United States Court of Appeals for the Federal Circuit

03-1211, -1260

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS AG, NOVARTIS PHARMA AG, and
NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

Plaintiffs-Appellants,

v.

EON LABS MANUFACTURING, INC.,

Defendant-Appellee.

Robert L. Baechtold, Fitzpatrick Cella Harper & Scinto, of New York, New York, argued for plaintiffs-appellants. With him on the brief were Nicholas N. Kallas, Brian V. Slater, and Stevan J. Bosses.

Martin B. Pavane, Cohen, Pontani, Lieberman & Pavane, of New York, New York, argued for defendant-appellee. With him on the brief were William A. Alper and Mindy H. Chettih.

Appealed from: United States District Court for the District of Delaware

Judge Joseph J. Farnan, Jr.

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NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

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v.

EON LABS MANUFACTURING, INC.,

Defendant-Appellee.

DECIDED: April 2, 2004

Before CLEVENGER, DYK and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge DYK. Dissenting opinion filed by Circuit Judge CLEVENGER.

DYK, Circuit Judge.

Appellants Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, and Novartis International Pharmaceutical Ltd. (collectively "Novartis") appeal the final judgment of the United States District Court for the District of Delaware granting Eon Labs Manufacturing, Inc. ("Eon") summary judgment of non-infringement of U.S. Patent No. 5,389,382 ("the '382 patent"). Novartis Pharm. Corp. v. Eon Labs Mfg., Inc., No. 00-800-JJF (D. Del. Dec. 9, 2002) ("NovartisII"). We affirm.

BACKGROUND

The central issue in this case is the meaning of the claim term "hydrosol" in the '382 patent.

Cyclosporin is an important immunosuppressant drug, typically administered to organ transplant patients to reduce the risk of rejection. The patent for cyclosporin itself has expired. The '382 patent is directed toward solving a problem concerning administration of the drug. Because it is not very soluble in water, cyclosporin is difficult to administer in a formulation that will be readily absorbed by the aqueous environment of the human body.

Novartis addressed this problem by discovering a formulation for administering cyclosporin as a hydrosol. As explained in the '382 patent, a hydrosol formulation can be prepared by dissolving cyclosporin in a water-miscible solvent and then adding a comparatively large amount of water to that solution. This results in an aqueous dispersion of very small solid particles of the drug that is more readily absorbed by the body. In addition a stabilizing compound is added to keep those small solid particles from growing larger. Novartis claimed this invention in the '382 patent. All of the claims in the '382 patent claim the invention as a hydrosol. Claim 1 is representative:

> 1. A hydrosol which comprises solid particles of a cyclosporin and a stabilizer which maintains the size distribution of said particles, wherein said cyclosporin has a water solubility below 0.5 grams per 100 milliliters, and said particles have a weight ratio of cyclosporin to water of about 1:300 to about 1:1500 and a weight ratio of cyclosporin to said stabilizer of about 1:1 to about 1:50.

'382 patent, col. 9, ll. 20-27.

Novartis filed suit against Eon for infringement of the '382 patent. Novartis concedes that Eon does not sell cyclosporin in the form of a hydrosol. Instead, Eon manufactures capsules that contain cyclosporin dissolved in a small amount of ethanol. Because there is no water in these capsules, and the cyclosporin inside is completely dissolved, the mixture contained in Eon's capsules is not a hydrosol. However, Novartis contends that when one of Eon's capsules is ingested an infringing hydrosol is formed when the capsule mixes with the aqueous environment of the user's stomach. Novartis therefore alleges that Eon is liable for indirect infringement arising from the use of its capsules.

After reviewing the parties' claim construction briefs and expert declarations, the district court issued an order construing the claims on August 9, 2002. Before the district court, Novartis argued that

the plain meaning of the term "hydrosol" was a dispersion of solid particles in an aqueous medium, and thus included a dispersion formed in a user's stomach upon ingestion. The district court disagreed and construed "hydrosol" to require the following two elements:

> a) a synthetic pharmaceutical preparation, i.e. it does not encompass a dispersion of solid particles of cyclosporin which only forms in the stomach of a patient; and
> b) all the cyclosporin is in solid particle form and not in solution, excepting for a very small amount of cyclosporin which the water in the hydrosol can solubilize.

