UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED: 03/25/2013

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

Each side shall bear its own costs.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT

/s/ Jan Horbaly

Jan Horbaly
Clerk

Aamer S. Ahmed
Natalia V. Blinkova
Joel Mark Freed
Steven B. Kelber
12-1214 - Chandler Dawson v. Dawson and Bowman
United States Patent and Trademark Office, Case No. 105,719, 105,729

United States Court of Appeals for the Federal Circuit

CHANDLER DAWSON,
Appellant,

v.

CHANDLER DAWSON AND LYLE BOWMAN,
Cross-Appellant.

2012-1214,-1215,-1216,-1217

Appeals from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences in Interference Nos. 105,719 & 105,729

.

Decided: March 25, 2013

STEVEN B. KELBER, Berenato & White, LLC, of Bethesda, Maryland, argued for appellant.

JOEL M. FREED, McDermott Will & Emery, LLP, of Washington, DC, argued for cross-appellant. With him on the brief were NATALIA BLINKOVA and AAMER AHMED.

Before REYNA, BRYSON*, and WALLACH, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* BRYSON.
Dissenting opinion filed by *Circuit Judge* REYNA.

BRYSON, *Circuit Judge*.

This is a patent interference case concerning a method for topically treating and preventing infections of the eye. The patents and patent applications at issue describe well-known challenges in treating eyes and with topical eye treatments in particular. For example, antibiotics that are applied topically must be able to reach and penetrate the targeted tissue, and many antibiotics are not suitable for such a task. In addition, medications must be designed to minimize irritation and avoid toxic responses in the eye. The inventions at issue in this case claim to overcome such difficulties through a process for topically applying an azalide antibiotic to the eye; the question in the underlying interference proceedings was who conceived of the inventions, and when.

I

The relevant events begin in the summer of 1997, at the inaugural meeting of the World Health Organization ("WHO") Alliance for the Elimination of Trachoma. Trachoma is a bacterial infection of the eye that can lead to blindness. Chandler Dawson and Thomas Leitman, who at the time were both employed by the University of California, San Francisco ("UCSF"), attended the WHO meeting on behalf of the Francis I. Proctor Foundation, an ocular disease research institution affiliated with UCSF. At the meeting, Dr. Dawson gave a presentation related

* Judge Bryson assumed senior status on January 7, 2013.

to the topical use of an antibiotic called azithromycin to control trachoma.

The WHO released a report of the meeting, entitled Report of the First Meeting of the WHO Alliance for the Global Elimination of Trachoma ("WHO Report"), that contains a discussion of Dr. Dawson's presentation. The report stated that although oral azithromycin had been used successfully against trachoma, "a topical azithromycin preparation to treat the eye directly [wa]s not available" at that time. The report listed several benefits of a topical trachoma treatment and also a number of objections to such a treatment, including that "[n]o product is available" and that the "[e]fficacy and dosing schedule" would need to be determined. Similarly, the report acknowledged that even after a product was developed, it would need to be tested for "pharmacological characteristics . . . and toxicity in the eye." The report pointed out that "several vehicles" were available to administer drugs topically, and it listed a few of them, including a product called Durasite. It did not, however, rank those options, and it expressed uncertainty about how the "persistence of [azithromycin] may occur in the external eye with adequate topical delivery." The report's conclusion referred to Dr. Dawson's "preliminary report on the possibility of developing a topical application of azithromycin" and recommended that Dr. Dawson "continue to work with The Edna McConnell Clark Foundation and Pfizer Inc. to develop a topical application and report back at the next meeting."

A second document from the WHO conference is entitled Potential Use of Topical Azithromycin in Trachoma Control Programmes ("WHO document") and is attributed to Dr. Dawson. UCSF contends that the WHO document was Dr. Dawson's outline for his presentation. The document largely tracks the WHO Report and contains many of the same statements about the current unavailability

of a topical azithromycin formulation and objections to its use. The most relevant difference between the two documents is the addition of the following three sentences in the second document's discussion of delivery vehicles: "Because azithromycin has a low solubility in aqueous solutions, one obvious preparation would be an ointment like the 0.5% erythromycin ointment. The problems with ointments for trachoma treatment are well known . . . . Ointments are difficult to apply and poorly tolerated . . . ."

Shortly after the WHO meeting, Dr. Dawson sought help from others in developing his idea. He asked Kenneth Chern, a clinical fellow at the Proctor Foundation, to contact Lyle Bowman, an employee at InSite Vision Incorporated, a company engaged in research and development of ophthalmic products. Because Dr. Dawson did not have experience in preparing ophthalmic medication formulations, he suggested that Dr. Chern enlist Dr. Bowman's assistance in creating a suitable ophthalmic medication with azithromycin that could be applied topically to the eye. Dr. Chern spoke with Dr. Bowman and followed up with a letter dated July 10, 1997. The letter conveyed Dr. Chern's "interest[] in making a topical preparation and testing the compound" and asked Dr. Bowman to report back if he was successful in formulating a topical preparation. Along with 100 milligrams of azithromycin, Dr. Chern enclosed "several articles which describe different concentrations of azithromycin as used in experimental studies as well as information about the minimum inhibitory concentrations that are necessary for killing bacteria."

A few weeks later, on July 31, 1997, Dr. Chern contacted a pharmacist associated with the Proctor Foundation named Charles Leiter. According to Dr. Chern, he did so because he had not yet heard back from Dr. Bowman in response to his July 10 letter; there is no indication that Dr. Chern contacted Dr. Leiter at Dr. Dawson's

request. Dr. Chern sent Dr. Leiter some azithromycin and asked to be notified "if [Dr. Leiter was] success[f]ul in making an ointment or suspension from the powder." Dr. Chern noted that they were "looking to compare [Dr. Leiter's preparation] with erythromycin 0.5% ointment." The same day, Dr. Chern wrote to Pfizer to request more azithromycin, explaining that they were "investigating the possible formulation and use of azithromycin as a drop or suspension" and needed more to "continue [their] studies."

