No. 21-757

IN THE
Supreme Court of the United States

AMGEN, INC. ET AL.,
Petitioners,

v.

SANOFI. ET AL.,
Respondents.

ON WRIT OF CERTIORARI TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF ABBVIE INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Section 112 of the Patent Act provides that a patent's "specification shall contain a written description of the invention, and of the manner and process of making and using it," sufficient "to enable any person skilled in the art * * * to make and use the" invention. 35 U.S.C. § 112(a). The requirement that the specification teach skilled artisans "to make and use" the invention is referred to as the "enablement" requirement. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996).

The question presented is:

Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "*to reach the full scope* of claimed embodiments" without undue experimentation — i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "time and effort," Pet. App. 14a (emphasis added).

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INTEREST OF AMICUS CURIAE

AbbVie Inc. ("AbbVie"), a global, research-based biopharmaceutical company, has a significant interest in ensuring a fair, predictable, and robust system of patent protection.[1] Since its creation in 2013, AbbVie has invested more than $50 billion in research and development of new medicines. Today, AbbVie employs approximately 50,000 employees around the world. AbbVie's mission is to discover and deliver innovative medicines and products that solve serious health issues and enhance people's lives today and address the medical challenges of tomorrow.[2]

SUMMARY OF ARGUMENT

Genus claims are critically important, particularly in the chemical, pharmaceutical, and biotechnology industries. A genus claim allows an inventor to obtain patent protection not only for the particular examples of the invention disclosed in the patent application, but also for the "genus" of related species sharing the same innovation. Genus claims often contain functional language to cover the embodiments of the invention sharing the common innovative feature. When a pioneering inventor files a patent application disclosing to the world a breakthrough invention with broad applicability, the

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[1] This brief is filed with the written consent of all parties. No counsel for either party authored this brief in whole or in part, nor did any party or other person or entity other than amicus curiae or its counsel make a monetary contribution to the brief's preparation or submission.

[2] Amicus takes no position on the validity of the particular claims at issue and submits this brief solely to address the legal defects in the "full scope" test.

inventor deserves a correspondingly broad scope of patent protection. Genus claims with functional limitations promote the progress of science.

The Federal Circuit has improperly created a heightened enablement standard for genus claims with functional limitations, which the Court of Appeals described as "*rais[ing] the bar* for enablement." Pet. App. 13a (emphasis added). In particular, the Federal Circuit has held that patent specifications for genus claims with functional limitations do not comply with the enablement requirement of 35 U.S.C. § 112 unless they enable those skilled in the art "to reach *the full scope* of claimed embodiments" without "undue experimentation." Pet. App. 14a-15a (emphasis added). That is, the specification must enable a person having ordinary skill in the art ("PHOSITA") to cumulatively identify and make the various embodiments of the invention without "substantial time and effort." *Id.* at 14a. The Court of Appeals stressed that "it is important to consider the quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the *full scope* of the claim." *Id.* at 11a (emphasis added).

This Court should reject the Federal Circuit's "full scope" test for enablement, which has proven to greatly reduce valid claim breadth, especially in the chemical, pharmaceutical, and biotechnology sectors. The test has no basis in the statutory language or structure of the Patent Act, chills innovation and investment, and disserves fundamental congressional objectives embodied in patent law. The "full scope" test is also inconsistent with this Court's historical precedent.

The Federal Circuit opined that the "full scope" test poses "high hurdles in fulfilling the enablement requirement for claims with broad functional language." Pet. App. 12a. Indeed, those hurdles are not simply "high" but virtually insuperable, as the Federal Circuit's track record shows. Under the "full scope" test, the Court of Appeals has invalidated genus claim after genus claim, particularly in chemical, pharmaceutical, and biotechnology patents, leading scholars to proclaim the "death" of judicially enforceable genus claims in those fields.[3]

The "full scope" test destroys the basic "bargain" of patent law, because it does not give pioneering inventors adequate range of patent protection for breakthrough inventions with broad applicability. Groundbreaking inventions typically require significant risk, substantial investment, and years of research. The "full scope" test curtails the incentives to engage in such efforts.