Novartis Pharm. Corp. v. Eon Labs Mfg., Inc., No. 00-800-JJF, slip op. at 6 (D. Del. Aug. 9, 2002) ("Novartis I"). The district court based its construction on statements in the intrinsic record indicating that the claimed hydrosol was intended to be administered via intravenous injection. Id. at 5. Based on these statements the court concluded that "hydrosol" must be limited to "synthetic pharmaceutical preparations . . . not formed within the stomach of a patient." Id.

Subsequently, the district court granted summary judgment against Novartis, holding that there was no direct infringement, either literally or under the doctrine of equivalents, arising from use of Eon's capsules. Novartis II, slip op. at 14. The court therefore granted summary judgment dismissing Novartis's claims of induced and contributory infringement. Id. Final judgment under Federal Rule of Civil Procedure 54(b) against Novartis on its infringement claim and for Eon on its counterclaim of non-infringement was entered on January 28, 2003. Novartis timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Determination of patent infringement requires a two-step analysis: (1) the scope of the claims must be construed; and (2) the allegedly infringing device must be compared to the construed claims. PSC Computer Prods., Inc. v. Foxconn Int'l, Inc., 355 F.3d 1353, 1357 (Fed. Cir. 2004). When indirect infringement is at issue, it is well settled that there can be no inducement or contributory infringement absent an underlying direct infringement. Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1033 (Fed. Cir. 2002); Carborundum Co. v. Molten Metal Equip. Innovations, Inc., 72 F.3d 872, 876 n.4 (Fed. Cir. 1995). We review the district court's claim construction and the grant of summary

judgment based thereon without deference. Kumar v. Ovonic Battery Co., 351 F.3d 1364, 1367 (Fed. Cir. 2003).

I

The key issue on appeal is whether "hydrosol" as it appears in all of the '382 patent claims is limited to medicinal products prepared outside of the body or whether it also includes products formed within the stomach of a patient after a particular medicinal product has been ingested. Novartis argues that the plain meaning of hydrosol includes products formed inside the stomach and that this definition controls the outcome of this case. We disagree.

Neither party has suggested that hydrosol has a specialized meaning inconsistent with the ordinary dictionary definition, (see Br. for Pls.-Appellants at 9 (urging definitions "consistent with the definitions found in dictionaries"); Br. for Def.-Appellee at 21-22 (urging a definition consistent with the dictionary definition)), thus under our precedent, we begin our claim construction analysis with an examination of general purpose dictionary definitions. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203-04 (Fed. Cir. 2002); see also Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1378 (Fed. Cir. 2002). Webster's Third New International Dictionary (2002) ("Webster's") [1] defines the term "hydrosol" as "a sol in which the liquid is water." Webster's at 1110. In turn a "sol" is "a dispersion of solid particles in a liquid colloidal solution." Id. at 2167.[2] The term "solution" has two pertinent definitions. These are: "(1) : a liquid containing a dissolved substance" and "(2) : a liquid and usu. aqueous medicinal preparation with the solid ingredients soluble." Id. at 2170. The first of these definitions is broad enough to include a solution (i.e., the liquid medium in which the solid particles are dispersed) within the body, but, as explained below, the second definition is not.[3]

"Medicinal" means "of or relating to medicine" and the relevant definition of "medicine" is "a substance or preparation used in treating disease." Webster's at 1402.

The Oxford English Dictionary, offers a similar definition of "medicine" as "[a]ny substance or

preparation used in the treatment of disease; a medicament . . . . Now commonly restricted to medicaments taken internally." 9 The Oxford English Dictionary 549 (2d ed. 1989). Medical dictionaries define "preparation" in terms of a substance that is made prior to being administered. See Merriam Webster (defining preparation as "something that is prepared; specifically: a medicinal substance made ready for use); Dorland's at 1502 (defining "preparation" as "a medicine made ready for use"); Stedman's at 1440 (defining "preparation" as "[s]omething made ready, as a medicinal or other mixture, or a histologic specimen"). Thus, contrary to the suggestion in the dissent, post at 5-6, a "medicinal preparation" is a preexisting product that is administered to treat disease and therefore must necessarily be prepared outside the body. Indeed, Novartis (the patentee) conceded at oral argument that the normal connotation of medicinal preparation would lead you to believe it was something prepared outside the body.

Our analysis of the dictionary definition of hydrosol therefore yields a range of possible meanings consisting of two competing definitions. The claim term "hydrosol" is either broadly defined to include a dispersion of solid particles in aqueous colloidal solution formed in a patient's stomach, or limited to a medicinal preparation consisting of a dispersion of solid particles in an aqueous colloidal solution formed outside the body.

