NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., ADAMAS PHARMACEUTICALS, INC.,
Plaintiffs-Appellants

MERZ PHARMA GMBH & CO. KGAA, MERZ PHARMACEUTICALS GMBH,
Plaintiffs

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee

2016-2550, 2016-2553

Appeals from the United States District Court for the District of Delaware in Nos. 1:14-cv-00121-LPS, 1:14-cv-00686-LPS, Chief Judge Leonard P. Stark.

Decided: December 11, 2017

GEORGE FRANK PAPPAS, Covington & Burling LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by JEFFREY B. ELIKAN, JEREMY D. COBB, BRADLEY KEITH ERVIN, ERIC RITLAND SONNENSCHEIN;

DAVID SCOTT DENUYL, San Francisco, CA; PETER J. ARMENIO, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY.

MARK DAVID SCHUMAN, Carlson, Caspers, Vandenburgh, Lindquist & Schuman, P.A., Minneapolis, MN, argued for defendant-appellee. Also represented by M. JEFFER ALI, JENNELL CHRISTINE BILEK.

Before LOURIE, REYNA, and TARANTO, *Circuit Judges*.

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

Concurring opinion filed by *Circuit Judge* LOURIE.

TARANTO, *Circuit Judge*.

Forest Laboratories, Inc.; Forest Laboratories Holdings, Ltd.; and Adamas Pharmaceuticals, Inc. (collectively, Forest) filed patent infringement actions against Teva Pharmaceuticals USA, Inc., in the U.S. District Court for the District of Delaware. During claim construction, the district court determined that all of the asserted patent claims are invalid for indefiniteness and on that basis entered judgment against Forest. We affirm.[1]

I

A

Adamas is the owner, and Forest Laboratories Holdings, Ltd., is the exclusive licensee, of six related patents:

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[1] Merz Pharma GmbH & Co. KGAA and Merz Pharmaceuticals GmbH were plaintiffs in one of the two civil actions now before us, namely, No. 1:14-cv-00121-LPS. Their asserted claims (against parties other than Teva) were eventually resolved by stipulation. *See* J.A. 281, 288.

U.S. Patent No. 8,168,209; U.S. Patent No. 8,173,708; U.S. Patent No. 8,283,379; U.S. Patent No. 8,329,752; U.S. Patent No. 8,362,085; and U.S. Patent No. 8,598,233. The patents describe and claim pharmaceutical compositions, and methods of administering pharmaceutical compositions, that contain extended-release formulations of memantine, an N-methyl-D-aspartate (NMDA) receptor antagonist. '209 patent, col. 1, lines 23–25.[2]

The NMDA receptor, which contains a calcium ion channel, is activated by the neurotransmitters glutamate and glycine. *Id.*, col. 1, lines 40–43. In patients with an overactive NMDA receptor, the calcium channel will remain open longer than necessary and calcium will build up, causing symptomatic and neurodestructive effects in the patient. *Id.*, col. 1, lines 51–56. NMDA receptor antagonists such as memantine can be used to prevent such calcium build-up and detrimental effects. *Id.*, col. 1, lines 57–63.

Memantine was traditionally administered in an immediate-release formulation, which, when administered, quickly released the active ingredient for absorption by the body. *See id.*, col. 1, lines 63–64; *id.*, col. 2, lines 38–42. For a patient newly taking the drug, introducing the active ingredient so quickly could lead to troublesome side effects; to temper those side effects, treatment with an immediate-release formulation required starting with a low dose, administered frequently, with increases of the dose level over time. *Id.*, col. 1, lines 64–67. Problems with such a dosing regimen are that starting with low

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[2] The '209, '708, '752, '085, and '233 have materially the same specification. The specification of the '379 patent is slightly different, but the parties rely entirely on the shared specification for their arguments on appeal. For simplicity, we refer only to the specification of the '209 patent.

doses delays the achievement of a therapeutically effective, steady-state level of the drug and that many patients find the complex dosing schedules hard to follow. *See id.*, col. 1, line 67 through col. 2, line 4.

