United States Court of Appeals for the Federal Circuit

FERRING B.V., FERRING INTERNATIONAL CENTER SA, FERRING PHARMACEUTICALS INC.,
Plaintiffs-Appellants

v.

ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, SEYMOUR H. FEIN, RONALD V. NARDI,
Defendants

SERENITY PHARMACEUTICALS CORPORATION, SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC,
Defendants-Appellees

2020-1098

Appeal from the United States District Court for the Southern District of New York in No. 1:12-cv-02650-PKC, Senior Judge P. Kevin Castel.

Decided: November 10, 2020

MARY W. BOURKE, Womble Bond Dickinson (US) LLP, Wilmington, DE, argued for plaintiffs-appellants. Also represented by KRISTEN HEALEY CRAMER, DANA KATHRYN SEVERANCE; JOHN W. COX, JOSHUA A. DAVIS, Atlanta, GA.

SARAH ELIZABETH SPIRES, Skiermont Derby LLP, Dallas, TX, argued for defendants-appellees. Also represented by PAUL SKIERMONT.

Before O'MALLEY, REYNA, and CHEN, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

When a district court enters judgment at the summary judgment stage, it is at times difficult to discern on appeal whether the nonmovant failed to raise sufficient factual disputes to prevent judgment or the court acted despite such disputes. Where the matter adjudged is a quintessentially fact-laden one, such as the equitable matter at issue here, it is especially important that we guard against a rush to judgment. We conclude that such a rush to judgment happened here. Accordingly, we vacate and remand for further development of the record and a later-stage resolution of whether Appellants are equitably estopped from seeking to correct inventorship of the patents at issue in these proceedings.

BACKGROUND

I

Seymour Fein worked as a consultant for Ferring Pharmaceuticals Inc. from December 1998 until the company terminated his consulting agreement on November 7, 2002. While Fein was consulting for Ferring Pharmaceuticals Inc., he became involved in a Ferring[1] project involving desmopressin. Desmopressin is a synthetic analog of the naturally occurring hormone arginine vasopressin, which

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[1] We refer collectively to Appellants Ferring B.V., Ferring International Center SA, and Ferring Pharmaceuticals Inc. collectively as "Ferring."

regulates the body's retention of water. Among other things, desmopressin is used to treat nocturia (disruption of nighttime sleep due to the need to urinate).

As early as 1999, Ferring scientists Jens Peter Nørgaard and Thomas Senderovitz were involved in a clinical trial studying the bioavailability and pharmacokinetics of desmopressin. The trial demonstrated that orally administered desmopressin had a duration of action in the range of six hours. A 2000 presentation authored by Nørgaard acknowledged low bioavailability and high variation of absorption as known problems with using desmopressin to treat nocturia, hypothesized that "[t]he need for high plasma levels of desmopressin" to achieve an antidiuretic effect "is overestimated," and suggested that increased desmopressin doses may pose a safety issue. S.A. 4431–32, 4435, 4455.[2] Ferring initiated a follow-on study in October 2000, shepherded by Nørgaard and Senderovitz, to model the desmopressin dose-response relationship. The results of the follow-on study supported their hypothesis that low doses and plasma concentrations of desmopressin could be clinically effective.

As Fein recalls events, Ronald V. Nardi, a Ferring employee, approached him in 2001 seeking assistance with a Ferring project involving clinical studies using a desmopressin oral tablet to treat adult nocturia. Nardi sought ideas from Fein regarding how to minimize the high incidence of hyponatremia Ferring had observed in its clinical trials. Hyponatremia is a condition in which sodium levels in the blood fall to abnormally low levels, and can lead to seizures, cardiac arrhythmias, cerebral edema, and death. Fein recounts that, in August 2001, he suggested to Nardi

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[2] "S.A." refers to the corrected supplemental appendix filed by the parties on September 17, 2020. Corrected Supplemental Appendix, *Ferring B.V. v. Allergan, Inc.*, No. 20-1098 (Fed. Cir. Sept. 17, 2020), ECF No. 39.

that hyponatremia could be reduced or avoided by using lower dosages of desmopressin than Ferring had previously tested, and that such dosages could be administered in a waterless orodispersible form (a "melt") sublingually through the mucosal membranes of the mouth to improve bioavailability of the desmopressin.

In March 2002, Nørgaard and Senderovitz began designing additional clinical studies to test a new orodispersible form of desmopressin known within Ferring as "NEWMIN." By then, a study comparing NEWMIN to Ferring's previously marketed tablet had demonstrated that the bioavailability of NEWMIN was approximately double that of the previously marketed tablet. NEWMIN's increased bioavailability "open[ed] up the possibility of studying lower doses of desmopressin than currently marketed." J.A. 3632. By April 2002, Ferring had designed a clinical study protocol, sponsored by Senderovitz and designated CS007. CS007 would investigate the pharmacokinetics and antidiuretic effect of orodispersible desmopressin tablets containing five low doses of desmopressin alongside a placebo.

In May 2002, Ferring filed Great Britain Patent Application No. GB0210397.6 covering various dosage forms of an orodispersible desmopressin formulation. Ferring's application includes a claim directed to "[a] pharmaceutical dosage form of desmopressin adapted for sublingual absorption." J.A. 286. The application does not list any inventors.

When Ferring experienced delays in production of the orodispersible tablets to be used in its CS007 study, Nørgaard and Senderovitz planned another clinical study to investigate the pharmacokinetic and antidiuretic effects of various low desmopressin doses. The study was designated CS009 and used an intravenous desmopressin formulation to approximate the CS007 orodispersible doses. Fein did not participate in the design of the CS009 clinical

study protocol. In June 2002, Fein was selected to oversee United States operations of CS009. As part of that role, Fein received via email a copy of Ferring's CS009 clinical study protocol. J.A. 3741. After reviewing the protocol, Fein suggested certain changes, including converting the original dose levels (expressed in nanograms) to doses on a per-weight basis (nanograms per kilogram) to accommodate study participants within a greater weight range.