II

For more than 45 years we, and our predecessor court, have looked to the intrinsic record to determine as a matter of claim interpretation which of the available, relevant definitions should be applied to the claim term at issue. As our predecessor court explained, "[o]ne need not arbitrarily pick and choose from the various accepted definitions of a word to decide which meaning was intended as the word is used in a given claim. The subject matter, the context, etc., will more often then not lead to the correct conclusion." Liebscher v. Boothroyd, 258 F.2d 948, 951 (CCPA 1958); see also, e.g., Inverness, 309 F.3d at 1379 ("[W]e must determine whether the specification or prosecution history clearly demonstrates that only one of the multiple meanings was intended."); Texas Digital, 308 F.3d at 1203 ("Because words often have multiple dictionary definitions, some having no relation to the claimed

invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor."); Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("[W] here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meaning.").

In the present case, the specification describes the claimed hydrosol in terms of a pharmaceutical composition and makes no mention of the term in any other context. Novartis concedes "that the specification contains no description or examples of making hydrosols in the patient's body." (Reply Br. for Plaintiffs-Appellants at 4.) Rather, the abstract states that "[t]he invention provides a hydrosol of a pharmacological active agent in an intravenous applicable, stabilised, pharmaceutically acceptable form." '382 patent, abstract; see also id. at col. 4, l.32; col. 5, ll.26-27 (describing the hydrosol as comprising solid particles of the drug "in an intravenously applicable, stabilised, pharmaceutically acceptable form."). The specification repeatedly describes the invention as a "pharmaceutical composition," see id. at col. 6, ll.66-68; col. 7, ll.1-2; col. 7, l.8, a method for "preparation of a pharmaceutical composition," id. at col. 6, l.65, and a "method of treatment using the corresponding pharmaceutical compositions," id. at col. 7, ll.10. Since the dictionary defines "pharmaceutical" as a "medicinal drug," Webster's at 1694, these descriptions support adoption of the narrower definition of hydrosol. Moreover, another aspect of the claimed hydrosol, an "injectable solution" is distinguished from the prior art on the ground that "it was never [previously] proposed to use pharmacologically active agent particles in an aqueous hydrosol form for intravenous injection purposes." '382 patent col. 1, ll.51, 56-58.[4] Because an injectable hydrosol must necessarily be prepared outside the body, these statements further support adoption of the more limited definition of "hydrosol" as a medicinal preparation prepared outside the body.

The prosecution history of the '382 patent points to the same conclusion. The examiner initially rejected Novartis's claims as obvious. Novartis distinguished the prior art, arguing that its invention "form[ed] finely divided solid drug compound particles in amorphous colloid form." (App. at 974.) Novartis argued that this "dispersion contains particles of such small diameters that they can be

administered by intravenous injection." Id. This description likewise supports the narrower definition of hydrosol as it clearly suggests that the hydrosol is a "pharmaceutical composition" that can be injected into a patient.

In light of the specification and prosecution history, we conclude that the narrower definition of "hydrosol" applies; that is, the term "hydrosol" is limited to a medicinal preparation consisting of a dispersion of solid particles in a liquid colloidal solution prepared outside the body. While none of the statements in the intrinsic record is an explicit disclaimer of subject matter sufficient to vary the scope of the claim from its ordinary meaning,[5] these statements are helpful in guiding us to choose between competing dictionary definitions of a claim term.

In this regard, the present case is different from Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed. Cir. 1994), where we held that the claimed compound was not limited to its pre-ingested form. Id. at 1422. There the claim at issue was drafted to a specific chemical compound, cefadroxil monohydrate, in a crystalline form characterized by specific x-ray diffraction properties. See Id. at 1420. Since the plain meaning of the claim language was clear and there was no express or implied pre-ingestion limitation, we found no basis for so limiting the claim. Thus, we held that "while the claim . . . is limited to the crystalline form of cefadroxil exhibiting the specified x-ray diffraction pattern, it is not limited to the compound in its pre-ingested form." Id. at 1422. However, in the present case the plain meaning of "hydrosol" is not clear, and nothing in Zenith purports to change the long-standing precedent that we look to statements made in the specification and prosecution history to choose between competing dictionary definitions.

