Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.
135 S. Ct. 831 (Jan. 20, 2015)

Justice BREYER delivered the opinion of the Court.

In *Markman v. Westview Instruments, Inc.,* we explained that a patent claim is that "portion of the patent document that defines the scope of the patentee's rights." We held that "the construction of a patent, including terms of art within its claim," is not for a jury but "exclusively" for "the court" to determine. That is so even where the construction of a term of art has "evidentiary underpinnings."

Today's case involves claim construction with "evidentiary underpinnings." And, it requires us to determine what standard the Court of Appeals should use when it reviews a trial judge's resolution of an underlying factual dispute. Should the Court of Appeals review the district court's factfinding *de novo* as it would review a question of law? Or, should it review that factfinding as it would review a trial judge's factfinding in other cases, namely by taking them as correct "unless clearly erroneous?" See Fed. Rule Civ. Proc. 52(a)(6). We hold that the appellate court must apply a "clear error," not a *de novo,* standard of review.

I

The basic dispute in this case concerns the meaning of the words "molecular weight" as those words appear in a patent claim. The petitioners, Teva Pharmaceuticals (along with related firms), own the relevant patent. The patent covers a manufacturing method for Copaxone, a drug used to treat multiple sclerosis. The drug's active ingredient, called "copolymer–1," is made up of molecules of varying sizes. And the relevant claim describes that ingredient as having "a molecular weight of 5 to 9 kilodaltons."

The respondents, Sandoz, Inc. (and several other firms), tried to market a generic version of Copaxone. Teva sued Sandoz for patent infringement. Sandoz defended the suit by arguing that the patent was invalid. The Patent Act requires that a claim "particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶ 2 (2006 ed.). The phrase "molecular weight of 5 to 9 kilodaltons," said Sandoz, did not satisfy this requirement.

The reason that the phrase is fatally indefinite, Sandoz argued, is that, in the context of this patent claim, the term "molecular weight" might mean any one of three different things. The phrase might refer (1) to molecular weight as calculated by the weight of the molecule that is most prevalent in the mix that makes up copolymer–1. (The scientific term for molecular weight so calculated is, we are told, "peak average molecular weight.") The phrase might refer (2) to molecular weight as calculated by taking all the different-sized molecules in the mix that makes up copolymer–1 and calculating the average weight, *i.e.,* adding up the weight of each molecule and dividing by the number of molecules. (The scientific term for molecular weight so calculated is, we are told, "number average molecular weight.") Or, the phrase might refer (3) to molecular weight as calculated by taking all the different-sized molecules in the mix that makes up copolymer–1 and calculating their average weight while giving heavier molecules a weight-related bonus when doing so. (The scientific term for molecular weight so calculated, we are told, is "weight average molecular weight.") In Sandoz's view, since Teva's patent claim does not say which method of calculation should be used, the claim's phrase "molecular weight" is indefinite, and the claim fails to satisfy the critical patent law requirement.

The District Court, after taking evidence from experts, concluded that the patent claim was sufficiently definite. …

On appeal, the Federal Circuit held to the contrary. It found that the term "molecular weight" was indefinite. And it consequently held the patent invalid. In reaching this conclusion, the Federal Circuit reviewed *de novo* all aspects of the District Court's claim construction, including the District Court's determination of subsidiary facts. …

II

A

Federal Rule of Civil Procedure 52(a)(6) states that a court of appeals "must not … set aside" a district court's "[f]indings of fact" unless they are "clearly erroneous." …

Our opinion in *Markman* neither created, nor argued for, an exception to Rule 52(a). The question presented in that case was a Seventh Amendment question: Should a jury or a judge construe patent claims? We pointed out that history provides no clear answer. The task primari-

ly involves the construction of written instruments. And that task is better matched to a judge's skills. We consequently held that claim construction falls "exclusively within the province of the court," not that of the jury.

When describing claim construction we concluded 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. But this does not imply an exception to Rule 52(a) for underlying factual disputes. We used the term "question of law" while pointing out that a judge, in construing a patent claim, is engaged in much the same task as the judge would be in construing other written instruments, such as deeds, contracts, or tariffs. Construction of written instruments often presents a "question solely of law," at least when the words in those instruments are "used in their ordinary meaning." But sometimes, say when a written instrument uses "technical words or phrases not commonly understood," those words may give rise to a factual dispute. If so, extrinsic evidence may help to "establish a usage of trade or locality." And in that circumstance, the "determination of the matter of fact" will "preced[e]" the "function of construction." This factual determination, like all other factual determinations, must be reviewed for clear error. …

While we held in *Markman* that the ultimate issue of the proper construction of a claim should be treated as a question of law, we also recognized that in patent construction, subsidiary factfinding is sometimes necessary. Indeed, we referred to claim construction as a practice with "evidentiary underpinnings," a practice that "falls somewhere between a pristine legal standard and a simple historical fact." We added that sometimes courts may have to make "credibility judgments" about witnesses. In other words, we recognized that courts may have to resolve subsidiary factual disputes. And, as explained above, the Rule requires appellate courts to review all such subsidiary factual findings under the "clearly erroneous" standard. …

Finally, practical considerations favor clear error review. We have previously pointed out that clear error review is "particularly" important where patent law is at issue because patent law is "a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience." A district court judge who has presided over, and listened

to, the entirety of a proceeding has a comparatively greater opportunity to gain that familiarity than an appeals court judge who must read a written transcript or perhaps just those portions to which the parties have referred.