In September 2002, Ferring filed Application No. PCT/IB02/04036 under the Patent Cooperation Treaty ("PCT"), claiming priority from Ferring's Great Britain application. Ferring's PCT application lists six inventors, including Senderovitz, Fein, and Nardi. Fein and Nardi were included as inventors based on Nardi's representation that they had conceived the sublingual route of administration. Two months later, Ferring terminated Fein's consulting agreement.

II

From November 21, 2002 to December 14, 2004, Fein's attorney, William Speranza, corresponded with Ferring regarding Fein's purportedly inventive contribution of the sublingual administration route. We refer to the letters and emails exchanged between Ferring and Speranza collectively as "the Speranza correspondence."

A letter from Speranza dated November 21, 2002 asserted that Fein invented material included in Ferring's PCT application, characterizing Fein's contribution as "a sublingual, transmucosal route of delivery which affords a number of advantages . . . including enabling the effective use of formulations having reduced concentrations of desmopressin." J.A. 531. The letter asserted that Fein had no obligation to assign to Ferring any rights in inventions Fein conceived while consulting for Ferring. Consequently, Fein would have ownership rights in any patents that may issue from Ferring's PCT application. Speranza requested that Ferring provide copies of all prosecution documents

and any documents filed in subsequent national phase applications. Ferring and Speranza then exchanged several letters regarding the events underlying Fein's contribution. In January 2003, Speranza sent Ferring another letter reiterating Fein's "ownership rights in the invention, the pending application therefor and any patents that may issue on his invention." J.A. 534. The letter renewed Speranza's request that Fein "be kept fully apprised" of the status of Ferring's PCT application. *Id.* Speranza also raised the possibility that "it may be necessary for [Fein] to take steps independent of Ferring as may be necessary to protect his interests." J.A. 534–35.

Ferring responded on April 9, 2003, advising Speranza that it had "now taken the decision to drop the feature 'adapted for sublingual administration.'" J.A. 537. Considering the prior art, Ferring found it "clear . . . that the feature does not in this context confer a delimitation i.e. novelty." *Id.* Accordingly, Ferring relayed that Fein would "not be one of the designated inventors in the modified PCT application to be filed." *Id.*

Approximately one week later, on April 17, Speranza sent an email to Ferring stating that Fein "ha[d] no fundamental problem with" Ferring's decision to omit "the feature of sub-lingual administration invented by Dr. Fein." J.A. 539. Speranza stated that "Fein also is the inventor of the associated low dosage possibilities enabled by the sublingual administration route," expressed Fein's understanding that this was not "specifically claimed in the UK application," and noted his "assum[ption] that Ferring is not pursuing that subject matter in the planned PCT filing." *Id.* The email also informed Ferring that "Fein is planning to himself proceed with pursuing patent protection covering the sub-lingual administration route and the associated low dosage possibilities enabled by same which he invented, all at his own expense going forward and with the understanding that Ferring relinquishes any ownership claims thereto." *Id.* Finally, Speranza notified

Ferring that Fein "plans to claim priority to [Ferring's] UK application," and requested that Ferring provide "the particulars of the UK filing." *Id.*

On April 29, 2003, Ferring responded, explaining that it would not pursue patent protection for the invention described by Speranza in his April 17 letter, because "[t]he low dosage possibilities enabled by the sublingual administration route are already available in the public domain." J.A. 542. Ferring noted, however, that it "cannot of course say now that Ferring will not make any claim as to ownership of any other material Dr[.] Fein may include in any patent application . . . without seeing the text." *Id.* Without "knowing what claims for novelty or inventive steps [Fein] ha[d] in mind," Ferring cautioned that it "cannot be sure that [Fein's forthcoming application] does not cover matters to which employees of the Ferring Group have contributed or regarding which Dr[.] Fein is bound to [Ferring] by terms of confidentiality." *Id.* Ferring provided Fein with the filing date and application number for its Great Britain application, but refused to provide Fein with a copy of the application, asserting that "Fein has no entitlement to the patentable subject matter disclosed therein." *Id.*

On May 6, 2003, Fein filed Application No. PCT/US2003/014463, claiming priority from Ferring's Great Britain application and listing Fein as the sole inventor. Fein's application claims low-dose pharmaceutical compositions comprising desmopressin and methods of treating various conditions with such compositions. Though some of Fein's PCT application claims recite desmopressin formulations adapted for various routes of administration, none of his PCT application claims are limited to desmopressin formulations administered sublingually.

The next day, Ferring filed a modified PCT application, which was assigned Application No. PCT/IB03/02368. Ferring's modified application claims priority from Ferring's

Great Britain application and Ferring's September 2002 PCT application and does not list Fein as an inventor or contain claims directed to sublingual administration of desmopressin. Ferring ultimately obtained U.S. Patent Nos. 7,569,429 ("the '429 patent") and 7,947,654 ("the '654 patent") claiming priority from its Great Britain application.

During 2003 and 2004, Fein conducted clinical studies related to low-dose desmopressin. Relevant here, in August 2003, Fein initiated a study designated CNF Desmo PK200301, titled "A Cross-Over Study Investigating the Antidiuretic Effects and Pharmacokinetics of Three Low Doses of Desmopressin Administered via Intravenous Infusion for 2 Hours in Over-Hydrated Healthy Non-Smoking Male and Female Volunteers." J.A. 653. Fein's CNF Desmo PK200301 used substantially the same protocol as Ferring's CS009 clinical study. *Compare* J.A. 3823–26, *with* J.A. 4153–56.