Likewise our more recent decision in Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373 (Fed. Cir. 2003), does not require us to construe the '382 patent to encompass hydrosols formed only after ingestion. In Schering the parties agreed that the claims at issue covered a metabolite of the drug Loratadine, i.e., "the compound formed in the patient's body upon ingestion of [that] pharmaceutical." Id. at 1375. We held that these claims were anticipated by an earlier patent for the drug itself. Id. at 1382. This conclusion was based in part on the assumption that ingesting the earlier

claimed pharmaceutical would create the metabolite and thus infringe the metabolite patent. Id. at 1380. However, in the present case there is no agreement that the claim encompasses the product formed after ingestion (in Schering the metabolite). Here that is at the heart of the dispute.

III

Having concluded that "hydrosol" as used in the '382 patent is limited to an aqueous medicinal preparation prepared outside the body, we must determine if the accused product infringes prior to ingestion. Novartis concedes that "Eon does not sell cyclosporin in the form of a hydrosol," and argues only that a hydrosol is formed after ingestion. (Br. for Pls.-Appellants at 7.) Therefore, applying the appropriate construction of hydrosol there is no direct infringement of the '382 patent. Because there can be no induced or contributory infringement without an underlying direct infringement, see, e.g., Epcon, 279 F.3d at 1033, we affirm the district court's grant of summary judgment against the patentee on literal infringement.

IV

Novartis argues that even if the claimed hydrosol is limited to products prepared outside the body, the formation of a hydrosol inside the body infringes under the doctrine of equivalents. The district court granted summary judgment of no infringement under the doctrine of equivalents in part because doing so would vitiate a claim limitation. We agree.

Here the formation of a particulate dispersion inside the body cannot infringe under the doctrine of equivalents because this would vitiate the claimed requirement that the dispersion be prepared outside the body. Infringement under the doctrine of equivalents requires that any difference between the claim elements at issue and the corresponding elements of the accused product be insubstantial. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39-40 (1997). To extend the scope of the claims at issue to encompass a dispersion formed inside the stomach would necessarily read the "hydrosol" limitation out of those claims. See Moore U.S.A., Inc. v. Standard Register Co., 229 F.3d 1091, 1106 (Fed. Cir. 2000) ("[I]t would defy logic to conclude that a minority—the very antithesis of a majority—

could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise."); see also Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1562 (Fed. Cir. 1994) ("A conclusion that the 162.9:1 formulation infringes [a claim requiring a ratio of 'about 40:1'] under the doctrine of equivalents would eviscerate the plain meaning of that limitation."); Dolly, Inc. v. Spalding & Evenflo Cos., Inc., 16 F.3d 394, 398 (Fed. Cir. 1994) ("The doctrine of equivalents is not a license to ignore claim limitations."). Consequently, the district court did not err in granting summary judgment of non-infringement under the doctrine of equivalents.

CONCLUSION

The plain meaning of the claim term "hydrosol" is ambiguous. The intrinsic record in this case leads us to adopt the narrower definition of that term as a medicinal preparation consisting of a dispersion of solid particles in an aqueous colloidal solution prepared outside the body. The doctrine of equivalents cannot here expand the claim so as to include particle dispersions formed within the body. We therefore affirm the district court's grant of summary judgment of non-infringement.[6]

AFFIRMED.

COSTS

No costs.

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CLEVENGER, Circuit Judge, dissenting.

At trial, the parties disputed the meaning of "hydrosol" as it appears in the '382 patent. Novartis argued that the term should have its accepted normal meaning, i.e., solid particles dispersed in any aqueous medium. Eon did not disagree with this meaning of the term, but insisted that "hydrosol" as claimed in the patent must be limited to hydrosols made outside the body, and exclude any hydrosol that is formed in the stomach. Eon claimed support for its view from the references in the specification and the file history describing the invention as directed to a hydrosol that is intravenously acceptable and in injectable form. Since the specification and file history made no reference to formation of the claimed hydrosol anywhere other than outside the body, the district court agreed with Eon that the "intravenous-injectable" connotations required the term to be restricted to the preferred embodiments shown in the patent.

