroneous, given the district court's direct observation of Dr. Durette at the trial; the documentary evidence of his participation, including pre-participation emails (some that he reviewed during his deposition); and

the sufficiently supported findings that aspects of his testimony were "inconsistent, contradictory, and untruthful." *Id.* at *29; *see id.* at *12–16.

Regarding the role of the January 2005 Clark Application in Dr. Durette's decision to file new claims in February 2005, Dr. Durette downplayed that role in ways that the district court reasonably found incredible. Most starkly, at his deposition, he stated that he simply did not recall whether he saw the Clark Application before filing the February 2005 amendment and hence could not state that it played a role in the amendment. *See id.* at *16; J.A. 22343–44 (48–52), 22348–49 (66–69).

Before trial, the court denied Merck's motion to exclude all evidence post-dating 2002 from the jury trial regarding invalidity—a denial not separately challenged as incorrect here. J.A. 19220–22 (denying exclusion because the information was relevant to invalidity issues). Once that motion was denied, Merck itself indicated that it would call Dr. Durette as a witness. J.A. 19404 (42) (Merck explaining that Dr. Durette is "planning to come and testify in our case"). Gilead then took the opportunity to call Dr. Durette first, cross-examining him before Merck conducted its direct examination regarding validity issues, including the origin of the February 2005 amendment.

In his trial testimony, Dr. Durette continued to downplay the role of the Clark Application, though to a lesser extent than during the deposition. *See Gilead*, 2016 WL 3143943, at *16. Explaining his decision to file the amendment, he stressed that he narrowed the claims to "expedite" examination, *id.* at *17; J.A. 19944–45 (371–75), and said that "he amended the '499 claims to focus on 'get[ting] allowance on the subject matter that was most important to the [Merck-Isis] collaboration,'" *Gilead*, 2016 WL 3143943, at *17; J.A. 19952 (404). He also testified, however, that he had "bec[o]me convinced that it was the

publication of the [Clark] [A]pplication that led [him] to reexamine" the prosecution of the application that became the '499 patent and file the February 2005 amendment. J.A. 19949 (390–91); *Gilead*, 2016 WL 3143943, at *16. The district court could reasonably find that, by stating that it was surrounding circumstances that so convinced him, not his own recollection, Dr. Durette was continuing to minimize the actual role of the Clark Application and what he learned in the March 2004 call, *i.e.*, the role of Pharmasset's work, in his amendment decision for Merck. As already noted above, the court reasonably found that he had in mind the information he learned in the March 2004 call, that he was waiting for publication of PSI-6130's structure to avoid violating the non-disclosure agreement, and that he filed the February 2005 amendment once publication of the Clark Application occurred. In light of those findings, it was also reasonable for the district court to find Dr. Durette's trial testimony a misleading effort to downplay the role of Pharmasset's work in the February 2005 amendment.

The district court found that "Dr. Durette's changing and evasive explanations for why he narrowed the claims undermine his testimony" and that "his testimony [was] not credible." *Id.* at *17. It found that Dr. Durette's testimony that "he amended the '499 claims to focus on 'get[ting] allowance on the subject matter that was most important to the [Merck-Isis] collaboration' is contrary to the evidence and is not credible because Merck never tested any of the claimed compounds" until after the Clark Application was published. *Id.* The testimony downplaying the role of Pharmasset's work—published in the Clark Application, first disclosed to Dr. Durette in March 2004—the court found "not credible" and "false." *Id.*

2

The district court properly charged Merck with the consequences of the testimony, at the deposition and at the trial, that the court found to be intentionally false. *Id.* at *29 ("[T]he record shows that . . . [Dr. Durette's] testimony was sponsored by Merck."). As already noted, not only did Merck's counsel appear as counsel for Dr. Durette at his deposition, and prepare him for it, but Dr. Durette was Merck's official corporate representative on matters (the origin of the '499 patent) to which the testimony at issue was relevant. As also already noted, Dr. Durette appeared at trial after Merck indicated that it was going to call him to testify about invalidity matters, to which the testimony at issue here had been held relevant.