On November 12, 2003, Fein filed U.S. Patent Application No. 10/706,100 ("the '100 application") as a continuation-in-part of his May 2003 PCT application. Like Fein's PCT application, the '100 application claims low-dose pharmaceutical compositions comprising desmopressin and methods of treating various conditions with such compositions. J.A. 651. None of the '100 application claims are limited to desmopressin formulations administered sublingually. *Id.* Fein's May 2003 PCT application published on May 21, 2004. His '100 application published approximately two months later on July 15, and ultimately issued on September 21, 2010 as U.S. Patent No. 7,799,761 ("the '761 patent"). The '761 patent claims recite pharmaceutical compositions comprising varying low doses of desmopressin administered by various routes of delivery. Some dependent claims further require that the claimed desmopressin doses establish a particular desmopressin plasma/serum concentration range, or that that a particular desmopressin plasma/serum concentration range be

maintained for a specified duration. None of the claims recite pharmaceutical compositions limited to sublingual administration.

On December 9, 2004, Ferring sent Speranza a letter advising Speranza that Ferring was "truly surprised" that Fein had proceeded with his May 2003 PCT application, which "contain[s] an invention to which we believe he has no entitlement and which in particular discloses information confidential and proprietary to Ferring." J.A. 544. Ferring's letter notified Speranza that it would "take all necessary steps to protect its rights and interests but before taking formal legal action [Ferring] wish[ed] to give [Fein] an opportunity to explain himself." *Id.* Ferring further informed Speranza that if it "d[id] not receive a full and satisfactory explanation within 14 days of this letter [Ferring] will commence formal action." *Id.*

Speranza responded five days later, sending Ferring two letters on December 14. The first letter reminded Ferring that it had acknowledged Fein's intent to proceed with his own patent application. Speranza also posited three possible reasons for Ferring's assertion that Fein had "no entitlement" to the invention in his published PCT application. First, and "as would appear" from Ferring's December 9 letter, Fein's PCT "application 'discloses information confidential and proprietary to Ferring.'" J.A. 546. Second, Ferring believes "that this low dosage invention of Dr. Fein is simply not patentable because of prior art." *Id.* Third, "Fein is not the inventor of the claimed low dose invention and/or . . . Fein cannot assert ownership rights to it." *Id.* Speranza expressed his opinion that "[o]ur dealings and communications throughout 2003 made clear that Ferring made no claim to low dosage desmopressin as its invention." J.A. 546–47. Despite the earlier communications regarding claims involving the sublingual route of delivery, Speranza made no mention of the use of a sublingual route for the delivery of low dosages. To the extent Ferring's allegation referred to misuse of confidential information,

Speranza explained that "[w]hatever Ferring data is set forth in Dr. Fein's subject patent application comes solely from the text of the UK priority application filed by Ferring in May 2002, naming Dr. Fein as a co-inventor." J.A. 547. In closing, Speranza stated that he "trust[ed] this response will put this matter to rest." *Id.* "[I]n view of the fact that Ferring itself published over a year ago the allegedly 'confidential and proprietary' information to which [Ferring's] letter refers," Speranza deemed it "irresponsible for Ferring to level such serious accusations at Dr. Fein and to threaten immediate legal action based thereon." *Id.*

Speranza's second December 14, 2004, letter to Ferring focused on Ferring's allegations of misuse of confidential information. It acknowledged Ferring's "apparent concern with the content of Dr. Fein's published applications" and informed Ferring that Fein filed a continuation-in-part U.S. patent application (i.e., the '100 application) "which has since published as U.S. Patent Application Publication No. 2004/0138098, dated July 15, 2004, also directed to low dose desmopressin." J.A. 550. Speranza's letter stated that a copy of the '100 application was included as an attachment, but Ferring disputes that it ever received a copy of the '100 application. Referencing Example 8 and Figures 1–9 of the '100 application, Speranza's letter noted that the '100 application "contains data beyond that included in the original Ferring UK application," which data "did not emanate from Ferring." J.A. 551. This letter was Speranza's last communication with Ferring before Ferring filed suit in April 2012.

With his patent applications pending, Fein took steps to commercialize his invention. In 2006, Fein and Samuel Herschkowitz formed Serenity Pharmaceuticals Corporation and Serenity Pharmaceuticals, LLC to raise funds to cover the prosecution of Fein's patents and pursue clinical development. In late 2006, Fein founded Reprise Biopharmaceutics, LLC, a holding company having five members. Fein transferred to Reprise his intellectual property rights

related to his claimed desmopressin invention. We refer to Reprise, Serenity Pharmaceuticals Corporation, and Serenity Pharmaceuticals, LLC collectively as "Serenity."

In May 2007, Fein filed U.S. Patent Application No. 11/744,615 ("the '615 application") as a divisional of the '100 application. The '615 application published on November 15, 2007 and matured into U.S. Patent No. 7,405,203 ("the '203 patent") on July 29, 2008. The '203 patent claims recite methods of administering low doses of desmopressin by various routes of delivery to establish various desmopressin plasma/serum concentration ranges. Some claims further require that the plasma/serum concentration range be maintained for a specified duration. None of the claims recite sublingual administration of desmopressin.

In July 2008, Fein filed U.S. Patent Application No. 12/173,074 ("the '074 application") as a continuation of the '615 application. The '074 application published on January 1, 2009 and issued as U.S. Patent No. 7,579,321 ("the '321 patent") on August 25, 2009. The independent claims of the '321 patent recite methods of administering low doses of desmopressin by various routes of delivery to produce an antidiuretic effect or a particular urine osmolality in a patient. Several claims of the '321 patent further require that the urine osmolality or antidiuretic effect be maintained for a specified duration. Again, none of the claims recite sublingual administration of desmopressin. We refer to the '203 patent, '761 patent, and '321 patent collectively as "the Fein patents."

By the end of 2008, Fein had conducted Phase I and Phase II clinical studies of a low-dose desmopressin intranasal spray adapted for transmucosal delivery. Fein proceeded with Phase III clinical trials in 2009 and 2010. On March 31, 2010, Serenity Pharmaceuticals, LLC and Reprise entered into agreements with Allergan Sales, LLC, Allergan USA, Inc., and Allergan, Inc. (collectively, "Allergan") to develop and commercialize a low-dose

desmopressin intranasal spray, assigning all of their desmopressin intellectual property rights to Allergan. As part of the agreements, Reprise and Serenity Pharmaceuticals, LLC warranted that there was no threat of litigation from any third party regarding the Fein patents. Allergan made a $43 million up-front payment to acquire the desmopressin intellectual property rights.