In response to Dr. Chern's request, Dr. Leiter prepared an ointment that used a mineral oil and petrolatum carrier to release the antibiotic. The label is dated August 4, 1997, and indicates that the ointment contained 0.5% azithromycin by weight. Dr. Leiter gave three tubes of his formulation to Drs. Chern and Leitman, and Dr. Chern applied some to his own eye. Dr. Chern stated that he "did so not to treat an infection, but to establish for [himself] that the medication was safe, and well-tolerated—that it would not cause significant discomfort or distress as applied." Dr. Chern then told Drs. Dawson and Leitman about his experience.

From that point forward, UCSF contends that Dr. Dawson was no longer involved in UCSF's efforts to develop a topical azithromycin treatment. In February 1998, however, the Proctor Foundation submitted a grant request for additional funds related to trachoma research. A section of that request entitled "Associated Studies on Trachoma" is said to have been written by Dr. Dawson. That section conveyed many of the same concerns with, and objections to, topical azithromycin use that were reflected in the WHO Report and the WHO document, often word-for-word. In addition, the request reported that Dr. Dawson was "now working with InSite" and that "[c]hemists at InSite . . . feel that azithromycin is an ideal compound to use with their 'Durasite' vehicle." But it also

stated that no final product had been developed and asserted, for example, that "the primary problem is to determine if azithromycin is absorbed to the tissue after topical application to the eye" and that "[t]he immediate hurdle to the development of a topical form of azithromycin is testing the drug levels in the conjunctiva."

On March 31, 1999, Drs. Dawson and Bowman submitted a patent application for their invention. They signed a declaration of joint inventorship and assigned their rights to InSite. The application eventually led to the issuance of the two patents at issue in this case—U.S. Patent No. 6,239,113 ("the '113 patent"), which issued on May 29, 2001, and U.S. Patent No. 6,569,443 ("the '443 patent"), which issued on May 27, 2003. Both patents are entitled "Topical Treatment or Prevention of Ocular Infections," and the specifications point out many of the difficulties with topical eye treatments that had been noted earlier by Dr. Dawson and others during the development process.

II

On May 8, 2007, in order to provoke an interference, UCSF filed a patent application that named Dr. Dawson as the sole inventor and generally copied the specification and claims from the '113 and '443 patents. Dr. Dawson, however, declined to join UCSF's submission. The Patent and Trademark Office's Board of Patent Appeals and Interferences declared two interferences between UCSF's application and the two InSite patents. Interference 105,719 contains the following count ("the '719 count"), which tracks claim 3 of the '113 patent:

A process for treating an eye, which comprises:

> topically applying an aqueous polymeric suspension of an azalide antibiotic, wherein said suspension comprises water,
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> 0.01% to 1.0% of an azalide antibiotic, and
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> 0.1 to 10% of a polymeric suspending agent which is a water-swellable water-insoluble cross-linked carboxy-vinyl polymer which comprises at least 90% acrylic acid monomers and 0.1% to 5% cross-linking agent.

Interference 105,729 contains the following count ("the '729 count"), which tracks claim 1 of the '443 patent:

> A process for treating an eye, comprising:
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> topically applying an azalide antibiotic to an eye in an amount effective to treat infection in a tissue of the eye, wherein said topically applying comprises supplying a depot of a composition containing said azalide antibiotic on the eye.

Both interferences named UCSF as the junior party and InSite as the senior party. That meant that UCSF bore the burden of proving, by a preponderance of the evidence, that Dr. Dawson alone had conceived of the inventions recited in the counts prior to March 1999.

Lengthy proceedings ensued before the Board. The parties filed numerous motions, exhibits, transcripts of sworn testimony, and declarations. In November 2011, the Board heard oral argument and issued its decision on the merits. The Board began its opinion by construing the interference counts. In so doing, it looked to the patent specifications to define the term "treating" and the related term "treat." The specifications state, in relevant part: "The amount of azalide antibiotic topically supplied

is effective to treat or prevent infection in a tissue of the eye. This means that the conditions of application result in a retarding or suppression of the infection." Based on those statements, the Board construed the '719 count to cover "[a] process for retarding or suppressing infection in a tissue of an eye," and it construed the pertinent phrase in the '729 count to cover "topically applying an azalide antibiotic to an eye in an amount effective to retard or suppress infection in a tissue of the eye."

As to the issue of conception, the Board found that UCSF had failed to prove sole conception by Dr. Dawson. The Board found that Dr. Dawson "did not fully appreciate how [his] idea was to be implemented in actual practice"; rather, the Board held, "[w]hat emerges from the facts of this case is that inventor Dawson had a general idea for a future research plan to come up with a composition for topical azithromycin to be applied to the eye to treat infection." The Board rejected UCSF's contention that Dr. Dawson's contemporaneous disclosures of the invention, such as the WHO Report, would have enabled one of skill in the art to practice the invention because, the Board concluded, "[t]he facts . . . show 'more' was needed." The Board determined that it was only after Dr. Bowman became involved that "'something' significant happened," leading to the joint patent application in March 1999.

The Board also addressed conception in the specific context of the two interference counts. As to the '719 count, the Board found "no evidence to suggest a complete conception of the specific formulation." The Board ruled that it was not enough for UCSF to claim that Durasite is the "polymeric suspending agent" described in the count because the WHO documents "consider Durasite® but fail to establish a concentration of azithromycin" and because the ointment made for Dr. Chern did not use Durasite. Similarly, the Board held that the '729 count "explicitly

calls for use of an amount effective to treat infection in a tissue of the eye" and that UCSF did not "establish[] that inventor Dawson appreciated a precise formulation to put his 'idea' into practice." The Board reiterated that Dr. Dawson needed Dr. Bowman's collaboration to reach that point.