Pioneering inventors should not be limited to narrow patent claims that underrepresent the full benefits of their inventions, thus allowing competitors to make "design-around" solutions capturing a patent's economic returns. In addition, the "full scope" test has spawned wasteful and debilitating litigation, by giving competitors an opportunity to attack previously issued patents, many of which were written, filed, and granted years before the "full scope" test was articulated.

The "full scope" test is fatally flawed because it is not tied to the text or purpose of the enablement

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[3] Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J. L. & TECH. 1 (2021).

requirement. Nothing in Section 112 suggests that enablement depends on the cumulative time and effort required to make virtually all variations of the invention. Instead of asking whether a patent specification sufficiently enables a PHOSITA to "make and use" *the invention* without undue experimentation, the "full scope" test asks whether the specification enables *virtually every species within the genus* without undue experimentation. But there is no evidence in this case (or anywhere else) that a PHOSITA needs "full scope" enablement in order to practice an invention. In fact, a PHOSITA may need only a small number of embodiments — sometimes only a single one — to fully appreciate and practice the invention. An inventor who has taught PHOSITAs how to make and use individual embodiments across the scope of the claim should not lose patent protection simply because substantial time and effort would be required to make almost every one of them.

This Court should make clear that the factors articulated in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), remain the proper standard for deciding whether a patent specification adequately enables a claim, regardless of its scope or whether it contains functional limitations. Those factors represent a familiar and time-tested approach that has guided innovators in all fields for over three decades. The Federal Circuit's ill-advised attempt to engraft a "full scope" requirement on top of the enablement standard has spawned uncertainty and created the risk of chilling innovation.

ARGUMENT

I. THE FEDERAL CIRCUIT'S "FULL SCOPE" TEST FRUSTRATES THE GOALS OF PATENT LAW.

The Patent Act embodies "a carefully crafted bargain." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). In exchange for a disclosure that teaches a PHOSITA how to make and use the invention, the patentee receives a time-limited right to exclude others from practicing the invention. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974). This bargain increases scientific progress as well as economic competition. More knowledge in the art is more promptly delivered to PHOSITAs, and subsequent inventors can more quickly build upon past innovations.

The "full scope" test does not further the fundamental purposes of the enablement requirement. To the contrary, it disrupts the patent bargain, chills investment in new discoveries and innovation, and creates uncertainty and litigation by adding an unnecessary layer of analysis to the settled *Wands* factors for determining enablement.

A. The "Full Scope" Test Chills Investment and Innovation.

Inventors in nearly every field engage in "genus claiming" – they seek patent claims broader than the specific embodiments they disclose. "It is an essential characteristic of all patent claims that they cover a set of entities rather than a single entity. Otherwise claims could not be infringed, save perhaps by the use

of the one physical entity that the inventor constructed."[4]

Genus claims with functional limitations are especially important in chemistry, pharmaceuticals, and biotechnology, where breakthrough innovations invariably require very significant investments of time and money. Pioneering inventions with broad applicability that substantially promote scientific progress deserve patent protection of robust and meaningful scope. Otherwise, the incentive to devote the extensive resources necessary to promote scientific progress would be greatly reduced.

When inventors' contribution to the art is genuinely significant, they are entitled to patent protection commensurate with the scope of their contribution. Accordingly, patent law appropriately protects not only the particular examples disclosed in the patent and the specific embodiment practiced by the inventor, but also the "genus" of related species sharing the same inventive concept.

But the Federal Circuit's "full scope" test undercuts the need for genus claiming and upends the Patent Act's carefully crafted bargain. The Federal Circuit acknowledged that the "full scope" test "raises the bar" and creates "high hurdles in fulfilling the enablement requirement." Pet. App. 12a-13a. The test has already been proven to have an especially harsh impact on genus claims, particularly in chemistry, pharmaceuticals, and biotechnology. In

[4] Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L. J. 1141, 1168 (2008).

those fields, the Federal Circuit in recent years has consistently held genus claims with functional limitations non-enabled under the "full scope" approach.[5] "[T]here are virtually no significant examples of genus claims in the life science fields upheld on appeal as compliant with § 112(a) outside the unique context of interference proceedings. The Federal Circuit's shift in its approach to genus claims and the regularity with which those claims are now struck down reflect a fundamental . . . change in patent doctrine."[6]

The Federal Circuit's predecessor court recognized the danger of a "full scope" approach. The court warned that "forc[ing] an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments" would "discourage inventors from filing patent applications in an unpredictable area." *In re Angstadt*, 537 F.2d 498, 502-03 (C.C.P.A. 1976). That warning is squarely applicable here.