On October 12, 2010, Ferring's counsel filed a request for reexamination of Fein's '203 patent, arguing that the prior art rendered the independent claims anticipated or obvious. The U.S. Patent and Trademark Office ("USPTO") rejected Ferring's request for reexamination of the '203 patent on January 19, 2011.

III

On April 5, 2012, Ferring filed a complaint in district court asserting New York state law claims and claims for correction of inventorship of the Fein patents under 35 U.S.C. § 256. The matter was assigned to District Judge Robert Sweet. The complaint named Allergan, Serenity, Fein, and Nardi as defendants (collectively, "Defendants"). Ferring alleged that Ferring scientists Nørgaard and Senderovitz should be substituted for Fein as the sole inventors, or at least added as co-inventors, to the Fein patents. Ferring filed an amended complaint in August 2013. Defendants answered Ferring's amended complaint. Allergan filed counterclaims to correct inventorship of Ferring's '429 and '654 patents (which issued from Ferring's modified PCT application), claiming that Fein should be named as the sole inventor or as a joint inventor on those patents.

In April 2015, Allergan moved for summary judgment that Ferring's § 256 claims were barred by equitable estoppel, and the non-Allergan defendants joined in Allergan's motion. Several months later, in September 2015, the district court granted Allergan's motion for summary judgment and dismissed Ferring's § 256 claims.

In considering Allergan's summary judgment motion, the district court decided as a threshold matter that conduct occurring before the issuance of the Fein patents could give rise to equitable estoppel of Ferring's claims for correction of inventorship. The district court then concluded that Ferring's inaction for over seven years following Speranza's December 2004 letters satisfied the misleading conduct prong of equitable estoppel. When Ferring was faced with Speranza's reference "to 'low dosage' applications of desmopressin as Fein's inventions," the district court reasoned, Ferring's response "was not that the low-dosage invention was Ferring's intellectual property, but that it was not patentable at all, and that Ferring would no longer be pursuing claims directed toward it." *Ferring B.V. v. Allergan, Inc.*, 253 F. Supp. 3d 708, 718 (S.D.N.Y. 2015). The district court found Ferring's threat of "immediate legal action with respect to [Fein's PCT] application" misleading, because "Ferring did not disagree or otherwise challenge Mr. Speranza's assertion that low dosage development was Fein's intellectual property," despite the fact that "Ferring was aware of two Fein patent applications that include claims for low desmopressin doses and low desmopressin plasma concentration levels." *Id.* Therefore, the district court concluded, "Ferring's present application to correct inventorship contradicts its earlier position in the Speranza correspondence." *Id.* The district court also concluded that the reliance and prejudice prongs of equitable estoppel were satisfied.

In June 2016, the district court denied Ferring's motion for a stay and for certification of judgment to allow Ferring to appeal the equitable estoppel summary judgment ruling. The non-Allergan defendants subsequently moved to be substituted for Allergan as counterclaim plaintiffs, and the district court granted that motion on September 14, 2017. Following Judge Sweet's passing, the action was reassigned to District Judge P. Kevin Castel, who refused to reconsider Judge Sweet's earlier rulings and proceeded to

address the counterclaims for correction of inventorship of Ferring's '429 and '654 patents. Following a bench trial on those counterclaims, the district court entered judgment in favor of Ferring, refusing to add Fein to Ferring's '429 or '654 patents as either the sole or a joint inventor. Final judgment in this matter was entered on September 30, 2019.[3]

Ferring appeals the district court's September 2015 equitable estoppel decision. Serenity also appealed Judge Castel's September 2019 judgment on its counterclaims, and we consolidated Ferring's appeal with

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[3] Ferring points out that, at least as to Fein's claim of co-inventorship of Ferring's '429 and '654 patents, Judge Castel found Dr. Fein's testimony not credible. *Ferring B.V. v. Allergan, Inc.*, No. 12-cv-2650, 2019 WL 6183501, at *11 (S.D.N.Y. Sept. 27, 2019). In the form of a supplemental letter pursuant to Federal Rule of Appellate Procedure 28(j), Ferring also brought to our attention that another district court judge, Chief Judge Colleen McMahon, also questioned Fein's credibility regarding his involvement with low-dose desmopressin formulations. *Ferring Pharm. Inc. v. Serenity Pharm., LLC*, No. 17-cv-09922, 2020 WL 4926458, at *63 (S.D.N.Y. Aug. 21, 2020) (concluding, after bench trial in parallel proceeding involving the validity of the '203 and '321 patents under 35 U.S.C. § 102(f), that "[c]ontrary to his absolutely incredible testimony, Dr. Fein did not suggest the idea of a 'low dose that is enabled [by sublingual administration]' . . . to Dr. Norgaard and his colleagues at Ferring" (second alteration in original) (citation omitted)).

While Fein has not moved to strike those references and the conclusions reached by those judicial officers on differently developed records, we must base our judgment on what was—and was not—presented to Judge Sweet during the summary judgment proceedings at issue here.

Serenity's appeal. We subsequently granted Serenity's motion to dismiss its appeal, leaving Ferring's appeal as the only pending appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal, Ferring argues that the district court erred by: considering conduct that preceded the issuance of the Fein patents in the equitable estoppel analysis; resolving disputed issues of fact in favor of Defendants; and ignoring evidence of Defendants' unclean hands. We address each argument in turn.