An extended-release memantine formulation can address those problems. Upon administration to a patient, the memantine in such a formulation "is released into a subject sample [such as by entering a patient's bloodstream] at a slower rate than observed for an immediate release . . . formulation." *Id.*, col. 4, lines 24–26, 39–41. According to the specification, the rate that the memantine in a particular formulation enters a patient's bloodstream is measured in terms of a ratio: "dC" designates the change in concentration of memantine in blood during a specified time; "dT" designates the length of the specified time; and "dC/dT" (despite its similarity to the usual notation for a derivative) simply designates dC divided by dT. *Id.*, col. 4, lines 24–26, 36–38.

The change in memantine concentration in blood over time can be portrayed graphically to generate a curve known as a concentration profile. *See id.*, col. 4, lines 17–22 & Figs. 1A, 2D. Figures 1A and 2D are graphs of concentration profiles for immediate- and extended-release formulations of memantine, where the numbers are generated by a computer. For the same 20 mg dose, the figures show the plasma memantine concentration of the immediate-release formulation starting from zero at time zero and increasing more quickly than the plasma memantine concentration of the extended-release formulation.

The specification describes comparing the dC/dT of an immediate-release formulation to the dC/dT of an extended-release formulation containing an equivalent amount of memantine, and the specification focuses particularly on comparing the two when measured between time zero (when the formulations are administered) and Tmax

(when the *immediate-release* formulation reaches its maximum concentration in the blood). *Id.*, col. 4, lines 29–30, 34–47. For that time period, the dC/dT is higher for the immediate-release formulation than for the extended-release formulation, because at the time the memantine in the immediate-release formulation reaches its maximum concentration in the blood, the memantine in the extended-release formulation has not yet been fully released into the blood. *See id.*, col. 4, lines 39–50. Unlike the immediate-release formulation, the extended-release formulation does not require starting at a low dose followed by dose escalation but instead allows patients to achieve desirable steady-state concentration levels soon after the start of therapy with a simple dosing schedule and decreased side effects. *Id.*, col. 2, lines 19–25; *see also id.*, col. 4, lines 55–60.

B

Forest Laboratories, Inc., holds New Drug Application No. 22–525 covering Namenda XR® (Namenda Extended Release formulation), a memantine hydrochloride formulation "indicated for the treatment of moderate to severe dementia of the Alzheimer's type." J.A. 524 (Namenda XR® prescribing information). Six patents are listed as covering Namenda XR® in the Food and Drug Administration's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

In December 2013, Teva filed an abbreviated new drug application seeking approval to sell a generic version of Namenda XR® and provided Forest with its Paragraph IV certification stating that the six patents were invalid or will not be infringed by Teva's generic. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Forest then sued Teva in the U.S. District Court for the District of Delaware for infringe-

ment of the six patents pursuant to 35 U.S.C. §§ 271(e)(2), 281.[3]

When the parties addressed issues of claim construction, they disputed the construction of a term appearing, with slight variations, in the claims at issue on appeal: claim 1 of the '209 patent; claims 1 and 6 of the '708 patent; claim 1 of the '379 patent; claim 1 of the '752 patent; and claim 1 of the '085 patent. *Forest Labs., Inc. v. Teva Pharms. USA, Inc.*, Nos. 14-121, -200, -508, -686, -1058, -1271, 2016 WL 54910, at *8 & n.7 (D. Del. Jan. 5, 2016). The parties agreed that the language in claim 1 of the '209 patent is representative. *Id.* at *8 n.7. With the language at issue highlighted, claim 1 reads:

> 1. A solid pharmaceutical composition in a unit dosage form for once daily oral administration comprising an extended release formulation of 5 to 40 mg memantine or pharmaceutically acceptable salt thereof, wherein administration of a dose of the composition to a human subject provides a plasma memantine concentration profile, as measured in a single-dose human PK [pharmacokinetic] study, characterized by a ***change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the composition***, wherein the dC/dT is measured between the

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[3] In addition to the six patents, Teva filed a Paragraph IV certification regarding U.S. Patent No. 8,039,009, which is owned by Forest and is also listed in the Orange Book as covering Namenda XR®. Forest included the '009 patent in the infringement suit. The parties settled the infringement case regarding that patent in June 2016.

