United States Court of Appeals for the Federal Circuit

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
TEVA NEUROSCIENCE, INC.,
YEDA RESEARCH AND DEVELOPMENT CO., LTD.,
Plaintiffs-Appellees

v.

SANDOZ, INC., MOMENTA PHARMACEUTICALS INC.,
Defendants-Appellants

MYLAN PHARMACEUTICALS INC., MYLAN INC., NATCO PHARMA LTD.,
Defendants-Appellants

SANDOZ INTERNATIONAL GMBH, NOVARTIS AG,
Defendants

2012-1567, 2012-1568, 2012-1569, 2012-1570

Appeals from the United States District Court for the Southern District of New York in Nos. 08-CV-7611, 09-CV-8824, Judge Barbara S. Jones.

Decided: June 18, 2015

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Before MOORE, MAYER, and WALLACH, *Circuit Judges.*[1]

Opinion for the court filed by *Circuit Judge* MOORE.

Dissenting opinion filed by *Circuit Judge* MAYER.

MOORE, *Circuit Judge*.

This case comes to us on remand from the Supreme Court, which vacated our earlier opinion reversing the

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[1] Pursuant to Fed. Cir. Internal Operating Procedure 15 ¶ 2(b)(ii), Circuit Judges Mayer and Wallach were designated to replace Circuit Judge Randall R. Rader, now retired, and District Judge Dee V. Benson, United States District Court for the District of Utah.

district court's judgment that certain claims were not indefinite (Group I claims), and affirming the district court's holdings that other claims (Group II claims) were valid and infringed.[2] *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363 (Fed. Cir. 2013), *vacated, Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015). Relevant to the Group I claims, the Supreme Court held that the ultimate construction of a claim term is a question of law, subject to de novo review, and that underlying subsidiary fact findings are subject to clear error review. *Teva*, 135 S. Ct. at 837–38, 841–42. During that same time, the Supreme Court issued its opinion in *Nautilus, Inc. v. Biosig Instruments, Inc.* (*Nautilus II*), 134 S. Ct. 2120 (2014), addressing the standard for indefiniteness. On remand, the parties submitted supplemental briefing explaining how the appeal should be resolved in light of the Supreme Court's *Teva* decision. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, No. 12-1567 (Fed. Cir. Feb. 20, 2015), ECF No. 137. Applying the legal standards set forth in the Supreme Court's *Teva* and *Nautilus II* decisions, we hold that the Group I claims are invalid for indefiniteness.[3]

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[2] The asserted patents were: U.S. Patent Nos. 5,800,808; 5,981,589; 6,048,898; 6,054,430; 6,342,476; 6,362,161; 6,620,847; 6,939,539; and 7,199,098. The Supreme Court decision does not affect our prior holding with respect to the Group II claims. For the reasons articulated in our earlier opinion, we adopt those holdings.

[3] While the case was pending at the Supreme Court, all of the patents-in-suit expired, with the exception of U.S. Patent No. 5,800,808. Thus, claim 1 of the '808 patent is the sole unexpired Group I claim. Our analysis will therefore focus on that claim, but to the extent that issues relating to the expired Group I claims

BACKGROUND

The facts of this case were recited in this court's previous opinion. In summary, Appellants submitted Abbreviated New Drug Applications (ANDAs) to the Food and Drug Administration (FDA) seeking approval to market generic versions of Copaxone®. Teva, which markets Copaxone®, sued Appellants for patent infringement under 35 U.S.C. § 271(e)(2)(A). Claim 1 of the '808 patent recites a method of making a product called copolymer-1:

> A method of manufacturing copolymer-1, comprising reacting protected copolymer-1 with hydrobromic acid to form trifluoroacetyl copolymer-1, treating said trifluoroacetyl copolymer-1 with aqueous piperidine solution to form copolymer-1, and purifying said copolymer-1, to result in copolymer-1 having a *molecular weight of about 5 to 9 kilodaltons*.

'808 patent claim 1 (emphases added).

Copolymer–1 consists of four different amino acids (alanine, glutamic acid, lysine, and tyrosine) combined in a certain ratio to make a polypeptide product. A sample of polymeric material like copolymer–1 typically consists of a mixture of individual polymer molecules that have varying molecular weights. There are three different measures of molecular weight relevant to this appeal: peak average molecular weight (M_p), number average molecular weight (M_n), and weight average molecular weight (M_w). Each measure is calculated in a different manner. The claim does not specify which measure to use and in a typical polymer sample, M_p, M_n, and M_w have different values.