The Board noted "several problems with [UCSF's] case" and expressed considerable concern with UCSF's evidence as presented. The Board remarked that UCSF had decided not to seek the testimony of either inventor on the merits of the conception issue and stated that UCSF "now lives with that litigation decision." The Board also indicated that the passage of time had left some evidence stale and that memories had faded. For example, the Board pointed out that there were several unanswered questions about the ointment that Dr. Leiter prepared for Dr. Chern; it explained that "no contemporaneous documents describ[e] exactly how the . . . 'medication' was made," and it highlighted inconsistencies in Dr. Leiter's testimony about the ointment.

UCSF now appeals, contending that the Board erred in finding that Dr. Dawson did not conceive of the claimed inventions by himself prior to his collaboration with Dr. Bowman. InSite (proceeding as appellee in the name of Drs. Dawson and Bowman) cross-appeals from the Board's failure to rule that all of the claims in UCSF's application are unpatentable under 35 U.S.C. §§ 102(b) and 135(b). At oral argument, we ruled that InSite's cross-appeals are inappropriate because they do not present the prospect of enlarging InSite's rights or lessening those of UCSF. *See Bailey v. Dart Container Corp. of Mich.*, 292 F.3d 1360, 1362 (Fed. Cir. 2002). Accordingly, we treat the arguments in InSite's cross-appeals as alternative grounds for affirmance and dismiss the cross-appeals. Because we affirm the Board's decision on the

issue of conception, we do not reach those alternative grounds for affirmance.

III

The definition of conception in patent law has remained essentially unchanged for more than a century. It is the "'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 *Robinson on Patents* 532 (1890)). At that point, "all that remains to be accomplished, in order to perfect the art or instrument, belongs to the department of construction, not creation." 1 *Robinson* 532. Based on that definition, we have held that "[c]onception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation," and that "[a]n idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). Moreover, "[b]ecause it is a mental act, courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention." *Id.*

Applying these principles, we find no basis for overturning the Board's conclusion that UCSF failed to establish sole conception by Dr. Dawson.[1] We first note, as the

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[1] The dissent states that we erroneously "conclude[] that Dr. Dawson conceived his invention while working at InSite." It is important to bear in mind, however, that we

Board did, that the nature of the evidence presented in this case is unusual. We are asked to decide whether and when an invention formed definitely, permanently, and particularly in the mind of the alleged inventor, but to do so without any testimony from the supposed inventor himself. Instead, UCSF has focused its proof on what normally serves as corroborating evidence—i.e., contemporaneous disclosures of the alleged conception.

UCSF contends that the WHO Report and the WHO document prove Dr. Dawson's conception and that subsequent events, most notably Dr. Leiter's preparation of an ointment for Dr. Chern, "further corroborate[]" it. We disagree. At best, as the Board found, the WHO Report and WHO document announce a general idea, acknowledge many of the difficulties associated with making that idea operative, and offer some thoughts on how one might proceed (including by listing a few potential delivery vehicles). The WHO document is entitled "Potential Use of Topical Azithromycin in Trachoma Control Programmes," and the WHO Report describes Dr. Dawson's presentation as a "preliminary report on the possibility of developing a topical application of azithromycin," while "recommend[ing] that [Dr.] Dawson contin-

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are reviewing a decision by the Board, not assessing the evidence in the first instance. The issue of conception turns in large part on the facts, and we review the Board's many factual findings in this case for substantial evidence. *In re Gartside*, 203 F.3d 1305, 1311-15 (Fed. Cir. 2000). In addition, we are required to assess the Board's findings and its ultimate legal conclusion in light of the burden of proof, which rested on UCSF. As such, we "conclude" only that substantial evidence supports the Board's relevant factual findings and that the Board did not err in holding that UCSF failed to meet its burden of proof as to the legal issue of conception.

ue to work with [others] to develop a topical application and report back at the next meeting." A "preliminary" statement about a "possibility" or "potential use," alongside a recommendation for continued work and a "report back" in the future, falls short of a "'definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" *Hybritech*, 802 F.2d at 1376.

The inadequacy of UCSF's showing is equally clear in the context of the specific interference counts. The limitations of the '719 count include specific concentrations, such as "0.01% to 1.0% of an azalide antibiotic" and "0.1 to 10% of a polymeric suspending agent which is a water-swellable water-insoluble cross-linked carboxy-vinyl polymer which comprises at least 90% acrylic acid monomers and 0.1% to 5% crosslinking agent." As the Board found, UCSF failed to provide "evidence to suggest a complete conception of th[at] specific formulation." The claimed "polymeric suspending agent," for example, is said to be Durasite, but nothing in the record shows that Dr. Dawson knew of those concentration ranges when he listed Durasite as one of many potential vehicles in his WHO presentation. Moreover, the Board declined UCSF's invitation to "assume that 1999 Durasite® is the same as 1997 Durasite®."