> time period of 0 to Tmax of the immediate release form of memantine.

'209 patent, col. 37, lines 11–22.

Forest proposed that the highlighted language either be left unconstrued or be construed to mean a "change in *plasma* memantine concentration *of the extended [sustained] release dosage form* as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the *extended [sustained] release dosage form*." *Forest Labs.*, 2016 WL 54910, at *8 (emphases added to indicate Forest's proposed changes to the plain language) (brackets in original).

Teva contended that the claim term is indefinite under 35 U.S.C. § 112, ¶ 2 (2006).[4] According to Teva, the term requires the comparison of a concentration profile of an immediate-release formulation and a concentration profile of an extended-release formulation, as measured in human pharmacokinetic studies. But, Teva asserted, neither the claim language nor the specification adequately describes how to conduct the studies to obtain those concentration profiles, and differences in study design lead to variable results in the claim-required comparison. In response, Forest argued that, under the claim language, the dC/dT of the extended-release formulation is to be derived from a *human* study, and then compared to the dC/dT from the computer-derived curve of the immediate-release formulation shown for Namenda 20 mg in Figures 1A and 2D of the specification.

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[4] The Leahy-Smith America Invents Act (AIA), Pub. L. No. 112–29 (2011), changed paragraph 2 into subsection (b), but it did not change the indefiniteness standard. The AIA amendment does not apply to this case.

Teva also proposed an alternative construction if the court did not find the language at issue to be indefinite. This alternative construction would call for both the immediate-release and extended-release profiles to be measured in the same human study. The relevant claim language would be read to refer to a

> change in mean plasma concentration of memantine as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the extended release composition, where the plasma concentration of the extended release and the immediate release memantine are measured in the same PK [pharmacokinetic] study conducted in human subjects.

Forest Labs., 2016 WL 54910, at *8. Forest expressly opposed that construction, arguing that it would be improper to read into the claim a requirement that the dC/dT of both the extended- and immediate-release formulations be measured in the same human study. *E.g.*, J.A. 502–03 (Forest's opening claim construction brief: "The claims do not include this [same human study] requirement; the proposed insertion of this limitation is merely an attempt—by certain Defendants [including Teva]—to rewrite this portion of the asserted claims.").

The district court construed the claim to require that the concentration profile of the extended-release formulation and the concentration profile of the immediate-release formulation be measured in human pharmacokinetic studies. *Forest Labs.*, 2016 WL 54910, at *8. The court concluded that the intrinsic evidence does not disclose a specific human-study design or provide guidance as to how to design a human study. *Id.* at *8–9; *see also* '209 patent, col. 5, lines 14–17 ("The precise slope for a given individual will vary according to the NMDA [receptor] antagonist being used, the quantity delivered,

or other factors, including, for some active pharmaceutical agents, whether the patient has eaten or not."). The court also found that the extrinsic evidence of how a person of skill in the art would understand the language at issue, including undisputed expert testimony, showed that "measurements from human [pharmacokinetic] studies vary widely in terms of the concentration profiles they generate" for any particular memantine formulation. *Forest Labs.*, 2016 WL 54910, at *9; *see also* J.A. 553 (Namenda package insert reports Tmax of "about 3-7 hours"); J.A. 660–61 (New Drug Application data shows Tmax values ranging from 1.6 hours to 9.8 hours). Because "[a] person of ordinary skill in the art would not know, with reasonable certainty, which 'human [pharmacokinetic] study' on which to rely when considering whether a formulation of memantine might infringe" and because human-study results are so variable, the court ruled, claim 1 and the other claims it represented are indefinite. *Forest Labs.*, 2016 WL 54910, at *8–9. The court did not address whether the claim required that the profiles be measured in the same human study, as proposed in Teva's alternative construction but opposed by Forest, and whether such a construction would render the claims indefinite. *See id.* at *8–9.