There are no adequate alternatives to genus claiming. Trade secret protection is often not an option for pharmaceutical and biotechnology companies, which must disclose a drug's Active Pharmaceutical Ingredient ("API"), i.e., the biologically active component producing the intended therapeutic effects. Even if available, trade secret law is a much weaker choice. *See Kewanee Oil*, 416 U.S. at 475 ("A trade secret law, however, does not offer

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[5] Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J. L. & TECH. 1, 23-35 (2021).

[6] *Id.* at 23.

protection against discovery by fair and honest means, such as by independent invention, accidental disclosure, or by so-called reverse engineering, that is by starting with the known product and working backward to divine the process which aided in its development or manufacture."). And trade secrets do not serve the interest in public disclosure that the patent system is meant to promote. The "full scope" test thus frustrates basic goals of U.S. patent law.

B. The "Full Scope" Test Is Disconnected from the Purpose of the Enablement Requirement.

The "full scope" test does not further the purpose of the enablement requirement because it departs from the practical inquiry of what a PHOSITA needs to know in order to make and use an invention. This Court has always described enablement in practical terms. A patent's disclosures "satisf[y] the law" if they are "sufficiently definite to guide those skilled in the art to" the "successful application" of "the invention," *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916), "point[ing] out some practicable way of putting [the invention] into operation," *The Telephone Cases*, 126 U.S. 1, 536 (1888). These decisions reflect the fact that patent claims are not written for courts or lay audiences, but for a specialized target group — skilled artisans already familiar with the field. Before the "full scope" test, the enablement standard had focused on whether "the specification described the invention well enough to allow members of the appropriate trade to reproduce it." *Markman*, 517 U.S. at 379.

But the "full scope" test substitutes a different inquiry: whether a patent specification enables a

PHOSITA to make and use virtually *every species* within the genus without undue experimentation – even if a PHOSITA would not have needed to make (or even to know) all of the species in order to practice the invention. In this case, for example, there was no evidence that PHOSITAs needed to see all potential species to make their own antibodies. Innovators should not have their patents invalidated on the basis of "substantial time and effort" or "undue experimentation" in which PHOSITAs would never engage. Such an approach completely undermines the bargain created by the Patent Act.

An example illustrates the fatal flaws in the "full scope" test. Consider an inventor who discovers revolutionary manufacturing processes that render ice cream calorie-free. The inventor ought be entitled to patent claims covering calorie-free ice cream of any flavor, even if the patent only teaches processes making two flavors, vanilla and chocolate. The inventor deserves a genus claim with a scope commensurate to the pioneering contribution. The flavor makes no difference to the innovative feature of the invention, which is the groundbreaking creation of calorie-free ice cream. And a "full scope" test that limits the inventor to narrow claims covering only vanilla and chocolate, because the inventor did not exemplify strawberry, salted caramel, and "far corner" flavors, does not incentivize disclosure, innovation, or competition. The proper enablement inquiry should not be whether a PHOSITA can make virtually every conceivable calorie-free ice cream flavor without substantial time and effort. The proper enablement inquiry ought to be whether a PHOSITA, armed with the teachings of the patent, can make a calorie-free ice cream without undue

experimentation. The "full scope" test is not tethered to the purpose of the enablement standard.

C. The "Full Scope" Test Should Not Be Engrafted on Top of the *Wands* Factors Framework.

For over three decades, the *Wands* factors have provided a predictable framework for analyzing enablement and undue experimentation. Those factors include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

858 F.2d at 737.

The *Wands* factors are derived from this Court's precedent[7] and afford all the guidance that is needed. They have demonstrated a time-tested ability to operate effectively for all kinds of claims. The factors allow for consideration of expert testimony and contextual facts about what sort of experimentation a PHOSITA would actually conduct, the state of knowledge in the relevant art, and the accused infringer's real-world experience in deriving working embodiments from the patent's specification. The *Wands* factors provide for a case-by-case assessment of whether the specification teaches a PHOSITA to

[7] *See* 858 F.2d at 737 n.19 (citing *Mineral Separation*, 242 U.S. at 270–71).

make and use the invention without undue experimentation.