Nor did UCSF's evidence establish conception of the "0.01% to 1.0% of an azalide antibiotic" to be used in a suspension. The statement in the WHO document that "one obvious preparation would be an ointment like the 0.5% erythromycin ointment" and Dr. Chern's similar assertion to Dr. Leiter that they wanted to "compare [Dr. Leiter's preparation] with erythromycin 0.5% ointment" do not do so. An "ointment" is not an aqueous "polymeric suspending agent," and erythromycin is not an "azalide antibiotic." Azithromycin is an azalide antibiotic, but the Board found "no correlation between a topical formulation

having 0.5% erythromycin and a topical formulation having 0.5% azithromycin" during the relevant time period. *See also* '113 patent, col. 3, ll. 53-57 ("Azithromycin is a broad spectrum antibiotic that is generally more effective in vitro than erythromycin. Moreover, because azithromycin is an azalide . . . , it exhibits improved acid-stability, half-life, and cellular uptake in comparison to erythromycin."). There would have been no need for Dr. Chern to send Dr. Bowman "several articles which describe different concentrations of azithromycin as used in experimental studies as well as information about the minimum inhibitory concentrations" if Dr. Dawson had already known what concentration to use. At bottom, Dr. Dawson's idea to develop a product that was "like" another product does not establish that Dr. Dawson had a "specific, settled idea [or] a particular solution" for his invention. *Burroughs*, 40 F.3d at 1228; *see also Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1312 (Fed. Cir. 2011) ("speculat[ion]" that one method "should be the same" as another method does not show conception).

UCSF's proof was similarly lacking with respect to the '729 count. That count calls for "an azalide antibiotic . . . in an amount effective to treat infection in a tissue of the eye," and the Board correctly found that UCSF failed to establish that Dr. Dawson on his own determined what that amount was. Both the WHO Report and the WHO document state that the "[e]fficacy and dosing schedule of topical azithromycin will need to be determined." Moreover, the patents and patent applications all explain that "in order for a topical application to be effective, the antibiotic must be able to penetrate the desired tissue." *E.g.*, '113 patent, col. 1, ll. 36-38. The WHO papers make clear that Dr. Dawson did not know at that time what that would entail. The documents state, for example, that "[i]n other tissues, azithromycin has a half-life of 68 to 72 hours, and a similar persistence of the drug *may* occur in

the external eye with adequate topical delivery" (emphasis added), and "[o]nce a product has been developed, it must first be tested for pharmacological characteristics (tissue levels and persistence of drug in conjunctiva)."

The ointment prepared by Dr. Leiter for Dr. Chern likewise does not establish, or corroborate, that Dr. Dawson on his own conceived of "topically applying an azalide antibiotic . . . in an amount effective to treat infection in a tissue of the eye" or of the aqueous suspension covered by the '719 count. There is no evidence that Dr. Dawson instructed Dr. Chern to contact Dr. Leiter or otherwise had any direct connection to the preparation of the ointment. As the Board found, the evidence also did not show, for example, that the ointment contained azithromycin "in an amount effective to treat infection in a tissue of the eye" or "what amount of azithromycin was homogeneously distributed in the Leiter-prepared composition or whether it degraded [or] that any or sufficient azithromycin reached tissue in Chern's eyes." As such, the Board permissibly "decline[d] to accord the Chern testimony and experimental work much, let alone, controlling weight." Dr. Chern's use of the ointment, with no verified ties to Dr. Dawson, was mere experimentation, not proof that the idea of the invention was so clearly defined in Dr. Dawson's mind "that only ordinary skill would be necessary to reduce the invention to practice." *Burroughs*, 40 F.3d at 1228; *see also In re Jolley*, 308 F.3d 1317, 1325 (Fed. Cir. 2002) ("if there is no evidence in record that all of the elements of the count resided in the inventor's mind, a noninventor's testimony cannot supply the missing pieces"). In sum, we sustain the Board's conclusions with respect to the issue of conception in both interference proceedings.

IV

UCSF argues that the Board's decision on conception was infected by errors in claim construction and the admission of evidence. We disagree.

First, UCSF's claim construction arguments are either beside the point or without merit. As to the '719 count, UCSF argues that the preamble—"[a] process for treating an eye"—should not be read as limiting, and that, in any event, the Board erred in construing the preamble to mean "a process for retarding or suppressing infection in a tissue of an eye." UCSF asserts that treatment can be proactive (and thus can occur absent an active infection) and that the preamble simply recites an intended use of the invention. The proper meaning and scope of the preamble, however, is irrelevant to our conclusion that UCSF failed to prove sole conception by Dr. Dawson. As the Board found, UCSF did not show that Dr. Dawson alone had conceived of the specific concentrations and limitations recited in the body of the '719 count. The construction of the term "treating" has no bearing on that finding.

UCSF's complaint about the Board's construction of the '729 count is equally unpersuasive. UCSF focuses on the "effective amount" requirement but offers different theories about where the Board went wrong. At various points, UCSF claims (1) that the Board mistakenly required that an azalide antibiotic actually treat an infection in the eye, when all that is required is that it must be applied in an effective amount, and (2) that applying an "effective amount" conveys an intended result, but the count does not require actual efficacy. These arguments again miss the point. Conception requires an idea to be so "definite and permanent" that "all that remains to be accomplished . . . belongs to the department of construction." 1 *Robinson* 532. The WHO Report and the WHO

document, on which UCSF relies, note that the "[e]fficacy and dosing schedule of topical azithromycin [still] need[ed] to be determined," which undermines UCSF's argument that Dr. Dawson had permanently and concretely settled on the effective dosage amounts and how to achieve efficacy. This case is therefore different from those cited by UCSF, in which the claims contained "express dosage amounts [as] material claim limitations," *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001), and in which "efficacy [wa]s inherent in carrying out the claim steps," *In re Montgomery*, 677 F.3d 1375, 1381 (Fed. Cir. 2012).