The court entered a final judgment of invalidity based on indefiniteness. Forest timely appealed.[5] We have jurisdiction under 28 U.S.C. § 1295(a)(1).

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[5] The appeal is limited to the claims listed above. Forest has not appealed the district court's judgment of invalidity as to claims 10 and 15 of the '708 patent, claim 1 of the '379 patent, claim 9 of the '752 patent, claim 7 of the '085 patent, and claim 1 of the '233 patent. *See Forest Labs.*, 2016 WL 54910, at *9–10.

II

A

We review de novo a district court's determination of indefiniteness, but we review for clear error any of the district court's underlying findings of fact based on extrinsic evidence. *Sonix Tech. Co., Ltd. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *UltimatePointer, L.L.C. v. Nintendo Co., Ltd.*, 816 F.3d 816, 826 (Fed. Cir. 2016). A patent claim must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2006). "[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." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

B

Forest contends that the district court erred by construing the claim to require that both of the concentration profiles being compared—the profiles of the extended- and immediate-release formulations—be derived from measurements in human pharmacokinetic studies. Forest argues that, under the proper construction, while the profile for the extended-release formulation must be measured in a human study, the profile to which it is being compared—the profile for the immediate-release formulation—must be the computer-generated profile shown in Figures 1A and 2D. We agree with the district court in rejecting Forest's argument.

The language of claim 1 requires "a plasma memantine concentration profile, as measured in a single-dose human PK [pharmacokinetic] study." '209 patent, col. 37, lines 16–17. While it is grammatically possible to read that phrase as referring to only the profile of the extend-

ed-release formulation, such a reading is unreasonable in the context of the intrinsic evidence.

The specification describes Figures 1A and 2D as showing concentration profiles of a 20 mg memantine immediate-release formulation and a 20 mg memantine extended-release formulation generated by a predictive pharmacokinetic software program called GastroPlus. '209 patent, col. 6, lines 58–65 ("F[igure] 1A is a graph showing the memantine plasma concentration over a period of 24 hours, as predicted by Gastro-Plus software package v.4.0.2, following the administration of a single dose of an immediate release (IR) formulation of memantine (Namenda) or a sustained release formulation of memantine (NPI-6701). The sustained release formulation exhibits a dC/dT during the initial phase that is about 20% of that for the immediate release (IR) formulation."); *id.*, col. 7, lines 26–32 (same description, in all material respects, of Figure 2D).[6] Those descriptions of Figures 1A and 2D are the only intrinsic evidence highlighted by Forest to support its argument that the immediate-release profile in those figures supplies the immediate-release profile recited in the claim. That is not enough to support the argument.

The descriptions of the figures are no more than what they purport to be: descriptions of the figures. They do not constitute a definition and are not even directed to the meaning of the claim terms. Elsewhere, the specification does expressly define terms, such as "dC/dT," *e.g.*, col. 4, lines 36–38, but it does not use such language for the

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[6] Forest equates the "sustained release" language of the specification with the "extended release" language of representative claim 1 of the '209 patent. (Other claims at issue use "sustained release" language.) We proceed on Forest's premise that the difference is immaterial to the issue before us.

immediate-release concentration profile. Indeed, the merely illustrative character of the figures is confirmed by the fact that the figures show profiles only for particular doses, not profiles for the full range of doses covered by the claims—for which immediate-release profiles are needed but not found in those figures.