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remain unresolved, this analysis should be understood to apply equally to the other Group I claims.

The district court rejected the Appellants' argument that the term "molecular weight" was indefinite. *Teva Pharm. USA, Inc. v. Sandoz, Inc.* (*Markman Order*), 810 F. Supp. 2d 578, 586–93, 596 (S.D.N.Y. 2011). The district court found credible Dr. Grant's testimony that M_p is the only type of average molecular weight that can be directly obtained from a chromatogram and calibration curve obtained by the analytical method described in Example 1 (Size Exclusion Chromatography or SEC). *Id.* at 588, 590. It noted that experts testified that M_n and M_w can be obtained from the chromatogram and calibration curve, but doing so would require additional data manipulation and calculations not disclosed in the specification. *Id.* It therefore credited Dr. Grant's opinion that Example 1 implies the use of M_p. *Id.* The district court also found that Example 1 corresponds to Figure 1 in the patent specification. *Id.* at 588. It considered Appellants' argument that Figure 1 does not disclose M_p because the peaks of the depicted curves do not match the molecular weight values reported in the legend. *Id.* at 590. The district court, however, accepted Dr. Grant's opinion that a person of ordinary skill would understand that the process of transferring data from a chromatogram could cause a shift in the peak of the curves. *Id.* It therefore concluded that the fact that the peaks do not match the listed molecular weights does not dissuade the conclusion that "molecular weight" means M_p. *Id.* at 590–91. The district court determined that "the prosecution history also indicates [average molecular weight] refers to M_p in the context of the patents-in-suit." *Id.* at 589. It rejected as irrelevant the patentee's response to an indefiniteness rejection during the prosecution of the '847 patent that "[o]ne of ordinary skill in the art could understand that kilodalton unit implies a weight average molecular weight." *Id.* at 591–92. It did so on the basis that the "statement was incorrect" because each type of average

molecular weight can use the kilodalton. *Id.* at 592. It then concluded that one of ordinary skill would accept the patentee's statement during the prosecution of the '539 patent that average molecular weight means M_p. *Id.* Having considered the claims, specification, prosecution history and extrinsic evidence, the district court determined that "molecular weight" means M_p in the context of the claimed invention and held that the claims are not indefinite. *Id.*

We reversed the district court's judgment with respect to the Group I claims, holding them indefinite. *Teva*, 723 F.3d at 1368–69. Teva filed a petition for a writ of certiorari, arguing to the Supreme Court that in holding the claims indefinite, we erred by giving no weight to the district court fact findings. Pet. for Writ of Cert., *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, No. 13-854, 2014 WL 230926, at *13–14 (2014). Teva argued that this court's determinations in *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc) and *Lighting Ballast Control LLC v. Philips Elecs. North America Corp.*, 744 F.3d 1272 (Fed. Cir. 2014) (en banc) that we review all aspects of claim construction de novo was incorrect and inconsistent with Fed. R. Civ. P. 52(a)(6). Brief for the Petitioner at 18, *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, No. 13-854 (2014). It argued that under Fed. R. Civ. P. 52(a)(6), we should only set aside a district court fact finding if such finding is clearly erroneous. The Supreme Court agreed.

The Supreme Court held that "it was proper to treat the ultimate question of the proper construction of the patent as a question of law in the way that we treat document construction as a question of law." *Teva*, 135 S. Ct. at 837. The reviewing court, however, should review subsidiary factual findings under the clearly erroneous standard. *Id.* at 838. The Court explained that "when the

district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law" which will be reviewed de novo. *Id.* at 841. If a district court needs to consult extrinsic evidence, for example, to understand the meaning of a term in the relevant art at the relevant time, the court may need to make subsidiary factual findings about that extrinsic evidence. *Id.* The Court explained that

> if a district court resolves a dispute between experts and makes a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention, the district court must then conduct a legal analysis: whether a skilled artisan would ascribe that same meaning to that term *in the context of the specific patent claim under review*.

Id. Experts may explain terms of art and the state of the art at any given time, but they cannot be used to prove the legal construction of a writing. *Id.* If a district court resolves a subsidiary factual dispute, it will then interpret the patent claim in light of the facts as the court found them. *Id.* As the Court cautioned, an "issue does not lose its factual character merely because its resolution is dispositive of the ultimate legal question." *Id.* at 842 (citations and quotation marks omitted). Regardless of whether a subsidiary factual finding plays a small or large role in the ultimate conclusion about the meaning of the patent term, "the ultimate question of construction will remain a legal question." *Id.* at 841–42.