I

Our review of a district court's grant of summary judgment of equitable estoppel proceeds in two steps. *John Bean Techs. Corp. v. Morris & Assocs., Inc.*, 887 F.3d 1322, 1327 (Fed. Cir. 2018) (citing *Scholle Corp. v. Blackhawk Molding Co.*, 133 F.3d 1469, 1471 (Fed. Cir. 1998)). First, applying the law of the regional circuit (here, the Second Circuit), we review whether there are genuine issues of material fact. *See Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1340 (Fed. Cir. 2013) (citing *Teva Pharm. Indus. v. AstraZeneca Pharm. LP*, 661 F.3d 1378, 1381 (Fed. Cir. 2011)); Fed. R. Civ. P. 56(a). The Second Circuit reviews a grant of summary judgment de novo, construing the evidence in the light most favorable to the nonmoving party and drawing all reasonable inferences in that party's favor. *Kuebel v. Black & Decker Inc.*, 643 F.3d 352, 358 (2d Cir. 2011) (citation omitted). "Second, we review the district court's application of equitable estoppel for abuse of discretion." *John Bean*, 887 F.3d at 1327 (citing *Radio Sys. Corp. v. Lalor*, 709 F.3d 1124, 1130 (Fed. Cir. 2013)).

II

Ferring first argues that "[t]he district court's application of equitable estoppel to Ferring's claims for correction

of inventorship under 35 U.S.C. § 256 prior to the issuance of any patents is contrary to the plain language of the statute and this [c]ourt's precedent." Appellants' Br. 28. Stated more clearly, Ferring claims that, because its written exchanges with Fein predated the issuance of the Fein patents, those exchanges should not have been factored into the court's equitable estoppel analysis, leaving nothing else upon which to predicate the judgment on Ferring's claims. During oral argument, however, Ferring conceded that our decision in *MCV, Inc. v. King-Seeley Thermos Co.*, 870 F.2d 1568, 1572 (Fed. Cir. 1989), stands for the proposition that a court may consider pre-issuance conduct in assessing the application of equitable estoppel to § 256 claims, and that *MCV* remains good law. Oral Arg. at 1:48–3:02, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1098_09032020.mp3.

MCV applied a formulation of equitable estoppel that included an element of "unreasonable and inexcusable delay in filing suit." 870 F.2d at 1571. This court subsequently overruled that aspect of the formulation in *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1042 (Fed. Cir. 1992) (en banc), *abrogated on other grounds by SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954, 959 (2017). *See Aukerman*, 960 F.2d at 1042 ("The test set out in *Jamesbury* [*Corp. v. Litton Industrial Products, Inc.*, 839 F.2d 1544 (Fed. Cir. 1988))] confusingly intertwines the elements of laches and equitable estoppel and is expressly overruled. Delay in filing suit may be evidence which influences the assessment of whether the patentee's conduct is misleading but it is not a requirement of equitable estoppel."). All other aspects of the analysis in *MCV*, however, were left intact.

In *MCV*, we applied to a correction of inventorship claim the rule from "infringement situations" that "an assertion of right followed by silence on the part of the patentee may give rise to an estoppel if the patentee's silence is sufficiently misleading." 870 F.2d at 1572. The putative

co-inventor (and founder of MCV) "conferred with [patentee Halsey Taylor's representative] on drafts of the claims" and suggested that he be included as a co-inventor on Halsey Taylor's application. *Id.* at 1569. When Halsey Taylor "responded that company policy prohibited the naming of non-employees on company patents," MCV's founder replied that "the exclusive right to market the water coolers was more valuable to MCV than patent rights, and that he would 'help[] in any way [h]e could to facilitate the submission of the . . . patent.'" *Id.* (alterations in original). When things later soured between the parties with respect to their marketing agreement, MCV brought a correction of inventorship claim. *Id.* We affirmed the district court's grant of summary judgment that MCV was equitably estopped from asserting a correction of inventorship claim, noting that "MCV not only remained silent about co-inventorship after [its founder's] 1982 discussion with [Halsey Taylor], but affirmatively represented to Halsey Taylor that it would assist 'in any way [it] could' to obtain the patent." *Id.* at 1572 (third alteration in original). Because MCV's founder "knew Halsey Taylor was seeking a patent, and knew what was being claimed," we reasoned that "it was incumbent upon him timely, explicitly and tenaciously to apprise Halsey Taylor of his purported inventorship so it could be maturely considered." *Id.* at 1573.

Retreating from the per se rule it initially advanced, Ferring then suggested that *Radio Systems* and *John Bean* support a rule that "when the scope of the issued patents [is] different than what was before the parties that led to the alleged misleading conduct or inaction then the defense of equitable estoppel cannot apply." Oral Arg. at 2:47–3:45; *see Radio Sys.*, 709 F.3d 1124; *John Bean*, 887 F.3d 1322.

Radio Systems does not stand for Ferring's revised rule, however. The two patents at issue in *Radio Systems* differed in claim scope, but only the first-issued patent was mentioned in a 2005 demand letter accusing Radio Systems's predecessor of infringement. 709 F.3d at 1126,

1131. Radio Systems's predecessor responded that the first-issued patent was invalid. *Id.* at 1126. The second patent issued about two and a half years after the 2005 demand letter. *Id.* There was no further communication between the parties until 2009, when Radio Systems received a second demand letter accusing Radio Systems of infringing both patents. *Id.* In 2010, Radio Systems filed an action seeking declaratory judgment of noninfringement and invalidity of both patents and the patent owner counterclaimed for infringement of both patents. *Id.* at 1126–27. The district court held that equitable estoppel barred the patent owner's infringement claims as to both patents based on the 2005 demand letter and subsequent silence. *Id.* at 1130. We affirmed the district court's holding as to the first patent, concluding that Radio Systems and its predecessor were in privity and equitable estoppel applied to Radio Systems as a successor-in-interest. *Id.* at 1131. We then reversed the district court's holding that equitable estoppel applied to bar the patent owner's infringement claims as to the second patent. *Id.* Because "[t]he first notice of infringement to Radio Systems regarding the [second] patent" occurred in the 2009 demand letter, there was "simply no misleading conduct or silence by [the patent owner] to indicate that it did not intend to enforce the [second] patent against Radio Systems." *Id.* Differences in claim scope did not alone dictate the second of our conclusions. It was the absence of any communication regarding what became the claims in the second patent that was most critical to our holding.