In addition, the figures and the accompanying descriptions supply the same amount of detail for the immediate-release profile as for the extended-release profile. But it would make no sense to say that the figure descriptions "define" the extended-release formulation profile—which must be generated for any given potentially infringing product by (as Forest agrees) a human pharmacokinetic study. The figures are computer-to-computer comparisons that merely illustrate a possible relation between an immediate-release and extended-release formulation. *See* '209 patent, col. 29, lines 50–67 (Example 16: "Predicted Plasma Profile of Memantine Sustained Release").

Nor do Figures 1A and 2D define a fixed baseline for the claim-required comparison simply because they provide the only immediate-release concentration profile disclosed in the specification. Forest points to *Liberty Ammunition, Inc. v. United States*, 835 F.3d 1388, 1393 (Fed. Cir. 2016), in which this court rejected an indefiniteness challenge to a claim term requiring a "reduced area of contact" between the "interface" and "rifling" of a firearm. The court concluded that the claim language "necessarily calls for a comparison against some baseline." *Id.* at 1395. The specification narrowed "the ambiguity by disclosing that the patent's proposed projectile has a 'reduced contact area as compared to conventional projectiles'" and also "identifie[d] the M855 round as a specific conventional projectile that the invention seeks to improve upon." *Id.* at 1396. On that basis, the court determined that the specification's disclosure of one conventional round "strongly suggest[ed] that the M855

round is the point of comparison for the claims." *Id.* at 1396. In this case, by contrast, the basic descriptions of Figures 1A and 2D do not provide a clear point of comparison to narrow the claim language at issue.

The prosecution history also provides no support for Forest's proposed construction. The inventor declaration submitted during prosecution describes the results of a human pharmacokinetic study from which both immediate-release and extended-release profiles were derived. The inventor compared those two profiles measured in the human study; he did not compare the extended-release profile from the human study to the immediate-release profile in Figures 1A and 2D.

For those reasons, Forest's claim construction is contrary to the intrinsic evidence. And Forest does not argue that extrinsic evidence—about usage or other facts external to the patent—requires its reading of the claims as calling for a comparison of a human-study profile to a computer-generated profile. We therefore conclude, in agreement with the district court, that human-study comparisons are required.

C

The district court, having concluded that the claims require human-study comparisons, determined that there is no study design specified in the patents, that the patents are not limited to the particular human study reported in the prosecution history, that Forest's extrinsic evidence did not persuasively identify particular human studies a relevant skilled artisan would know to use, and that different human pharmacokinetic studies produce widely varying concentration profiles for particular formulations. *Forest Labs.*, 2016 WL 54910, at *8–9. In these circumstances, the district court's indefiniteness ruling is supported by precedents that hold claims indefinite in particular circumstances where the claims require measured quantities (absolute or relative), different

techniques for such measurements are known in the art and some produce infringing results and others not, the intrinsic evidence does not adequately specify the technique or techniques to use, and extrinsic evidence does not show that a relevant skilled artisan would know what technique or techniques to use. *See*, *e.g.*, *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 803 F.3d 620, 633–35 (Fed. Cir.), *rehr'g denied*, 809 F.3d 1223 (Fed. Cir. 2015); *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1339–42 (Fed. Cir. 2003).

Forest makes only one argument for setting aside the indefiniteness ruling if this court agrees with the district court's rejection of its human-to-computer comparison construction. In that event, Forest argues, this court should adopt the claim construction that Teva presented in the alternative in the district court. Specifically, Forest argues that, if the claim requires that both the extended- and immediate-release profiles be measured in a human study, the claim requires that both profiles be measured in the same study.