The Court vacated our decision, concluding that Teva identified at least one factual finding by the district court which we did not review for clear error. Appellants had argued that "molecular weight" could not mean M_p be-

cause the molecular weight values in the Figure 1 legend did not match up with the peak values on the Figure 1 curves. The Supreme Court concluded that the district court's finding "about how a skilled artisan would understand the way in which a curve created from chromatogram data reflects molecular weights" was a factual finding. *Id.* at 843. Distinguishing between the factual and legal components of the analysis, the Court explained that "[b]ased on that factual finding, the District Court reached the legal conclusion that figure 1 did not undermine Teva's argument that molecular weight referred to the first method of calculation (peak average molecular weight)." *Id.* The Court vacated our decision instructing that the district court fact findings should be reviewed for clear error. *Id.* The Court acknowledged that Teva claimed there were two additional instances in which the Federal Circuit rejected fact findings without finding clear error. Expressing no opinion on those arguments, the Court left these matters for us to consider. *Id.*

While *Teva* was pending at the Supreme Court, the Court issued its opinion in *Nautilus II*. In *Nautilus II*, the Court evaluated our standards for indefiniteness under 35 U.S.C. § 112, ¶ 2 (2006),[4] rejecting our "not amenable to construction or insolubly ambiguous" standard. Those standards were the ones applied in our *Teva* decision. The Supreme Court articulated the standard to be applied: "[W]e hold that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to

[4] Paragraph 2 of 35 U.S.C. § 112 was replaced with newly designated § 112(b) when § 4(c) of the Leahy–Smith America Invents Act ("AIA"), Pub. L. No. 112–29, took effect on September 16, 2012. Because this case was filed before that date, we will refer to the pre-AIA version of § 112.

inform, with *reasonable certainty*, those skilled in the art about the scope of the invention." *Nautilus II*, 134 S. Ct. at 2124 (emphasis added). As we explained on remand, "[t]he Court has accordingly modified the standard by which lower courts examine allegedly ambiguous claims; we may now steer by the bright star of 'reasonable certainty,' rather than the unreliable compass of 'insoluble ambiguity.'" *Biosig Instruments, Inc. v. Nautilus, Inc.*, No. 2012-1289, slip op. at 8 (Fed. Cir. Apr. 27, 2015).

We therefore reconsider the district court's claim construction and indefiniteness determination in light of the Supreme Court's guidance.

DISCUSSION

A patent's specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention" 35 U.S.C. § 112, ¶ 2. A patent is indefinite "if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus II*, 134 S. Ct. at 2124. The definiteness requirement must take into account the inherent limitations of language. "Some modicum of uncertainty . . . is the 'price of ensuring the appropriate incentives for innovation.'" *Id.* at 2128 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002)). On the other hand, "a patent must be precise enough to afford clear notice of what is claimed, thereby appris[ing] the public of what is still open to them." *Id.* at 2129 (internal quotation marks and citations omitted). Indefiniteness is a question of law that we review de novo. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1365–66 (Fed. Cir. 2011).

To determine whether the Group I claim at issue is indefinite, we look to the patent record—the claims, specification, and prosecution history—to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed. We conclude in this case that they do not convey with reasonable certainty the measure of molecular weight to be used. Claim 1 of the '808 patent recites "molecular weight" without specifying the meaning of that term. The parties agree that "molecular weight" could refer to M_p, M_w, or M_n. And they agree that each of these measures is calculated in a different way and would typically yield a different result for a given polymer sample. But the claim on its face offers no guidance on which measure of "molecular weight" the claims cover.

There is no express definition of "molecular weight" in the '808 patent specification. Nowhere in the specification are the terms M_p, M_w, or M_n used. Neither party argues to the contrary. Instead, in its supplemental briefing to this court, Teva argues that:

> The factual findings establish that to a skilled artisan, 'average molecular weight' has a presumed meaning in this context, which means that the patent's specification resolves any ambiguity; that the presumed meaning is consistent with Figure 1 of the specification; and that the only statement causing ambiguity in the prosecution history was an error. . . . And no intrinsic evidence defeats that definite meaning—not Figure 1, and not the prosecution history.