D

Now that we have set forth *why* the Federal Circuit must apply clear error review when reviewing subsidiary factfinding in patent claim construction, it is necessary to explain *how* the rule must be applied in that context. We recognize that a district court's construction of a patent claim, like a district court's interpretation of a written instrument, often requires the judge only to examine and to construe the document's words without requiring the judge to resolve any underlying factual disputes. As all parties agree, 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, and the Court of Appeals will review that construction *de novo.*

In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.

For example, 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*. That is because "[e]xperts 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."

Accordingly, the question we have answered here concerns review of the district court's resolution of a subsidiary factual dispute that helps that court determine the proper interpretation of the written patent claim. The district judge, after deciding the factual dispute, will then interpret the patent claim in light of the facts as he has found them. …

In some instances, a factual finding will play only a small role in a judge's ultimate legal conclusion about the meaning of the patent term. But in some instances, a factual finding may be close to dispositive of the ultimate legal question of the proper meaning of the term in the context of the patent. Nonetheless, the ultimate question of construction will remain a legal question. Simply because a factual finding may be nearly dispositive does not render the subsidiary question a legal one. … It is analogous to a judge (sitting without a jury) deciding whether a defendant gave a confession voluntarily. The answer to the legal question about the voluntariness of the confession may turn upon the answer to a subsidiary factual question, say "whether in fact the police engaged in the intimidation tactics alleged by the defendant." An appellate court will review the trial judge's factual determination about the alleged intimidation deferentially (though, after reviewing the factual findings, it will review a judge's ultimate determination of voluntariness *de novo*). An appellate court similarly should review for clear error those factual findings that underlie a district court's claim construction.

III

We can illustrate our holding by considering an instance in which Teva, with the support of the Solicitor General, argues that the Federal Circuit wrongly reviewed the District Court's factual finding *de novo.* Recall that Teva's patent claim specifies an active ingredient with a "molecular weight of about 5 to 9 kilodaltons." Recall Sandoz's basic argument, namely that the term "molecular weight" is indefinite or ambiguous. The term might refer to the weight of the most numerous molecule, it might refer to weight as calculated by the average weight of all molecules, or it might refer to weight as calculated by an average in which heavier molecules count for more. The claim, Sandoz argues, does not tell us which way we should calculate weight.

To illustrate, imagine we have a sample of copolymer–1 (the active ingredient) made up of 10 molecules: 4 weigh 6 kilodaltons each, 3 weigh 8 kilodaltons each, and 3 weigh 9 kilodaltons each. Using the first method of calculation, the "molecular weight" would be 6 kilodaltons, the weight of the most prevalent molecule. Using the second method, the molecular weight would be 7.5 (total weight, 75, divided by the number of molecules, 10). Using the third method, the molecular weight would be more than 8, depending upon how much extra weight we gave to the heavier molecules.

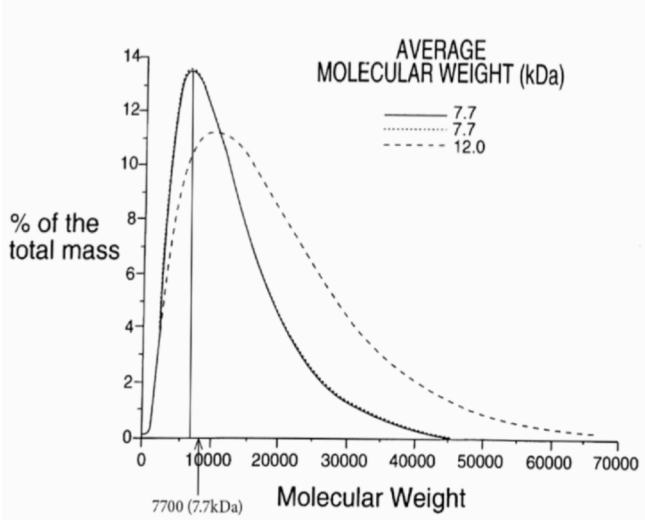

FIG. 1 (with minor additions to emphasize that the peak of the solid curve does not correspond precisely to 7.7kDa)