Second, UCSF objects that the Board erred in considering statements from the specifications of the '113 and '443 patents on the ground that those statements were inadmissible hearsay. As the Board explained, however, "[a]n admission should not be confused with hearsay," and UCSF adopted the words in the '113 and '443 patents as its own when it "'copied'" those words into the patent application that provoked these interferences. *See* Fed. R. Evid. 801(d)(2)(B) (a statement that a party has adopted is a party admission and thus is not hearsay).[2]

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[2] UCSF responds that its statements cannot be viewed as party admissions because paragraph 152.2.1 of the Board's Standing Order provides "that all statements in a specification are hearsay." That is incorrect. The cited portion of the Standing Order states that a specification "is admissible as evidence only to prove what the specification or patent describes" and requires an affidavit of first-hand knowledge only when "there is data in the specification upon which a party intends to rely to prove the truth of the data." The Board did not rely on any data, and in any event the provision in the Standing Order does not address the situation in which statements

Third, UCSF argues that the Board "erred in failing to consider statements made by InSite" to the European Patent Office ("EPO"). In 2005, InSite opposed an EPO patent application concerning the topical use of azithromycin as lacking "novelty" and "inventive step." InSite argued, in part, that the WHO document "disclos[es] . . . why topical azithromycin preparations for eye treatment are highly desirable" and provides "a concrete disclosure [of] how such preparations can be obtained" and "suggestions [on] how [they] could be made." Contrary to UCSF's assertion, however, the Board did not "fail[] to consider" that document. Rather, the Board set forth its general rule against giving controlling weight to documents from foreign patent proceedings and "decline[d] to give collateral estoppel effect" to the document in this case.

We hold that the Board did not abuse its discretion in its ruling on that evidentiary point. *See In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004). In addition to being reluctant to place dispositive weight on one document submitted in a foreign proceeding, the Board properly noted that this case "deal[s] with conception and actual reduction to practice . . . not lack of novelty or lack of inventive step." In the context of U.S. patent law, this court has distinguished conception from obviousness, explaining that the Patent and Trademark Office's determination that a claimed method was obvious is "irrelevant to the question whether the . . . inventors had conceived of the invention [at a particular point in time]. For conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea." *Burroughs*, 40 F.3d at 1232. InSite's EPO submission addresses a different

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in a party's specification are used against that party rather than being offered by that party.

issue and does not establish whether Dr. Dawson conceived of the complete inventions at issue by himself.

Finally, UCSF argues that the Board improperly required a showing of reduction to practice in order to prove conception. In a replay of arguments made elsewhere, UCSF's basic position is that the Board demanded proof that Dr. Dawson knew his invention would be effective to treat an actual infection, even though "[a]n inventor need not know that his invention works to conceive of it as that is the domain of actual reduction to practice." UCSF further contends that Dr. Dawson "did not need to know that his invention would work to satisfy conception [but] need[ed] only to have conceived that his topical use of azithromycin would be effective." UCSF then argues that Dr. Dawson "must have" conceived of the inventions because no medical professional would treat patients with ineffective doses.

UCSF's argument is based on an erroneous view of what is needed to prove conception. Quite apart from reduction to practice, conception requires that the inventor know how his "'definite and permanent idea of the complete and operative invention . . . is hereafter to be applied in practice.'" *Hybritech*, 802 F.2d at 1376. In other words, part of the conception inquiry asks whether the inventor "possess[ed] an operative method of making [the invention]." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005). So while UCSF is correct that "an inventor need not know that his invention will work for conception to be complete," *Burroughs*, 40 F.3d at 1228, there is a critical difference between conceiving a way to make an idea operative and knowing that a completed invention will work for its intended purpose. The Board held that UCSF's evidence of sole conception by Dr. Dawson was insufficient to prove the former. We have no reason to overturn that determination.

Each party shall bear its own costs for these appeals.

Nos. 2012-1214 and -1215, AFFIRMED; Nos. 2012-1216 and -1217, DISMISSED

United States Court of Appeals for the Federal Circuit

CHANDLER DAWSON,
Appellant,

v.

CHANDLER DAWSON AND LYLE BOWMAN,
Cross-Appellant.

2012-1214, -1215, -1216, -1217
(Interference Nos. 105,719 & 105,729)

Appeals from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

REYNA, *Circuit Judge*, dissenting.

Inventorship is perhaps the most fundamental question in patent law. The instant an inventor conceives her invention is the moment in which vests her right to a patent, thus perfecting her constitutional right to exclude.

The question on appeal is whether Dr. Dawson conceived his invention while employed at the University of California, San Francisco ("UCSF"), or instead after he joined InSite, a pharmaceutical manufacturer. The majority concludes that Dr. Dawson conceived his invention while working at InSite. I disagree.

The record before us demonstrates that Dr. Dawson possessed a definite and permanent idea of his complete and operative invention when, in the summer of 1997, he delivered a related presentation at a conference of the World Health Organization ("WHO"). At that time, Dr. Dawson was employed by UCSF, not InSite. Consequently, I find that Dr. Dawson, through UCSF, satisfied his burden of demonstrating prior conception. I therefore respectfully dissent.

CONCEPTION

Conception is the legally operative moment of invention. It consists of the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986). The law thus recognizes conception in the instant "when the inventor has a specific, settled idea, a particular solution to the problem at hand." *Burroughs Wellcome Co. v. Barr Labs.*, Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994). The inventor's settled solution must provide the ordinarily skilled artisan with enough guidance to "understand the invention," id., and its structure, *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). The inventor must be able to "describe h[er] invention with particularity." *Burroughs*, 40 F.3d at 1228; *Amgen*, 927 F.2d at 1206 (Conception requires that the inventor "be able to define" the compound "so as to distinguish it from other materials, and to describe how to obtain it."). Finally, the inventor must appreciate "the fact of what [s]he made," *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed. Cir. 2001), that is, she must "appreciate that which [s]he has invented." *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005).

The facts demonstrate that Dr. Dawson had a settled idea to solve a particular problem when he gave his

presentation at the 1997 WHO conference. Dr. Dawson's presentation was entitled, "Potential Use of Topical Azithromycin in Trachoma Control Programmes," and it was accompanied by a report. Dr. Dawson disclosed in his presentation and report the potential benefits of his new, topical azithromycin formulation.