Appellees' Supp. Br. 1; *see also id.* at 4–7 (Section 2. Heading: "The District Court Did Not Clearly Err in Finding That The Key Term Has A Presumed Meaning In The Art"). Teva's recitation of what was found below is inaccurate. The district court did not find that the term

molecular weight or average molecular weight had a presumed meaning in the art. And if there were such a finding, it would not have been supported by the record in this case. All parties agree that the term "molecular weight" or "average molecular weight" in the Group I claims could refer to any of the three weight measures M_p, M_n, or M_w. Even Teva's expert Dr. Grant repeatedly admitted that the term molecular weight has no default meaning to one of skill in the art. J.A. 3096-97. And while it is true that the district court used the word "presumed" once in its indefiniteness section, the use was in characterizing Teva's argument, not in making a fact finding: "Thus, Teva (and Dr. Grant) conclude, M_p can be read from the chromatogram generated by SEC without any 'further calculation' and would be understood by a person of ordinary skill in the art to be the presumed meaning of [average molecular weight] in the context of the patents-in-suit." *Markman Order* at 588.

The district court's determination about how a skilled artisan would understand the way in which SEC-generated chromatogram data reflects molecular weight is a question of fact. And we see no clear error in that fact finding—that one of skill in the art could read M_p from a chromatogram without further calculation and that M_w or M_n would both require further calculations. We see no clear error in the district court's decision to credit Dr. Grant's testimony that Figure 1 was created by transforming data from a chromatogram to the curves depicted in Figure 1. Nor do we see clear error in its acceptance of Dr. Grant's opinion that a person of ordinary skill would understand that the process of transforming such data could cause the peaks of each curve to shift slightly such that a person of skill would understand that the listed molecular weights fall approximately at the peaks of the curves, i.e., M_p. While Dr. Grant's argument that the peak positions on the curves are within a margin of error

(which he admits is as high as an error of 16.7%) is relatively cursory and unexplained, *see* J.A. 1016–17, nonetheless we do not find the district court's reliance on it clearly erroneous. But accepting these fact findings does not, as Teva suggests, mean that there now exists a *presumption* regarding the meaning of the claim term in the art in general or in the context of this patent.

To the extent that Teva argues that the meaning of "molecular weight" in the context of patents-in-suit is itself a question of fact, it is wrong. *See Teva*, 135 S. Ct. at 841–42. A party cannot transform into a factual matter the internal coherence and context assessment of the patent simply by having an expert offer an opinion on it. The internal coherence and context assessment of the patent, and whether it conveys claim meaning with reasonable certainty, are questions of law. The meaning one of skill in the art would attribute to the term molecular weight in light of its use in the claims, the disclosure in the specification, and the discussion of this term in the prosecution history is a question of law. The district court should not defer to Dr. Grant's ultimate conclusion about claim meaning in the context of this patent nor do we defer to the district court on this legal question. To the extent that Teva argues that this ultimate determination deserves deference, it is in error. To the extent that Teva or the dissent suggests that the specification's disclosure of SEC would "infer" that this claim term, molecular weight, in this patent refers to M_p, such an inference is part of the legal analysis, not a fact finding to be given deference. Determining the meaning or significance to ascribe to the legal writings which constitute the intrinsic record is legal analysis. The Supreme Court made clear that the factual components include "the background science or the meaning of a term in the relevant art during the relevant time period." *Id.* at 841. Teva cannot transform legal analysis about the meaning or signifi-

cance of the intrinsic evidence into a factual question simply by having an expert testify on it. *Id.* at 841 ("experts may be examined to explain terms of art, and the state of the art, at any given time, but they cannot be used to prove the proper or legal construction of any instrument of writing" (citation omitted)). Determining the significance of disclosures in the specification or prosecution history is also part of the legal analysis. Understandings that lie outside the patent documents about the meaning of terms to one of skill in the art or the science or state of the knowledge of one of skill in the art are factual issues. Even accepting as correct the district court's factual determinations about SEC and the transfer of chromatogram data to create Figure 1, these facts do not resolve the ambiguity in the Group I claim about the intended molecular weight measure.

To determine whether one of skill in the art would be reasonably certain that the claim's use of molecular weight is M_p, we consider as well the prosecution history. Statements made during prosecution history are relevant to claim construction. *See Teva*, 135 S. Ct. at 841; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). Applicants can define (lexicography), explain, or disavow claim scope during prosecution. And whether their statements or disclaimers impact the meaning of a claim term in a given patent is a legal question, not a factual one. A statement made during prosecution of related patents may be properly considered in construing a term common to those patents, regardless of whether the statement pre- or post-dates the issuance of the particular patent at issue. *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004). The parties do not point to any portion of the '808 patent's prosecution history that is relevant to the construction of "molecular weight." However, they point to, and the district court considered, statements about the meaning of "molecular