Forest affirmatively opposed this very position in the district court when Teva raised it. Forest argued repeatedly that it would be improper to read into the claim a requirement that the dC/dT of both the extended- and immediate-release formulations be measured in the same human study. *E.g.*, J.A. 502–03 (Forest's opening claim construction brief: "The claims do not include this [same human study] requirement; the proposed insertion of this limitation is merely an attempt—by certain Defendants—to rewrite this portion of the asserted claims. . . . That construction is unduly restrictive, particularly where, as here, there is nothing in the claim language, specification, or prosecution history that remotely suggests the inventors intended to so limit the claims."); Pls.' Reply Claim Constr. Br., *Forest Labs., Inc. v. Teva Pharms. USA, Inc.*, No. 1:14-cv-121, Dkt. No. 125, at 7–8 (D. Del. July 15, 2015) ("In reaching his conclusion[] . . . [that the immedi-

ate and extended release profiles should be derived from the same human pharmacokinetic study], [Teva's expert] was not informed of the claim construction principle that limitations from the specification should not be read into claims. [His] opinions are premised on incomplete legal standards; they are unreliable and should not be credited.") (internal citation omitted); Claim Constr. Hr'g Tr., No. 1:14-cv-121, Dkt. No. 158, at 58 (D. Del. Aug. 3, 2015) (Forest's counsel: A same study requirement would impose on Forest "an onerous burden that we [would] have to go take their generic drug, take branded Namenda, and then go out and find human beings that are willing to participate in a study like that to prove infringement."); *see also* J.A. 1147–48 (declaration of Forest's expert, Dr. James Polli: "I also disagree with [Teva's expert] that the person of ordinary skill would understand the claims as requiring comparison of the [immediate-release] and [extended-release] dosage forms in the 'same' single dose human [pharmacokinetic] study.").

In many cases we have barred an appellant from urging a new claim construction on appeal. *See*, *e.g.*, *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1346 (Fed. Cir. 2001) (collecting cases). This case involves a particularly extreme situation, because the position Forest now proposes is not just different from any it urged the district court to adopt but is one that Forest affirmatively and unequivocally urged the district court to reject. *Cf. N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1290 (Fed. Cir. 2000) (noting that "we look with extreme disfavor on appeals that allege error in claim constructions that were advocated below by the very party now challenging them.") (internal quotation marks omitted). The important interests in judicial efficiency support finding waiver in these circumstances.

III

For the foregoing reasons, we affirm the judgment of the district court.

AFFIRMED

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

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LOURIE, *Circuit Judge*, concurring.

I fully join the thorough opinion of the court finding certain claims indefinite. We decide appeals based on the decision of the lower tribunal and the arguments raised before us. Thus, the opinion of the court properly and correctly addresses those issues and arguments.

However, Claim 1 is indefinite for a much more basic reason than the opinion recites, or the parties have briefed. Claim 1 of this patent recites a "solid pharmaceutical composition . . . comprising an extended release formulation of 5 to 40 mg memantine . . ., wherein administration of a dose . . . provides a plasma memantine concentration profile, as measured in a single-dose human PK study, characterized by a change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form." U.S. Patent 8,168,209 col. 37 ll. 11–19.

Pharmaceutical dosage forms containing memantine are old. This claim attempts to encompass an extended release formulation of memantine, but it does so without including any materials that cause the extended release. It attempts to serve that function by defining a result, a concentration profile. Claiming a result without reciting what materials produce that result is the epitome of an indefinite claim. Such a claim fails to delineate with any reasonable certainty the requirements of the formulation. The claim is thus indefinite irrespective of the twisting narrative that is recited concerning how the result is measured. It is a hollow claim.

In dependent claims 7–9, the patent does recite, in more definite terms, how to achieve the claimed result. Claim 7 focuses on an extended release coating. I will not appraise the definiteness of that claim, but at least it makes an attempt at definiteness by reciting some structure to cause extended release. Claim 8 then recites an insoluble matrix polymer and a water soluble material. And finally, claim 9 gets to the point, reciting ethyl cellulose and polyvinylpyrrolidone.

But it is claim 1 that is before us and, while I join the majority opinion finding claim 1 indefinite in the recitation of the means for determining the result, and admire its unwinding of that tortuous recitation, claim 1 is indef-

inite for the principal and simple reason that it claims a result without reciting how to achieve that result, as the subsequent dependent claims perhaps do. The measurement of that result is secondary to the basic defect of the claim.