Dr. Dawson presented the problem: "Aqueous (water-based) eye drops yield a diminished effective dose, and "azithromycin has a low solubility in aqueous solutions." Dr. Dawson then revealed his solution: "[T]here are now several vehicles that are administered as a drop and persist in the eye, releasing [the] drug over a long period of time (Table 1)." He produced a table entitled "Topical drug delivery to the eye" that identified five such drug delivery vehicles. The table included Durasite, a delivery depot comprised of acrylic acid polymers.

Dr. Dawson further disclosed the effective dosage for his azithromycin formulation. Dr. Dawson suggested that his topical azithromycin ointment should use the same dosage known for erythromycin, an alternative antibiotic for treating the eye. "[O]ne obvious preparation," he said, "would be an ointment like the 0.5% erythromycin ointment." In the patent Dr. Dawson would later obtain, six of the fourteen formulations specify precisely this amount, that is, 0.5%, by weight, azithromycin.

By February 1998, Dr. Dawson was working with InSite, presumably to explore commercial production of his azithromycin ointment. UCSF was unaware of Dr. Dawson's collaboration with InSite. In March 1999, Dr. Dawson and Dr. Bowman of InSite jointly filed a patent application relating to an azalide antibiotic ointment for treating infections of the eye. This application matured into the '113 and '443 Patents. Drs. Dawson and Bowman assigned the '113 and '443 Patents to InSite.

After the patents issued, UCSF provoked an interference. UCSF claimed that Dr. Dawson had conceived of

the patented invention before joining InSite, while still at UCSF.

CONCEPTION OF THE COUNT

In an interference proceeding, a "count" defines the interfering subject matter and corresponds to a patentable invention. *See Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1263 (Fed. Cir. 2002). The party seeking to establish prior conception must show possession of each feature recited in the count. *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985). Here, the Board defined the count in the '729 Interference as follows:

> A process for treating an eye, comprising:
>
> topically applying an azalide antibiotic to an eye in an amount effective to treat infection in a tissue of the eye,
>
> wherein said topically applying comprises supplying a depot of a composition containing said azalide antibiotic on the eye.

Board Op. 12. Dr. Dawson's WHO presentation and accompanying report teach each of the limitations, and they establish that he had possession of each recited feature.

First, both of the WHO references disclose treating an eye. The WHO presentation recites, "Reasons for local dosing of the eye," "effective local dosing of the eye with one daily treatment or less," "ocular delivery," and delivery depots "that are administered as a drop and persist in the eye." Dr. Dawson's WHO report discloses "ocular delivery," delivery depots "that are administered as a drop and persist in the eye," and "allowing the drug to be absorbed by tissues, particularly the conjunctival epithelial cells."

Second, both WHO references disclose topically applying an azalide antibiotic. Azithromycin is an azalide

antibiotic. The title of Dr. Dawson's presentation begins, "Potential Use of *Topical Azithromycin*." The title of the WHO report is "Alternative Vehicles for Ocular Delivery of *Topical Azithromycin*." 3812. Dr. Dawson's entire presentation and accompanying report are directed to topical delivery of azithromycin, an azalide antibiotic.

Third, Dr. Dawson's presentation discloses an effective dose. Specifically, Dr. Dawson suggested that his azithromycin formulation would use the same dosage known for erythromycin. "[O]ne obvious preparation," he said, "would be an ointment like the 0.5% erythromycin ointment." This dose, that is, 0.5% by weight, is used throughout Dr. Dawson's patent as a preferred formulation.

And fourth, the WHO presentation and report teach supplying a depot containing the azalide antibiotic. Both references contain the same table listing five alternative delivery depots, one of which is Durasite.[1] Both the WHO presentation and the report disclose "several vehicles that are administered as a drop and persist in the eye" and explain that "the advantage of such a preparation is that the azithromycin would be in contact with the conjunctiva for a prolonged period of time, allowing the drug to be absorbed by tissues." Listing several alternatives, only one of which is the claimed invention, does not preclude a finding of conception. *See In re Jolley*, 308 F.3d 1317, 1322 (Fed. Cir. 2002) ("But [the senior party] admits that if [the junior party] had proposed in his e-mail a small number of compounds, such as two esters, one inside and one outside the count, then [the junior party] would have established conception of the subject matter of the count-despite the inclusion of subject matter beyond the scope of

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[1] The majority characterizes the five alternative delivery depots as "many potential vehicles." Majority Op. 12.

the count."); *see also Snitzer v. Etzel*, 465 F.2d 899, 902-03 (C.C.P.A. 1972) ("Our principal difficulty with the argument is that we fail to see the relevance of the listing of several inoperative species when the species claimed is operative and performs as 'speculated.' Whether it is labeled 'discovery' or 'speculation,' appellant's conception of trivalent ytterbium as a laser-active material is no less his own, no less original, no less important technologically, and, on this record, earlier than appellees'.").

Dr. Dawson's WHO presentation and the accompanying report disclose each element of at least the '729 count, and as such, the two WHO references are sufficient to demonstrate Dr. Dawson's prior conception.

INVENTION IS THE WORK OF THE MIND

The majority discounts Dr. Dawson's work at UCSF as failing to achieve a fully developed idea of the invention. This conclusion reflects a misapplication of the law of conception to the facts of this case. To demonstrate conception, the law does not require that Dr. Dawson develop a working physical embodiment of his innovative idea. Indeed,

> Invention is not the work of the hands, but of the brain. The man that first conceived the complete idea by representing it on paper, or by clear and undisputed oral explanation, is the first inventor, and to avail himself of the rights or priority the law only requires that he shall use due diligence in embodying his idea in a practical working machine. The sketch need not be a "working drawing." The conception may be complete, while further investigation, and perhaps experiment, may be necessary in order to embody the idea in a useful physical form.