Nor does *John Bean* stand for a broad rule that equitable estoppel does not apply whenever there is a difference in scope between the issues implicated in discussions giving rise to potentially misleading conduct and the patent claims at issue in subsequent litigation. In *John Bean*, the reexamined claims that formed the basis of John Bean's infringement suit were "heavily amended" or added following an ex parte reexamination twelve years after the

defendant's original demand letter (to which John Bean never responded) challenging the validity of the asserted patent. 887 F.3d at 1324–26. John Bean did not allege any infringing activity occurring prior to the issuance of the reexamination certificate. *Id.* at 1326. We concluded that "[t]he district court abused its discretion by applying equitable estoppel to bar John Bean's infringement action without considering how the *ex parte* reexamination affected the [asserted] patent claims." *Id.* at 1329. Under the circumstances presented, we reasoned that John Bean narrowed its claims during reexamination to such an extent that the defendant's invalidity analysis communicated in the demand letter would not apply to John Bean's reissued claims. *See id.* at 1328. We did not announce a blanket rule that *any* change to claim scope between the time of communications giving rise to allegedly misleading conduct and the filing of a patent suit would preclude the application of equitable estoppel.

As "equitable estoppel is not limited to a particular factual situation nor subject to resolution by simple or hard and fast rules," *Aukerman*, 960 F.2d at 1041, we decline to adopt a bright-line rule that equitable estoppel cannot apply whenever the scope of the issued patent is different than what the parties discussed in communications leading to the allegedly misleading conduct. Thus, while differences in claim scope are relevant to the equitable estoppel inquiry, their mere existence does not render pre-issuance conduct or communications irrelevant.

While we reject Ferring's bright-line rule with respect to the relevance of pre-issuance communications, that does not mean material differences in the potential patent claims discussed pre-issuance and the claims that ultimately issue need not be considered. And it, importantly, does not mean that such differences may not give rise to material issues of fact regarding the implications of any period of silence following pre-issuance communications. We

turn to that question in the context of Ferring's second argument.

III

Ferring also asserts that, in granting Defendants' motion for summary judgment, the district court improperly resolved issues of fact in favor of Defendants. Ferring principally argues that the district court erred in concluding that Ferring engaged in misleading conduct because that was not the only possible inference from the evidence. On this point, we agree with Ferring.

A

In the "most common situation" giving rise to equitable estoppel, "the patentee specifically objects to the activities currently asserted as infringement in the suit and then does not follow up for years." *Id.* at 1042. Equitable estoppel has three elements:

> (1) the patentee engages in misleading conduct that leads the accused infringer to reasonably infer that the patentee does not intend to assert its patent against the accused infringer; (2) the accused infringer relies on that conduct; and (3) as a result of that reliance, the accused infringer would be materially prejudiced if the patentee is allowed to proceed with its infringement action.

John Bean, 887 F.3d at 1327 (citing *Scholle*, 133 F.3d at 1471); *see also Aukerman*, 960 F.2d at 1041 (quoting D.B. Dobbs, *Handbook on the Law of Remedies* § 2.3, at 42 (1973)). "To justify summary judgment of equitable estoppel, any inference that a patentee made a misleading communication by omission or acquiescence 'must be the *only* possible inference from the evidence.'" *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 767 F.3d 1339, 1350 (Fed. Cir. 2014) (quoting *Aukerman*, 960 F.2d at 1044), *vacated in part on other grounds*, 137 S. Ct. at 967.

B

We agree with Ferring that the Speranza correspondence is subject to interpretation and does not support the single inference that Ferring, by its statements in the letters and subsequent silence, acquiesced in Fein's sole inventorship of the material in the Fein patents, particularly because the claims in those patents are not limited to, and do not even mention, the sublingual route of delivery of desmopressin. We conclude that the district court erred when it concluded as a matter of law that "Ferring's present application to correct inventorship contradicts its earlier position in the Speranza correspondence," *Ferring*, 253 F. Supp. 3d at 718, and, accordingly, abused its discretion in granting summary judgment of equitable estoppel.

1

The district court's decision rested on the erroneous view that the scope of the Speranza correspondence and the scope of Fein's application claims were commensurate with the scope of Fein's issued claims. The district court abused its discretion by applying equitable estoppel to bar Ferring's § 256 claims because it failed to address material differences in the scope of Fein's issued patent claims as compared to the invention described in the Speranza correspondence and Fein's application claims. *See John Bean*, 887 F.3d at 1329.

To be sure, the parties understood from the Speranza correspondence that Ferring disavowed any ownership claim to the sublingual, transmucosal route of delivery of desmopressin and its associated low-dosage possibilities that Fein identified as his invention in the Speranza correspondence. When Fein advised Ferring that he intended independently to pursue patent protection for "the sub-lingual administration route and the associated low dosage possibilities enabled by same," J.A. 539, Ferring responded that it "will not be pursuing this claim" because "[t]he low dosage possibilities enabled by the sublingual

administration route are already available in the public domain," J.A. 542.

But, contrary to those representations to Ferring, Fein did not pursue patent protection for claims limited to sublingual (or transmucosal) administration of desmopressin. Instead, Fein pursued claims untethered to sublingual administration of desmopressin. *E.g.*, J.A. 587–89. In fact, most of Fein's PCT application claims are untethered to any route of administration. Most of Fein's PCT application claims cover pharmaceutical compositions comprising various low doses of desmopressin, some of which are further limited to require that the claimed pharmaceutical composition is effective to establish various desmopressin plasma/serum concentrations. Indeed, none of Fein's PCT or '100 application claims and none of his issued claims are limited to sublingual administration of desmopressin. *See* '203 patent at col. 28, ll. 7–56; '321 patent at col. 28, l. 34–col. 30, l. 18; '761 patent at col. 28, l. 39–col. 30, l. 19; J.A. 587–89, 651. Very few of Fein's PCT or '100 application claims and very few of his issued claims are limited to a transmucosal route of administration. *See id.* Fein's PCT and '100 application claims are a sweeping departure from his sublingual low-dose desmopressin invention as he described it to Ferring. Importantly, Fein sought patent protection for his claims despite Ferring's prior warning to him that Ferring could not "say now that Ferring will not make any claim as to ownership of any other material Dr[.] Fein may include in any patent application . . . without seeing the text." J.A. 542. In view of Ferring's representation to Fein that it could not disclaim ownership of any material beyond the sublingual administration route and associated low-dose possibilities, a reasonable factfinder could conclude that it would have been unreasonable for Fein to infer from Ferring's pre-2004 communications that Ferring intended to relinquish inventorship rights in the issued claims of the Fein patents.