On appeal, Novartis again asks why it is denied the ordinary meaning of hydrosol, which of course is not restricted to hydrosols made in any particular place, whether it be in a factory or in a

human stomach. See, e.g., Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 318 F.3d 1143, 1148-52 (Fed. Cir. 2003). Novartis challenges the rationale of the district court as contrary to our established law, which precludes narrowing a claim term simply because the specification and file history describe examples of embodiments that reflect the use of a contested term in a specific way. See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc., Nos. 03-1082, -1165, 2004 WL 241482, at *6-*10 (Fed. Cir. Feb. 11, 2004) (holding that claim terms are given the full breadth of their ordinary meaning unless a clear disavowal of scope is stated in the specification). The majority makes no attempt to defend the incorrect rationale of the district court's claim interpretation analysis. Instead, the majority uses multiple dictionaries to find an ambiguity in the meaning of "hydrosol" as claimed. With more than one possible pertinent meaning for "hydrosol" on the table, the majority can properly apply our precedent to look to the specification and file history of the patent to determine whether the patentee has eliminated the apparent ambiguity by choosing one definition over the other. The majority concludes that the specification teaches that the inventor here clearly limited the claimed hydrosol to medicinal varieties of the same prepared outside the body.

I differ not with the majority over the tools of claim interpretation to be applied; my difference is in how the majority has used those tools to arrive at its perceived ambiguity. Let me explain.

The majority starts with its dictionaries in hand, and goes first, as makes sense, to the word "hydrosol." It uses Webster's Third New International Dictionary to learn that "hydrosol" means "a sol in which the liquid is water." Other dictionaries could be used to arrive at the same definition, and in each instance the definition covers "hydrosol" no matter where it gets made. See, e.g., Dorland's Illustrated Medical Dictionary 873 (30th ed. 2003) ("a sol in which the dispersion medium is water"); Stedman's Medical Dictionary 385 (1995) ("a colloid with water as the dispersing medium"); Webster's Ninth New Collegiate Dictionary 590 (1985) ("a sol in which the liquid is water"). We all agree that this is a suitable definition of "hydrosol." For certain, the ordinary meaning of "hydrosol" carries no manufacturing site limitation with it. That being so, one would have thought that the majority would have applied our settled law to allow the term its full breadth, unless the patentee had made an explicit disclaimer or clear disavowal of scope to alter the ordinary broad meaning of the term. See, e.g., Liebel-

Flarsheim, Nos. 03-1082, -1165, 2004 WL 241482, at *6-*10; Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1341-48 (Fed. Cir. 2001); Specialty Composites v. Cabot Corp., 845 F.2d 981, 986-88 (Fed. Cir. 1988). As the majority correctly and candidly concedes, the patentee in this case did not make any explicit disclaimer or disavowal of hydrosols made inside the body, so under our precedent Novartis would appear to be correct in its understanding of the disputed term.

But not so, according to the majority. It pursues the search in the dictionary, relying on Webster's Third New International Dictionary (2002). There, it finds as a definition for "sol" the following: a "dispersion of solid particles in a liquid colloidal solution." For the majority, this definition from this particular chosen dictionary is crucial, for it permits the court to move to a further degree of separation away from the word "hydrosol" to investigate the meaning of "solution." Had the majority used the Merriam Webster Medical Dictionary (2003), available at http://www.intelihealth.com, definition of "sol," it would have been deprived of the opportunity to pursue the meaning of "solution," because the more pertinent medical dictionary defines "sol" simply as "a fluid colloidal system; especially: one in which the dispersion medium is a liquid." Id. The pursuit of the meaning of "solution" is also blocked if one had turned to Webster's Ninth New Collegiate Dictionary (1984) (the copy provided to my chambers by the court), which defines "sol" as "a fluid colloidal system; esp: one in which the continuous phase is a liquid." Id. at 1121; see also Merriam-Webster's Collegiate Dictionary 1117 (10th ed. 1998); id. at 1186 (11th ed. 2003).

Having found a need to define "solution"—remember, the need is in order to know the meaning of "hydrosol"—the majority again relies on its dictionary in the next degree of separation to produce two meanings for "solution." One meaning, "a liquid containing a dissolved substance" is deemed by the majority, correctly, to be broad enough to relate back to "hydrosol" without imposing any restrictions on the manufacturing site of the hydrosol. The other meaning, however, is pay dirt for the majority. That second definition of "solution" is "a liquid and usu. aqueous medicinal preparation with the solid ingredients soluble" (emphasis added).

At this stage in the dictionary expedition, the majority should have noticed the error of its ways.