Teva argued in the District Court that the term "molecular weight" in the patent meant molecular weight calculated in the first way (the weight of the most prevalent molecule, or peak average molecular weight). Sandoz, however, argued that figure 1 of the patent showed that Teva could not be right. [*Ed.: Figure 1 is shown above.*] That figure, said Sandoz, helped to show that the patent term did *not* refer to the first method of calculation. Figure 1 shows how the weights of a sample's molecules were distributed in three different samples. The curves indicate the number of molecules of each weight that were present in each of the three. For example, the figure's legend says that the first sample's "molecular weight" is 7.7. According to Teva, that should mean that molecules weighing 7.7 kilodaltons were the most prevalent molecules in the sample. But, look at the curve, said Sandoz. It shows that the most prevalent molecule weighed, not 7.7 kilodaltons, but slightly less than 7.7 (about 6.8) kilodaltons. After all, the *peak* of the first molecular weight distribution curve (the solid curve in the figure) is not at precisely 7.7 kilodaltons, but at a point just before 7.7. Thus, argued Sandoz, the figure shows that the patent claim term "molecular weight" did not mean molecular weight calculated by the first method. It must mean something else. It is indefinite.

The District Court did not accept Sandoz's argument. Teva's expert testified that a skilled artisan would understand that converting data

from a chromatogram to molecular weight distribution curves like those in figure 1 would cause the peak on each curve to shift slightly; this could explain the difference between the value indicated by the peak of the curve (about 6.8) and the value in the figure's legend (7.7). Sandoz's expert testified that no such shift would occur. The District Court credited Teva's expert's account, thereby rejecting Sandoz's expert's explanation. The District Court's finding about this matter was a factual finding—about how a skilled artisan would understand the way in which a curve created from chromatogram data reflects molecular weights. …

When the Federal Circuit reviewed the District Court's decision, it recognized that the peak of the curve did not match the 7.7 kilodaltons listed in the legend of figure 1. But the Federal Circuit did not accept Teva's expert's explanation as to how a skilled artisan would expect the peaks of the curves to shift. And it failed to accept that explanation without finding that the District Court's contrary determination was "clearly erroneous." The Federal Circuit should have accepted the District Court's finding unless it was "clearly erroneous." Our holding today makes clear that, in failing to do so, the Federal Circuit was wrong. …

We vacate the Federal Circuit's judgment, and we remand the case for further proceedings consistent with this opinion.

Justice THOMAS, with whom Justice ALITO joins, dissenting.

I agree with the Court's conclusion that there is no special exception to Federal Rule of Civil Procedure 52(a)(6) for claim construction. But that is not the question in this case. Because Rule 52(a)(6) provides for clear error review only of "findings of fact" and "does not apply to conclusions of law," the question here is whether claim construction involves findings of fact. Because it does not, Rule 52(a)(6) does not apply, and the Court of Appeals properly applied a *de novo* standard of review. …

Patents are written instruments, so other written instruments supply the logical analogy. And as the majority recognizes, the construction of written instruments is generally a question of law. But in certain contexts, a court construing a written instrument makes subsidiary determinations that the law treats as findings of fact.

The classic case of a written instrument whose construction does *not* involve subsidiary findings of fact is a statute. Our treatment of subsidiary evidentiary findings underlying statutory construction as conclusions of law makes sense for two reasons.

First, although statutory construction may demand some inquiry into legislative "intent," that inquiry is analytically legal: The meaning of a statute does not turn on what an individual lawmaker intended as a matter of fact, but only on what intent has been enacted into law through the constitutionally defined channels of bicameralism and presentment. This remains so even if deciding what passed through those channels requires a court to determine a "fact" of historical understanding through an examination of extrinsic evidence. The Court has given no hint that this practice changes when the statute it construes is a land patent—that is, a public land grant.

Second, statutes govern the rights and duties of the public as a whole, so subsidiary evidentiary findings shape legal rules that apply far beyond the boundaries of the dispute involved. Our rules of construction for legislative acts have long been consciously shaped by the public's stake in those acts. …

A patent, generally speaking, is "an official document reflecting a grant by a sovereign that is made public, or 'patent.'" …

Like the royal prerogatives that were their historical antecedents, patents have a regulatory effect: They "restrain *others* from manufacturing, using or selling that which [the patent holder] has invented" for a specified period of time. And because the regulatory scope of a patent is determined by the claims in the patent, the subsidiary findings that a court makes during claim construction contribute to rules that limit conduct by the public at large.

Because they are governmental dispositions and provide rules that bind the public at large, patent claims resemble statutes. The scope of a patent holder's monopoly right is defined by claims legally actualized through the procedures established by Congress pursuant to its patent power. Thus, a patent holder's actual intentions have effect only to the extent that they are expressed in the public record. …