Edison v. Foote, 1871 C.D. 80, 81 (Comm'r Pat. 1871). While conception thus requires "the formation, in the

mind of the inventor, of a definite and permanent idea of the complete and operative invention," *Mergenthaler v. Scudder*, 11 App. D.C. 264, 276 (D.C. Cir. 1897), it does not require reduction to practice.

The point of time at which an invention merits protection under the patent law is neither when the first thought occurs, nor when a practical working embodiment is completed. Rather, conception occurs

> when the 'embryo' has taken some definite form in mind and seeks deliverance, and when this is evidenced by such description or illustration as to demonstrate its completeness. It may still need much patience and mechanical skill, and perhaps a long series of experiments, to give the conception birth in a useful, working form. The true date of invention is at the point where the work of the inventor ceases and the work of the mechanic begins.

Cameron & Everett v. Brick, 1871 C.D. 89, 90 (Comm'r Pat. 1871).

Here, Dr. Dawson's WHO presentation manifested an inventive embryo which thereafter sought deliverance. In his presentation, he provided a description sufficient to illustrate the completeness of his invention. All that was left was the work of the mechanic—that is, reduction to practice. This Dr. Dawson was not required to do.

REDUCTION TO PRACTICE

After his WHO presentation, Dr. Dawson returned to UCSF and engaged Dr. Chern, a clinical fellow at UCSF, to help reduce his azithromycin ointment to practice. Having already identified Durasite as an appropriate delivery depot, Dr. Dawson suggested that Dr. Chern reach out to Dr. Bowman at InSite, the company that manufactures Durasite.

Meanwhile, Dr. Chern contacted Mr. Leiter, a pharmacist and associate of Dr. Dawson, to prepare a topical azithromycin ointment. Leiter prepared an ointment using azithromycin and a petroleum depot, and he provided several tubes of the ointment to Dr. Chern. The tubes were dated 4 August 1997. Dr. Chern administered the ointment to his own eye and based on this self-dosage he confirmed that petroleum depot was an appropriate vehicle to deliver the topical azithromycin ointment.

In the interference proceeding, the Board considered whether Dr. Chern's experiment showed reduction to practice before the critical date. The Board held that Dr. Chern's experiment could not be reduction to practice because Chern had not applied the ointment to an *actual* infection. The Board based its determination on its construction of "treating" an eye, which it construed as "retarding or suppressing infection in a tissue of" an eye. Because Dr. Chern had not applied the ointment to treat an actual infection, the Board held that Dr. Chern did not reduce Dr. Dawson's invention to practice. The Board erred in two fundamental aspects. First, the term "treating an eye" in the preamble of the count is not limiting. Second, "treating an eye" does not require an actual infection.

Generally, a preamble is not limiting "when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.,* 289 F.3d 801, 809 (Fed. Cir. 2002). Nor is a preamble limiting if it "merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention." *IMS Tech., Inc. v. Haas Automation, Inc.,* 206 F.3d 1422, 1434-35 (Fed. Cir. 2000).

Here, the body of the count recites the complete and operative invention. Indeed the body of the count clarifies

what is meant by "treating an eye": it means "topically applying an azalide antibiotic to an eye *in an amount effective* to treat an infection." The count does not require an infection, only an amount effective to treat an infection.

Second, even if the preamble is limiting, the correct construction of "treating an eye" does not require an actual infection. The specification of the '113 Patent explains what is meant by "treating an eye":

> The present invention relates to a process for *treating an eye* that comprises topically *applying an azalide antibiotic to an eye* in an amount effective to treat or prevent infection in a tissue of the eye.

'113 Patent col. 2 ll. 3–36. This explanation demonstrates clearly that "treating an eye" means "topically applying an azalide antibiotic to an eye." Although the applied dose must be "*effective* to treat or prevent an infection," an actual infection is not required. *Cf. Abbott Laboratories v. Baxter Pharm. Products, Inc.*, 334 F.3d 1274, 1277 (Fed. Cir. 2003) (noting that "effective amount" has a customary usage meaning an "amount sufficient" for the intended result); *accord The American Heritage College Dictionary* 1440 (3d. ed. 1997) (defining treat as "To subject to a process, an action, or a change, esp. to a chemical or physical process or application"); 18 *The Oxford English Dictionary* 468 (2d. ed. 1989) (defining treat as "To subject to a chemical or other physical action; to act upon *with* some agent"). The Board's construction of "treating an eye" in the '729 count was clear error. The Board further erred when it relied on its erroneous claim construction to discount Dr. Chern's experiment as evidence of reduction to practice.

POST CONCEPTION

The question is: because Dr. Dawson's WHO presentation demonstrated conception and Dr. Chern's experiment demonstrated reduction to practice, what is left to establish inventorship? The majority opinion leaves open for interpretation whether commercialization is required for full conception.

But conception does not require commercialization, nor does commercialization establish initial invention. On the contrary, the record shows that Dr. Dawson conceived his invention at UCSF. He turned to Dr. Bowman at InSite only for assistance in commercializing his invention.

In February 1998, UCSF submitted a grant proposal requesting funding from the Edna McConnell Clark Foundation of New York for a study of trachoma control strategies. The proposal fully described Dr. Dawson's invention: a topical azithromycin ointment using the 0.5% dosing and Durasite as a delivery vehicle. The proposal was funded in full. Yet following the proposal, having finished his inventive work, Dr. Dawson turned to InSite to commercialize his invention. Naming Dr. Bowman at InSite as a co-inventor, Dr. Dawson filed a patent application covering his invention and assigned his rights to InSite.