This is so, because the definition it adopts for "solution" requires that the solid ingredients be soluble. A purpose if not the purpose of the claimed hydrosol is to address the problem of cyclosporin's insolubility. A hydrosol solves the problem by finely dispersing the insoluble solid ingredient (cyclosporin) in a liquid. Cyclosporin is no more soluble than before. Indeed, Appellee Eon's brief informs us of this very fact: "Hydrosols are distinguishable from solutions in that in a solution there are no solid particles . . . ." (Appellee's Br. at 4). For this reason, the claimed hydrosol is not a "medicinal preparation with the solid ingredients soluble," and the preferred definition of "solution" cannot be tied back to the claim language. When such a disconnect occurs in the dictionary pathway, the dictionary exercise has gone too far.[7]

In the next degree of separation, the majority embraces the term "medicinal preparation," and forthwith abandons Webster's in favor of The Oxford English Dictionary 548-49 (2d ed. 1989), to plumb the depths of the meaning of the word "medicine." (The reader should not forget that the word we are trying to define is "hydrosol," not "medicine."). But The Oxford English Dictionary clearly does not state that a "medicine" must be manufactured outside the body, as the majority claims. Indeed, that dictionary emphasizes that "medicine" is taken internally, as is the case with Eon's alleged infringing substance. By no stretch does The Oxford English Dictionary require a medicine to be made in a pharmaceutical factory. As a matter of fact, the primary definition of "medicine" in that dictionary ("[a] ny substance or preparation used in the treatment of a disease") is broad enough to cover a hydrosol made in the body. The secondary definition of medicine, "medicament," leads to the concept of internal consumption on which the majority relies. Note also, that the definition of "medicine" in The Oxford English Dictionary, being restricted to "medicaments taken internally," is suspect, since many medicines are topically applied. Furthermore, appropriate medical dictionaries do not similarly restrict the ordinary definition of the word "medicine," i.e., "a substance or preparation used in treating disease." See Merriam Webster Medical Dictionary (2003), available at http://www.intelihealth.com; see also Stedman's Medical Dictionary (27th ed. 1999) (defining "medicine" as "[a] drug"); Dorland's Illustrated Medical Dictionary (30th ed. 2003) (defining "medicine" as "any drug or remedy"). In short, the ordinary meaning of "medicine" includes a hydrosol of cyclosporin formed in the stomach.

At the end of the long search in various dictionaries, the majority concludes that "hydrosol" is ambiguous because of "multiple possible" conflicting dictionary definitions. I am at a loss to understand why this dictionary search creates such an ambiguity. Indeed, at the end of the dictionary exercise, the majority narrows "medicine" to things made outside the body, even though the very dictionary on which the majority relies offers a primary meaning for the term that reaches hydrosols made anywhere. The majority's decision depends entirely on a suspect secondary meaning for "medicine" found in only a single dictionary.

"Hydrosol" simply means "a sol in which the liquid is water." Nothing in the dictionary listed under the word "hydrosol" speaks to the site where hydrosols are made. A "hydrosol" can be made anywhere, and manufacture outside the body is just a narrower subset of anywhere, with anywhere including inside the body. The existence of the narrower subset does not create ambiguity. It simply tells us what we know–that terms frequently have broad and narrow meanings. We then look to the specification and file history to determine whether the patentee made a clear disclaimer of the broader meaning. If not, the patentee is not taxed with narrowing references by way of examples (such as the intravenous and injection examples in the patent in suit) to narrow the broad scope.

Our case law has long recognized that medicines claimed in patents can be made inside or outside the body, and that infringement will lie in either case if the proper proofs are made. These cases are no less concerned with patient treatment than the instant case. In all of them, we have a "medicine" whose ordinary meaning carries no manufacturing site limitations. See Schering Corp. v. Geneva Pharms. Inc., 339 F.3d 1373 (Fed. Cir. 2003); Hoechst-Roussel Pharms., Inc. v. Lehman, 109 F.3d 756, 759 (Fed. Cir. 1997); Zenith Labs., 19 F.3d at 1421-22. Each of these precedents involved medical preparations. But until this case, no one had suggested that a suspect dictionary definition of the term "medicine" should be used to deny a patentee the right to prove infringement when the claimed composition is formed as a medicine in the body following the ingestion of a different composition that was manufactured outside the body.