Serenity argues that Ferring did acquiesce in Fein's inventorship of patent claims untethered to the sublingual route of administration when it remained silent after learning, in December 2004, "of exactly what [Fein] was claiming—through the claims in his published PCT Application and '100 Application."[4] Appellees' Br. 32. The district court agreed with Serenity, resting its decision that Ferring engaged in misleading conduct in part on its determination that "[t]he low-dosage invention as described in the PCT at issue in the Speranza correspondence is the same subject matter detailed in the patents-in-suit, down to the specific numerical quantity of desmopressin to be used." *Ferring*, 253 F. Supp. 3d at 718. The district court implicitly concluded that Ferring had notice of the invention in Fein's issued claims as of Ferring's December 2004 letter, by virtue of that letter's reference to Fein's 2003 PCT application.

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[4] Though Speranza's second December 14, 2004 letter states that Speranza included a copy of the '100 application with the letter, J.A. 550, Ferring argues that no copy was ever provided, Reply 24. Regardless, our assessment of Fein's PCT application applies equally to the '100 application, because like Fein's PCT application, the '100 application does not recite any claims with a duration of action limitation. *See* J.A. 651.

There is no evidence that Ferring had notice of Fein's '615 application (filed in 2007) or his '074 application (filed in 2008), which matured into Fein's method of treatment patents. Indeed, the Speranza correspondence does not indicate that Fein was pursuing any additional patents beyond those he expressly identified by application number. On this record, a reasonable factfinder could conclude that Ferring had no obligation or incentive to monitor patent filings to identify any additional patent applications Fein had chosen to prosecute.

But that conclusion rested on an inadequate claim scope analysis, particularly as to Fein's issued claims containing duration of action limitations. In discussing the relative scope of Fein's issued claims and the application claims, the district court did not point to any claims. Instead, the district court stated only that "[t]he low-dosage invention as described in the PCT at issue in the Speranza correspondence is the same subject matter detailed in the patents-in-suit, down to the specific numerical quantity of desmopressin to be used." *Id.* The district court's conclusion that the claim scope of Fein's issued claims is the same as that of his application claims fails to account for the fact that most of Fein's issued claims contain duration of action limitations completely absent from Fein's application claims. *Compare, e.g.*, '203 patent at col. 28, ll. 7–56, *with* J.A. 587–89. Ferring based its § 256 claims in part on the very duration of action limitations the district court overlooked. *See, e.g.*, Complaint at 26–33, *Ferring B.V. v. Allergan, Inc.*, No. 12-cv-2650 (S.D.N.Y. Apr. 5, 2012), ECF No. 1; J.A. 1155 ("Indeed, the '203, '321, and '761 patents claim the very . . . duration of action (around 4–6 hours) that Dr. Norgaard and Dr. Senderovitz developed before any of Fein's alleged conversations with Nardi.").

In the absence of notice to Ferring of Fein's claim to inventorship of the duration of action limitations, a reasonable factfinder could find that Ferring did not mislead Fein regarding Ferring's claims of inventorship with respect to any of Fein's application claims or issued claims reciting a duration of action limitation.

2

Setting aside the differences in scope between Fein's application claims and his issued claims, and the parties' dispute as to whether Ferring ever received or reviewed a copy of the '100 application, we must vacate the district court's summary judgment of equitable estoppel because the district court's interpretation of the Speranza

correspondence is not the only reasonable one. *See SCA Hygiene*, 767 F.3d at 1350 ("To justify summary judgment of equitable estoppel, any inference that a patentee made a misleading communication by omission or acquiescence 'must be the *only* possible inference from the evidence.'" (quoting *Aukerman*, 960 F.2d at 1044)).

In December 2004, Ferring wrote to Fein expressing surprise that Fein had proceeded with his PCT "application containing an invention to which [Ferring] believe[s] he has no entitlement and which in particular discloses information confidential and proprietary to Ferring to which Dr[.] Fein had confidential access during his agreement as [a] consultant." J.A. 544. Ferring's letter provided an example, noting that Ferring's confidential results from its CS004 study "appear virtually verbatim" on page 30 of Fein's PCT application. *Id.* Ferring further informed Fein that "Ferring will take all necessary steps to protect its rights and interests," and stated that Ferring would "commence formal action" if it "d[id] not receive a full and satisfactory explanation within 14 days." *Id.*

Serenity argues that Ferring's December 2004 letter stated concerns regarding both Fein's use of Ferring's confidential information and Fein's lack of inventorship interest (i.e., lack of "entitlement") in the invention in his published PCT application. Though Serenity's position is not unreasonable, Ferring's December 2004 letter could also reasonably refer only to Ferring's concerns regarding Fein's use of Ferring's confidential information. A reasonable factfinder could interpret Ferring's use of the phrase "and which in particular" to explain further the basis for Ferring's assertion that Fein had "no entitlement" to the invention in his PCT application, rather than to state Fein's misuse of confidential information as a separate concern from lack of "entitlement."