weight" made during the prosecution of the '847 and '539 patents which are both continuations of the '808 patent.[5] Such statements are legally relevant to the meaning one of skill in the art would attribute to the identical term in the '808 patent. In the prosecution of both patents, the examiner rejected the claims as indefinite because the term average molecular weight was meaningless without specifying whether M_p, M_n, or M_w should be used. *See* J.A. 3220 ("The term 'average' molecular weight . . . is meaningless as a limitation without specifying its basis, e.g. weight average molecular weight, number average molecular weight, etc."); J.A. 3245 ("[T]he term 'average molecular weight' . . . is indefinite since its method of measurement is not specified, i.e. number average molecular weight, weight average molecular weight, average molecular weight as determined by light scattering, etc."). The '808, '847, and '539 patents share a nearly identical specification, and all three patents identically include Example 1 and Figure 1, discussed above. That these applications containing the same Example 1 and Figure 1 as the '808 patent were rejected for indefiniteness suggests that, contrary to Teva's position, the specification does not conclusively establish that in the context of these patents a person of ordinary skill in the art would conclude that the meaning of "molecular weight" is M_p.

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[5] Prior to the expiration of the other patents-in-suit, Teva did not dispute the relevance of the prosecution history of related patents to the construction of the term "molecular weight." *See Markman Order* at 592; J.A. 1018. Now Teva argues that "the prosecution history of later patents . . . cannot override the specification or invalidate the patent." Appellees' Supp. Br. 1; *see also id.* at 12. But we have said before, and reaffirm today, that past and future prosecution of related patents may be relevant to the construction of a given claim term.

In response to the indefiniteness rejection concerning the meaning of "molecular weight" during the prosecution of the '847 patent, the earlier of the two continuations, the applicants argued that the term "molecular weight" was not indefinite because "[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight," i.e., M_w. J.A. 3229. To be clear, this was the only basis which the applicant argued in response to the indefiniteness rejection. And the applicant was successful. Defining "molecular weight" as M_w, as the applicant did in response to the rejection, was what overcame the rejection. The district court heard testimony that the statement made during the prosecution of the '847 patent was scientifically erroneous because each type of "molecular weight" can be expressed in kilodaltons. *Markman Order* at 592. The fact finding by the district court—that one of skill in the art would understand that each type of "molecular weight" could be expressed in kilodaltons—is not clearly erroneous. However, the fact that M_w, M_n, and M_p can each be expressed in kilodaltons does not erase the confusion created by the patentee about its claim scope. Regardless of the scientific accuracy of the statement, a person of ordinary skill in the art would have understood that the applicants defined the term "molecular weight" as M_w to gain allowance of the claims. This is a legal conclusion unaffected by the scientific error made during prosecution. To the extent that the dissent claims that the significance to be given to the patentee's express definition of molecular weight as M_w, made to overcome a rejection, is a question of fact, the dissent is wrong. The determination of the significance of statements made during prosecution to the claim construction is a question of law.

The examiner required the applicants to provide a meaning for "molecular weight" and they provided one: M_w. The fact that their explanation contained further

elaboration which itself included a scientific error does not undermine the statement's legal import. "The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent." *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003). We have held patentees to statements containing errors made during prosecution where, for example, nothing in the statement was at odds with the plain language of the claims or the specification. *See id.* at 995–96; *see also Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000) (rejecting patentee's "request for a mulligan that would erase from the prosecution history the inventor's disavowal of a particular aspect of a claim term's meaning" despite patentee's argument that a person of ordinary skill would have understood the statement during prosecution to be erroneous)*; cf. Biotec Biologische Naturverpackungen GmbH v. Biocorp, Inc.*, 249 F.3d 1341, 1348 (Fed. Cir. 2001) (declining to limit claims by erroneous statement made during prosecution that was contrary to the plain language of the claims, the specification, and other statements made during prosecution). Given the role of the statement in gaining allowance of the claims, a person of ordinary skill in the art would have understood the applicants to have defined "molecular weight" to mean M_w, and the fact that any of the measures (M_w, M_n or M_p) can be expressed in kilodaltons, does not change the significance of the choice made by the patentee, M_w, to overcome the rejection. And importantly, this determination is part of the legal analysis, not as the dissent claims, one of the fact findings to which we owe deference.

During the prosecution of the '539 patent, the applicants responded to a nearly identical indefiniteness rejection to the term "molecular weight" by arguing that a person "of ordinary skill in the art, upon reviewing the

specification, would understand that 'average molecular weight' refers to the molecular weight at the peak of the molecular distribution curve in Figure 1," i.e., M_p. J.A. 3258. Here too the specification was identical to the '808 and '847 patents in all respects relevant to the molecular weight question, and the examiner found the specification did not provide the reasonable certainty required for definiteness. The patentee overcame that rejection by again defining which measure of molecular weight to use, in that case M_p.