In short, the majority should have ended its dictionary analysis at the word "hydrosol." Only by

pressing on through several degrees of separation can the majority get to the definition of "medicine" on which it relies to confirm the existence of a second competing pertinent definition of "hydrosol." Dictionaries are fine tools to assist in the exercise of claim interpretation, for sure, but in this case the majority has simply overworked the dictionaries to a point of error.

My preference is to use our standard tools of claim interpretation, including proper use of dictionaries, in this case, and let it fit comfortably, as it should, in our body of law that recognizes that medicinal preparations made in the body can infringe valid claims. For the reasons set forth above, Novartis's patent should not be limited to injectable hydrosols of cyclosporin made outside the body. Novartis is entitled to a trial in which it can bring forward its proof of infringement.

With respect, I therefore dissent.

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[1] Neither party contends that the relevant definitions in this case have changed since the '382 patent application was filed and the patent issued.

[2] The dissent relies on the Merriam Webster Medical Dictionary (2003), available at http://www.intelihealth.com ("Merriam Webster"), which defines "sol" as "a fluid colloidal system; especially: one in which the dispersion medium is a liquid." Post at 3-4; see also Dorland's Illustrated Medical Dictionary 1718 (30th ed. 2003) ("Dorland's") (defining "sol" as "a colloid system in which the dispersion medium is a liquid"). Contrary to the dissent, we are not foreclosed from referring to the definition of "solution" simply because the medical dictionary it cites refers to a "fluid colloidal system" and does not use the word "solution." See post at 4. Other medical dictionaries make clear that "sol" is often used synonymously with "colloidal solution." Stedman's Medical Dictionary 528, 1653 (27th ed. 2000) ("Stedman's") (defining "sol" as "a colloidal dispersion of a solid in a liquid" and further indicating that "colloidal dispersion" is a synonym for "colloidal solution"); see also 4 Attorneys' Dictionary of Medicine, Vol. S-139 (1995) ("Some scientists refer to a sol as a colloidal solution, rather than a dispersion. . . ."). Thus, there is no indication that the general purpose dictionary definition is inconsistent with the medical dictionary definition.

[3] The dissent mistakenly suggests that the majority is equating the meaning of "hydrosol" with

the meaning of the term "solution." Post at 4. We are doing no such thing. Rather, we recognize that a hydrosol consists of two things: (1) solid particles (here the cyclosporin) suspended in (2) an aqueous solution. In this context we are simply holding that the solution component of the hydrosol can mean a medicinal preparation. We are unaware of any evidence that one of ordinary skill in the art would consider the solution dispersing the solid particles of cyclosporin to no longer be a "solution," as the dissent suggests here. Indeed, the patentee's brief informs us that "[t]here is no dispute that injectable solutions [including the cyclosporin] are one particular embodiment of the claimed invention." (Pls.-Appellants Br. at 11 (emphasis added).) Thus, contrary to the dissent's view, the narrower definition of solution is entirely consistent with the claim language.

[4] In addition, the specification teaches that the water portion of the hydrosol may be removed leaving the cyclosporin particles in a dry form that "is a starting material for preparation of pharmaceutical compositions," which after being "redispersed with distilled water . . . may be intravenously administrable." '382 patent, col. 6, ll. 50-60.

[5] Cf. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003) ("[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender."); SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1344 (Fed. Cir. 2001) (construing the claims to include a "coaxial" limitation, despite their ordinary meaning, because "portions of the . . . specification lead to the inescapable conclusion that the references . . . to an inflation lumen 'separate from' the guide wire lumen must be understood as referring to coaxial lumens"); see also Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906-08 (Fed. Cir. 2004) (discussing the appropriateness of limiting unambiguous claim language based on the intrinsic record).

[6] In light of our decision that there is no infringement because the claims are limited to medicinal preparations prepared outside the body, we need not reach other aspects of the district court's construction of "hydrosol." Nor do we address the parties' arguments related to other claim terms construed by the district court.

[7] The majority's attempted escape from our reasoning on this point also fails. Jumping away from the chosen dictionary definition (the one that allows a pursuit of the meaning of "medicinal preparation") because of the "solution" roadblock it presents, the majority finds another definition presenting the concept of dispersion, and uses that concept to read back into "solution" a fluid containing solid particles, such as the claimed hydrosol. This chase through the dictionary establishes one point with sparkling clarity: the majority eschews the preferred meaning of common terms, (i.e., solution means "a liquid containing a dissolved substance," Majority op. at 5), in favor of secondary, or tertiary, etc. meanings of the word in question.