Speranza's December 2004 responses confirm that Fein contemporaneously understood Ferring's "no entitlement"

assertion to lend itself to multiple reasonable interpretations. Indeed, Speranza's first responsive letter "confess[ed] to not entirely understanding" Ferring's "no entitlement" assertion and set forth three alternative interpretations. J.A. 546. First, and "as would appear" from Ferring's December 2004 letter, Ferring's "'no entitlement' statement relates to the assertion that the application 'discloses information confidential and proprietary to Ferring.'" *Id.* Second, Ferring's "no entitlement" assertion could "refer[] to the belief of Ferring that this low dosage invention of Dr. Fein simply is not patentable because of prior art, as was expressed in [Ferring's] letter of 29 April 2003." *Id.* Third, Ferring's "no entitlement" assertion could be "somehow intended to suggest that Dr. Fein is not the inventor of the claimed low dose invention and/or that Dr. Fein cannot assert ownership rights to it." *Id.*

Elaborating on the third possibility, Speranza mischaracterized Ferring's April 29, 2003 letter as "confirm[ing] that Ferring would not be pursuing any claim with respect to low dose desmopressin." J.A. 547. In fact, in that letter, Ferring explained only that it would not pursue claims directed to "[t]he low dosage possibilities *enabled by the sublingual administration route*." J.A. 542 (emphasis added). To the extent Speranza's articulation of the third possibility gave rise to a duty for Ferring to respond, a reasonable factfinder could find that Speranza's blatant mischaracterization of the scope of Ferring's prior disclaimer relieved Ferring of any such duty.

In finding that Ferring's December 2004 threat of "immediate legal action" and subsequent silence misled Fein into thinking that Ferring had relinquished any inventorship rights in the inventions claimed in Fein's PCT and '100 applications, the district court cast aside Speranza's first two interpretations of Ferring's "no entitlement" assertion in favor of the third. *See Ferring*, 253 F. Supp. 3d at 718. As the third possibility bears the closest relation to the inventorship dispute underlying Ferring's subsequent

§ 256 claims, the district court's decision to credit the third possibility over the first two drew an inference against Ferring. This was improper at summary judgment, particularly when the evidence shows that Fein believed the first possibility to be the most likely.[5] *See Kuebel*, 643 F.3d at 358 (explaining that at summary judgment, courts are to "construe the evidence in the light most favorable to the nonmoving party"). In view of the varying reasonable interpretations of the Speranza correspondence, we must vacate the district court's summary judgment of equitable estoppel and remand for further proceedings. *See SCA Hygiene*, 767 F.3d at 1350.

IV

Finally, Ferring asserts that the district court erred in deciding that Ferring was equitably estopped from asserting its § 256 claims because the court failed to consider "other evidence and facts respecting the equities of the parties." Appellants' Br. 49 (quoting *Aukerman*, 960 F.2d at 1043). Specifically, Ferring maintains that in assessing Defendants' unclean hands, the district court erred by ignoring evidence that Fein intentionally and deliberately copied Ferring's CS009 clinical study protocol for use in his own clinical studies. While we have already concluded that a remand is appropriate for other reasons, we address this issue because it will remain live on remand.

"[T]he trial court must, even where the three elements of equitable estoppel are established, take into consideration any other evidence and facts respecting the equities of the parties in exercising its discretion and deciding whether to allow the defense of equitable estoppel to bar the suit." *Aukerman*, 690 F.2d at 1043. Indeed, "equitable

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[5] Having concluded that the district court erred in its misleading conduct analysis, we do not address the parties' arguments regarding reliance and prejudice.

estoppel is not limited to a particular factual situation nor subject to resolution by simple or hard and fast rules." *Id.* at 1041.

Ferring's opposition to Defendants' motion for summary judgment of equitable estoppel raised four bases to support the argument that Defendants' unclean hands should preclude the district court from granting equitable relief. Ferring asserted: (1) Defendants misrepresented that Allergan had viewed the Speranza correspondence when conducting its diligence review prior to investing in Serenity and Reprise; (2) Defendants hired a third party to recover confidential Ferring documents from Nardi's computer, which documents Ferring had previously deleted pursuant to Nardi's employment agreement; (3) Defendants' counsel organized meetings between defense witnesses to coordinate their testimony, after which Fein submitted a supplemental witness statement modifying his testimony; and (4) Fein duplicated Ferring's CS009 clinical study protocol in his own CNF Desmo PK200301 clinical study, misrepresented it as his own, and subsequently included data from the study in the Fein patents as Example 8. J.A. 1169–71. With respect to Fein's copying, Ferring further argued that Fein had misrepresented to the USPTO in his patent applications that he had evaluated pharmacokinetic parameters at each desmopressin dose level. J.A. 1170, 1205–06. Ferring cited evidence that Fein did not attempt to measure plasma/serum levels of desmopressin in the CNF Desmo PK200301 study before he filed his patent applications, because the plasma samples from the study were still in frozen storage as of November 2006. *Id.* (citing S.A. 4234).

Despite the district court's statement that it "has also considered and rejects Ferring's unclean hands arguments," the court discussed only Ferring's first three arguments. *Ferring*, 253 F. Supp. 3d at 721. The district court's opinion does not mention Ferring's CS009 study or Example 8 of the Fein patents at all. This leaves us no basis to

infer that the district court considered Ferring's evidence that Fein copied Ferring's CS009 study and made related misrepresentations to the USPTO. We therefore conclude that the district court abused its discretion in granting summary judgment of equitable estoppel because the court failed to consider all relevant evidence regarding the equities of the parties. *See Aukerman*, 690 F.2d at 1043; *Rothschild Connected Devices Innovations, LLC v. Guardian Protection Servs., Inc.*, 858 F.3d 1383, 1388 (Fed. Cir. 2017) ("A district court abuses its discretion when, as here, it 'fail[s] to conduct an adequate inquiry.'" (alteration in original) (quoting *Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1360 (Fed. Cir. 2011))).

CONCLUSION

We have considered the parties' remaining arguments and do not find them persuasive. For the foregoing reasons, we vacate the district court's judgment and remand for further proceedings consistent with this opinion.

VACATED AND REMANDED

COSTS

The parties shall bear their own costs.