The testimony, relevant to issues in the case and reasonably found to be intentionally false, had an immediate and necessary relation to the equity of the patent-enforcement relief Merck seeks in this litigation. The district court held that the origin of the February 2005 amendment, and hence Dr. Durette's testimony about that, was relevant to the invalidity issues to be tried. *Id.* at *14 ("At trial, Dr. Durette provided key testimony for Merck on validity issues, including written description of the '499 Patent."); *id.* at *32 (determining that the testimony was "directed at and supported Merck's validity arguments, and went to the heart of significant issues in this case"). The verdict form made explicit that lack of written description and lack of enablement were tied to the defense of "derivation from Jeremy Clark" (the Pharmasset inventor of PSI-6130)—the latter to be addressed only if the jury found either lack of an adequate written description or lack of enablement. J.A. 21066–75. Merck's own policy of separating patent prosecutors from discussions like the ones held with Pharmasset is confirmation that Merck recognized, as Dr. Durette testified, that the origin of patent claims could matter in eventual

litigation over those claims. *See* J.A. 22341 (39–40). In this case, downplaying the role of the Clark Application (and the March 2004 call) naturally served to aid Merck's case that it did not derive the claimed inventions from Pharmasset's Jeremy Clark. In these circumstances, the district court could reasonably determine that the testimony at issue here held a significant potential to give Merck an advantage in the litigation, satisfying the *Keystone* standard.

C

We see no reversible error in the district court's balancing of the equities. *Gilead*, 2016 WL 3143943, at *37–39. As to the '499 patent, the equity balance follows directly from the determinations already described: the misconduct leading to the February 2005 amendment and the misconduct involved in the litigation defense of the resulting patent claims. On appeal, we have relied on a more limited set of wrongful conduct than recited in the district court's opinion, *see supra* nn.4–5, but we do not think that the equitable balance is altered by that narrowing. The conduct we have affirmed as wrongful is so clearly the core of the district court's analysis that we have no doubt that the equitable balancing by the district court would have been the same if it had limited its wrongful-conduct findings to those we have recited. On these facts, there is no abuse of discretion.

As the district court recognized, the question for the '712 patent is closer, but we also see no abuse of discretion in the district court's ultimate conclusion that the unclean hands defense extends to that patent as well. The district court connected the '712 patent to one portion of Merck's improper conduct: once Dr. Durette improperly learned PSI-6130's structure through participating in the March 2004 call at Merck's behest, Merck kept him in his patent-prosecution role—which, as noted, included filing the 2007 application that issued as the '712 patent, as well as

the initial substitute claims, after the (tainted) '499 patent had already issued. *Id.* at *10–11. While the district court said that its "finding of improper business conduct related to the March 2004 call was not considered by the Court in determining whether unclean hands prevented enforcement of the '712 Patent," *id.* at *36 n.5, that statement does not refer to the retention of Dr. Durette as the lead prosecutor of HCV applications, including the one that eventually issued as the '712 patent, and the court relied on that improper retention. *E.g.*, *id.* at *10–11. The district court relied on the connection between the two patents: "Dr. Durette played a key role in the prosecution of both the '499 and '712 Patents. He was responsible for filing the application that eventually matured as the '712 Patent and this application shares the same specification as the '499 Patent." *Id.* at *36.

More importantly, the district court, turning from the business misconduct to the litigation misconduct, reasonably concluded that "Merck's litigation misconduct infects the entire lawsuit, including the enforceability of the '712 Patent." *Id.* at *32. "[T]he untruthful testimony offered by Dr. Durette in his deposition and at trial was not incidental, but rather was directed at and supported Merck's validity arguments, and went to the heart of significant issues in this case." *Id.* The validity issues were largely the same for the two patents, focused on the common specification of the two patents and how that specification bore on written-description support for and enablement of claims in the two patents that have closely related scope. As indicated above, the jury verdict form tied both of those issues, for both patents, to the question of "derivation from Jeremy Clark" (the Pharmasset inventor of PSI-6130, disclosed in March 2004 and published in the Clark Application). J.A. 21066–75. Thus, the litigation misconduct "infected this entire case, covering both patents-in-suit." *Gilead*, 2016 WL 3143943, at *36. We

conclude that, contrary to Merck's suggestion, the district court set forth a sufficient explanation of the '712 patent's connection to Merck's misconduct.

Merck argues that even where there is misconduct related to one patent, "that does not defeat claims under another patent simply because they were 'brought . . . in the same lawsuit.'" Merck Br. 69. We agree; but the assertion does not undermine the district court's ruling here. The Supreme Court's decisions in *Keystone* and *Precision Instruments*, dealing with findings of unclean hands when multiple patents were at issue in the litigation and the alleged misconduct related to a subset of the patents, are instructive. In both cases, the Supreme Court applied the finding of unclean hands to all of the patents. *Keystone*, 290 U.S. at 246–47; *Precision Instruments*, 324 U.S. at 819. The district court in the present case had sufficient reason to find that both patents were tainted by the patentee's misconduct, especially the litigation misconduct. Thus, we see no abuse of discretion with respect to either the '499 patent or the '712 patent.

III

Because the district court did not abuse its discretion in applying the doctrine of unclean hands, we affirm.

Costs awarded to Gilead.

AFFIRMED