But nothing in the record indicates an inventive contribution by Dr. Bowman or anyone else at InSite. On the contrary, the record shows that Dr. Dawson had fully conceived his invention before he began working with InSite. UCSF's grant proposal in particular demonstrates completion of Dr. Dawson's inventive work. The record shows that InSite's contribution was limited to commercialization. I dare not read this record to take away Dr. Dawson's constitutional right to secure his own invention by virtue of another's commercialization. To do so would, among other things, invite mischievous entities to lay

hidden along the pathways of discovery, and to waylay industrious and deserving inventors, by laying claim to their ingenuities through commercialization. Conception is fundamental to U.S. patent law, and any changes made to our law on inventorship should be considered with caution and foresight.

CONCLUSION

The record in this case belies the majority's conclusion that Dr. Dawson conceived his invention while employed at InSite. Instead, Dr. Dawson's WHO presentation and accompanying report demonstrate that, while employed at UCSF, Dr. Dawson possessed a permanent and definite idea of his complete and operative invention. I therefore respectfully dissent.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Questions and Answers

Petitions for Rehearing (Fed. Cir. R. 40)
and
Petitions for Hearing or Rehearing En Banc (Fed. Cir. R. 35)

Q. When is a petition for rehearing appropriate?

A. Petitions for rehearing are rarely considered meritorious. Consequently, it is easiest to first answer when a petition for rehearing is not appropriate. A petition for rehearing should not be used to reargue issues already briefed and orally argued. If a party failed to persuade the court on an issue in the first instance, they do not get a second chance. This is especially so when the court has entered a judgment of affirmance without opinion under Fed. Cir. R. 36, as a disposition of this nature is used only when the appellant has utterly failed to raise any issues in the appeal that require an opinion to be written in support of the court's judgment of affirmance.

Thus, as a usual prerequisite, the court must have filed an opinion in support of its judgment for a petition for rehearing to be appropriate. Counsel seeking rehearing must be able to identify in the court's opinion a material error of fact or law, the correction of which would require a different judgment on appeal.

Q. When is a petition for hearing or rehearing en banc appropriate?

A. En banc decisions are extraordinary occurrences. To properly answer the question, one must first understand the responsibility of a three-judge merits panel of the court. The panel is charged with deciding individual appeals according to the law of the circuit as established in the court's precedential opinions. While each merits panel is empowered to enter precedential opinions, the ultimate duty of the court en banc is to set forth the law of the Federal Circuit, which merit panels are obliged to follow.

Thus, as a usual prerequisite, a merits panel of the court must have entered a precedential opinion in support of its judgment for a suggestion for rehearing en banc to be appropriate. In addition, the party seeking rehearing en banc must show that either the merits panel has failed to follow identifiable decisions of the U.S. Supreme Court or Federal Circuit precedential opinions or that the merits panel has followed circuit precedent, which the party seeks to have overruled by the court en banc.

Q. How frequently are petitions for rehearing granted by merits panels or petitions for rehearing en banc accepted by the court?

A. The data regarding petitions for rehearing since 1982 shows that merits panels granted some relief in only three percent of the more than 1900 petitions filed. The relief granted usually involved only minor corrections of factual misstatements, rarely resulting in a change of outcome in the decision.

En banc petitions were accepted less frequently, in only 16 of more than 1100 requests. Historically, the court itself initiated en banc review in more than half (21 of 37) of the very few appeals decided en banc since 1982. This sua sponte, en banc review is a by-product of the court's practice of circulating every precedential panel decision to all the judges of the Federal Circuit before it is published. No count is kept of sua sponte, en banc polls that fail to carry enough judges, but one of the reasons that virtually all of the more than 1100 petitions made by the parties since 1982 have been declined is that the court itself has already implicitly approved the precedential opinions before they are filed by the merits panel.

Q. Is it necessary to have filed either of these petitions before filing a petition for certiorari in the U.S. Supreme Court?

A. No. All that is needed is a final judgment of the Court of Appeals. As a matter of interest, very few petitions for certiorari from Federal Circuit decisions are granted. Since 1982, the U.S. Supreme Court has granted certiorari in only 31 appeals heard in the Federal Circuit. Almost 1000 petitions for certiorari have been filed in that period.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INFORMATION SHEET

FILING A PETITION FOR A WRIT OF CERTIORARI

There is no automatic right of appeal to the Supreme Court of the United States from judgments of the Federal Circuit. You must file a petition for a writ of certiorari which the Supreme Court will grant only when there are compelling reasons. (See Rule 10 of the Rules of the Supreme Court of the United States, hereinafter called Rules.)

Time. The petition must be filed in the Supreme Court of the United States within 90 days of the entry of judgment in this Court or within 90 days of the denial of a timely petition for rehearing. The judgment is entered on the day the Federal Circuit issues a final decision in your case. [The time does not run from the issuance of the mandate, which has no effect on the right to petition.] (See Rule 13 of the Rules.)

Fees. Either the $300 docketing fee or a motion for leave to proceed in forma pauperis with an affidavit in support thereof must accompany the petition. (See Rules 38 and 39.)

Authorized Filer. The petition must be filed by a member of the bar of the Supreme Court of the United States or by the petitioner representing himself or herself.

Format of a Petition. The Rules are very specific about the order of the required information and should be consulted before you start drafting your petition. (See Rule 14.) Rules 33 and 34 should be consulted regarding type size and font, paper size, paper weight, margins, page limits, cover, etc.

Number of Copies. Forty copies of a petition must be filed unless the petitioner is proceeding in forma pauperis, in which case an original and ten copies of the petition for writ of certiorari and of the motion for leave to proceed in forma pauperis. (See Rule 12.)

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1 First Street, NE
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No documents are filed at the Federal Circuit and the Federal Circuit provides no information to the Supreme Court unless the Supreme Court asks for the information.

Access to the Rules. The current rules can be found in Title 28 of the United States Code Annotated and other legal publications available in many public libraries.