To summarize, it is undisputed that "molecular weight" or average molecular weight can be ascertained by any of three possible measures: M_p, M_n, and M_w. The claims do not indicate which measure to use. The specification never defines molecular weight or even mentions M_p, M_w, or M_n. And the term "average molecular weight" does not have a plain meaning to one of skill in the art. The district court fact findings regarding how one of skill in the art would understand the way in which a curve created with chromatogram data reflects molecular weights was not clearly erroneous. Its fact findings about the additional calculations that would be required to determine M_w or M_n are not clearly erroneous. Its fact findings about how a skilled artisan would accept a curve "shift" when converting chromatogram data to a curve such as that illustrated in Figure 1 are not clearly erroneous. A skilled artisan, knowing a shift might occur, would still not be reasonably certain in light of the entire record as to which type of average was intended. During prosecution of the related '847 and '539 patents, which with respect to molecular weight have identical specifications, examiners twice rejected the term "molecular weight" as indefinite for failing to disclose which measure of molecular weight to use (M_p, M_n, or M_w). And the patentee in one instance stated that it was M_w and in the other stated it was M_p. We find no clear error in the district court's

fact finding that one of the statements contained a scientifically erroneous claim. We hold that claim 1 is invalid for indefiniteness by clear and convincing evidence because read in light of the specification and the prosecution history, the patentee has failed to inform with *reasonable certainty* those skilled in the art about the scope of the invention. On this record, there is not reasonable certainty that molecular weight should be measured using M_p. This is the legal question—and on this question—we reverse the district court.

AFFIRMED-IN-PART, REVERSED-IN-PART

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

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MAYER, *Circuit Judge*, dissenting.

"[I]n some instances, a factual finding may be close to dispositive of the ultimate legal question of the proper meaning of [a claim] term in the context of [a] patent." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841–42 (2015). This is such a case. After carefully evaluating the testimony of the parties' experts, the district

court made a factual finding that an artisan skilled in the art of polypeptide synthesis would have inferred from the use of an analytic technique known as size exclusion chromatography ("SEC") in U.S. Patent No. 5,800,808 (the "'808 patent") that the term "molecular weight" referred to peak average molecular weight. *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 810 F. Supp. 2d 578, 588 (S.D.N.Y. 2011) ("*District Court Decision*"). The court further found that a person of ordinary skill in the art would have accepted a statement made by the patentee during prosecution of U.S. Patent No. 6,939,539 (the "'539 patent") as "proof" of what was meant by the term "molecular weight." *Id.* at 592.* Because neither of these factual findings is clearly erroneous, we are not free to disregard or discount them in assessing whether the '808 patent withstands definiteness scrutiny. *See Pullman-Standard v. Swint*, 456 U.S. 273, 287 (1982) (emphasizing that Federal Rule of Civil Procedure 52(a) "does not make exceptions or purport to exclude certain categories of factual findings from the obligation of a court of appeals to accept a district court's findings unless clearly erroneous"). I therefore respectfully dissent.

I.

In some cases, a trial court can decide an indefiniteness dispute based solely on the intrinsic evidence. When a district court's review is confined to the intrinsic record, its conclusion on indefiniteness will be a legal determination which we can appropriately review *de novo*. *See Teva*, 135 S. Ct. at 841. In many instances, however,

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* Teva Pharmaceuticals USA, Inc. and related parties (collectively "Teva") own the '808 patent, which is the sole patent at issue in this appeal. The '808 patent is related to both the '539 patent and U.S. Patent No. 6,620,847 (the "'847 patent"), and the three patents share substantially identical specifications.

particularly where complex technology is at issue, a trial court will be required to look outside a patent and its prosecution history in order to fully apprehend matters such as "the background science or the meaning of a term in the relevant art during the relevant time period." *Id.*; *see Seymour v. Osborne*, 78 U.S. 516, 546 (1871) (emphasizing that a patent may be "so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning"). Those laboring in different fields of scientific endeavor often speak with words drawn from specialized lexicons, and in many cases it is only by delving into the background science and thoroughly evaluating the testimony of competing experts that a trial court can make an informed determination as to whether a claim provides a skilled artisan with reasonable certainty as to the scope of an invention. *See Loom Co. v. Higgins*, 105 U.S. 580, 585 (1881) (explaining that skilled artisans "understand the language of their brother scientist[s]").

The court here is once again led astray by its failure to afford sufficient deference to the trial court's findings of fact. *See Teva*, 135 S. Ct. at 842. The district court engaged in extensive fact-finding about the background science reflected in the '808 patent. *See id.* at 840 ("[T]his case provides a perfect example of the factfinding that sometimes underlies claim construction: The parties here presented the District Court with competing fact-related claims by different experts, and the District Court resolved the issues of fact that divided those experts."). After considering expert declarations and deposition testimony—and holding two hearings—the court determined that the term "molecular weight" was not indefinite because a skilled artisan would have understood its meaning. *See District Court Decision*, 810 F. Supp. 2d at 587–95. Relying in significant measure on the testimony of Dr. Gregory Grant, Teva's expert, the trial court made

three key factual determinations: (1) a person of ordinary skill in the art of polypeptide synthesis would infer from the use of the SEC method disclosed in the specification of the '808 patent that the term "molecular weight" referred to peak average molecular weight, *id.* at 589–90; (2) a skilled artisan would not rely upon a statement Teva made when prosecuting the '847 patent that the expression of molecular weight in kilodalton units "implie[d] a weight average molecular weight," because that statement rested on obvious scientific error, *id.* at 591–92; and (3) that artisan would instead rely on Teva's affirmative statement, made while prosecuting the '539 patent, that "molecular weight" meant peak average molecular weight, *id.* at 592.

We must be "mindful that we are a court of review, not of first view," *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005), and that our duty is to evaluate each case in light of the facts as the trial court has found them. This court's conclusion that the '808 patent is fatally indefinite hinges on the fact that Teva made divergent statements as to the meaning of "molecular weight" when prosecuting the '847 and '539 patents. *Ante* at 17. That conclusion, however, cannot be reconciled with the district court's express factual finding that a skilled artisan would not rely on the statement Teva made as to the meaning of "molecular weight" when prosecuting the '847 patent because it was scientifically incorrect. Peak average molecular weight, weight average molecular weight, and number average molecular weight are *all* expressed in kilodaltons. *See District Court Decision*, 810 F. Supp. 2d at 592. Accordingly, Teva's statement that the use of kilodalton units implied that "molecular weight" meant weight average molecular weight was a non sequitur and, as the district court correctly found, a skilled artisan would not have relied upon it. *See id.*

As this court has repeatedly made clear, obviously erroneous statements in the prosecution file carry little

weight in determining claim meaning. *See, e.g.*, *Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1090 (Fed. Cir. 2003) (emphasizing that an "incorrect statement in the prosecution history [did] not govern the meaning of the claims"); *Biotec Biologische Naturverpackungen GmbH v. Biocorp, Inc.*, 249 F.3d 1341, 1348 (Fed. Cir. 2001) ("An error in the prosecution record must be viewed as are errors in documents in general; that is, would it have been apparent to the interested reader that an error was made, such that it would be unfair to enforce the error."). Furthermore, a single statement by Teva during prosecution of the '847 patent—made years after the '808 patent issued—should not be deemed dispositive on the question of whether the '808 patent is sufficiently definite. *See Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1580 (Fed. Cir. 1996) (emphasizing that the ambiguity of the prosecution history made it "unhelpful as an interpretive resource" for determining the meaning of a claim term). While the prosecution history of one patent in a chain may be used to construe the same term in both earlier and later issued related patents with the same specification, *see Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004), the court is unable to cite to a single case in which a statement made in prosecuting a later related patent was deemed sufficient, standing alone, to render an earlier issued patent indefinite. The prosecution history of the '847 patent cannot trump the disclosure in the specification of the '808 patent which, by describing the use of the SEC method, indicates to a skilled artisan that "molecular weight" means peak average molecular weight. *See Vederi, LLC v. Google, Inc.*, 744 F.3d 1376, 1382 (Fed. Cir. 2014) (emphasizing that "the specification is the single best guide to the meaning of a claim term" and that "the prosecution history often lacks the clarity of the specification" (citations and internal quotation marks omitted)).

According to the court, although Teva's statement that the use of kilodalton units "implie[d] a weight average molecular weight" was scientifically incorrect, a skilled artisan would nonetheless have understood that the applicants defined the term "molecular weight" as weight average molecular weight to gain allowance of the claims. *Ante* at 16. This argument is unconvincing. Read as a whole, Teva's statement that the use of kilodalton units "implie[d] a weight average molecular weight" is nonsensical, and a skilled artisan would not rely upon any part of it. This is particularly true given that Teva confirmed, when subsequently prosecuting the '539 patent, that—consistent with the use of the SEC method disclosed in the specification—the term "molecular weight" meant peak average molecular weight. *See Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1372–73 (Fed. Cir. 2007) (concluding that an earlier, incorrect statement in the prosecution history did not override a later, correct statement as to claim scope).

In assessing obviousness, what the prior art teaches is a question of fact. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *see also Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1307 (Fed. Cir. 2014) (en banc) (O'Malley, J., dissenting), *judgment vacated sub nom. Lighting Ballast Control LLC v. Universal Lighting Techs., Inc.*, 135 S. Ct. 1173 (2015) ("Importantly, one of the key fact questions in an obviousness inquiry is what a prior art reference teaches—often, what is claimed and described in a previously issued patent. And, all findings regarding the scope and content of the prior art are subject to clear error review." (citation omitted)). In assessing indefiniteness, likewise, a trial court's determination, based on expert testimony, as to what a skilled artisan would glean from subsequently issued patents and their prosecution histories is a factual finding which can be set aside only for clear error. *See Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 498 (1984)

("It surely does not stretch the language of [Rule 52(a)] to characterize an inquiry into what a person knew at a given point in time as a question of 'fact.'" (footnote omitted)). We cannot substitute our assessment of the testimony for that of the trial court simply because from our appellate perch we might assess that testimony differently. If we credit—as we must because it is not clearly erroneous—the district court's explicit finding that a skilled artisan would not rely on the facially incorrect statement made during prosecution of the '847 patent, there is no reasonable basis for concluding that the prosecution history of patents related to the '808 patent would create, in the mind of the skilled artisan, ambiguity regarding the meaning of the term "molecular weight."

The court's approach here contravenes binding precedent. In *Enzo Biochem Inc. v. Applera Corp.*, we held that under *Teva* a trial court's conclusion, based on expert testimony, as to whether an example in the specification disclosed "direct detection" was a "factual finding" which was subject to clear error review. 780 F.3d 1149, 1156 (Fed. Cir. 2015). Likewise, in *EON Corp. IP Holdings LLC v. AT&T Mobility LLC*, we held that a district court's determination, based on the testimony from experts, that claims disclosed "complicated, customized computer software" was a "factual finding[]." 785 F.3d 616, 624 (Fed. Cir. 2015). Here, however, the court insists that the determination, based on extensive expert testimony, that a skilled artisan would not rely on a facially incorrect statement made during prosecution of the '847 patent was "part of the legal analysis, not as the dissent claims, one of the fact findings to which we owe deference." *Ante* at 16. The court's view that the universe of factual findings to which we owe deference includes only "[u]nderstandings that lie outside the patent documents," *ante* at 13, simply cannot be squared with *Enzo* and *EON*.

Although the ultimate conclusion of indefiniteness under 35 U.S.C. § 112 is a legal question, *see Eidos Dis-*

play, LLC v. AU Optronics Corp., 779 F.3d 1360, 1364-65 (Fed. Cir. 2015), *Teva* mandates that the trial court's factual findings are to be respected, barring clear error, and that the required legal analysis must be performed in view of those findings, 135 S. Ct. at 841. Here, however, the court takes the opposite tack, first embarking on an independent review of the record and then considering, as an afterthought, the important and carefully considered factual findings made by the trial court.

II.

In *Nautilus, Inc. v. Biosig Instruments, Inc.*, the Supreme Court rejected this court's view that a claim met definiteness requirements so long as it was "amenable to construction," and, as construed, was not "insolubly ambiguous." 134 S. Ct. 2120, 2124 (2014) (citations and internal quotation marks omitted). Because the district court here relied on the now discarded "insolubly ambiguous" standard when it held that the '808 patent was not invalid for indefiniteness, *see District Court Decision*, 810 F. Supp. 2d at 582, this case should be remanded so that the court can take additional evidence as it deems appropriate and assess in the first instance whether the '808 patent meets the more stringent *Nautilus* definiteness standard. *See* 134 S. Ct. at 2124 (explaining "that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention").

The '808 patent will expire in September 2015. This looming expiration date does not, however, permit us to overstep our appellate role or feign first-hand experience with the testimony or the technology. We are neither equipped nor authorized to make the predicate factual determinations necessary to assess whether the '808 patent withstands definiteness scrutiny under the *Nauti-*

lus standard. *See Anderson v. Bessemer City*, 470 U.S. 564, 574 (1985) (emphasizing that "[t]he trial judge's major role is the determination of fact, and with experience in fulfilling that role comes expertise").