The proceedings in this case illustrate the fact-based nature of the inquiry. This case featured heavily litigated trials with extensive expert testimony and fully developed factual records in which two different juries upheld Amgen's patents against enablement challenges. This case also shows the danger of after-the-fact judicial second-guessing based on a "full scope" test disconnected from the practical reality of how a PHOSITA would actually employ the invention.

The facts of the *Wands* case itself are instructive and show the proper approach to enablement. Like this case, *Wands* involved antibody technology — there, a novel immunoassay (a method for detecting or measuring the presence of an antigen) using certain monoclonal antibodies. The patent claim defined the antibody according to its affinity for binding to a specific protein (known as the hepatitis B surface antigen) on the surface of the hepatitis B virus. *Wands* held that no additional enablement was required. The court noted that "methods for obtaining and screening monoclonal antibodies were well known" and that making the high-affinity antibodies required only "routine screening." *Id.* at 736. *Wands* explained that "[e]nablement is not precluded by the necessity for some experimentation such as routine screening." *Id.* at 736-37.

That context-specific, case-by-case method provides a balanced and workable enablement test, as confirmed by other decisions following the same

approach.[8] This Court should reject the Federal Circuit's ill-advised attempt to add a new and uncertain "full scope" requirement to the enablement standard.

II. THE FEDERAL CIRCUIT'S "FULL SCOPE" TEST IS CONTRARY TO THE TEXT AND STRUCTURE OF THE PATENT ACT.

The "full scope" test should be rejected for the further reason that it runs counter to the text and structure of the Patent Act. Nothing in the text of 35 U.S.C. § 112 implies (let alone requires) that a patent specification must enable the PHOSITA to make and use virtually every embodiment or species covered by

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[8] *E.g., Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1352 (Fed. Cir. 1998) (finding enablement requirement met under the *Wands* factors, despite the need for skilled artisans to engage in "[r]outine repetition of a patent's specification to achieve a desired experimental result") (alteration in original); *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (finding claims at bar insufficiently enabled but cautioning that "[i]t is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art"). Prior to *Wands*, the Federal Circuit followed a similar approach. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (finding genus claim covering immunoassay method using antibodies to detect antigen was properly enabled because testing and screening were "well known"; "a patent need not teach, and preferably omits, what is well known in the art"); *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984) (finding claims enabled: "The district court held it would have been impossible for [the inventor] to list all operable emulsions and exclude the inoperable ones. Further, it found such list unnecessary, because one skilled in the art would know how to select a salt and fuel and then apply [a settled scientific principle] to determine the proper emulsifier.").

the claims without undue experimentation. Rather, the enablement requirement in Section 112(a) simply provides that a patent must "contain a written description of the invention" in "such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a).

The language of Section 112 does not suggest that enablement depends on the cumulative time and effort required to make all variations of the invention. The language of Section 112(a) refers to making and using "the invention" — not virtually every species embodying the invention. Nor is there any statutory language imposing a higher standard on genus claims with functional limitations than any other type of claim.

The "full scope" test is also at odds with the structure of the Patent Act. Nowhere else in the patent statute is the term "invention" meant to denote virtually every conceivable embodiment of the invention. For example, to determine the date of invention for priority purposes in an interference, an inventor must show conception and reduction to practice of only a "single embodiment." *Pioneer Hi-Bred Int'l, Inc. v. Monsanto Tech. LLC*, 671 F.3d 1324, 1331 (Fed. Cir. 2012); *see also Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002) (to show actual reduction to practice, only "an embodiment" is required).

In addition, Section 112 contains the requirement that applicants disclose what they subjectively believe to be the best embodiment of their invention, or the best mode of practicing their invention (the so-

called "best mode" requirement). The statute requires disclosure only of the "best mode" — not "every mode." Moreover, the law has never required an applicant to determine the absolutely "best" mode based on an examination of all possible embodiments.[9]

Any concerns about overly broad genus claims are already addressed by the *Wands* factors framework, without the "full scope" test. If a claim actually exceeds what the specification enables, the *Wands* factors allow a challenger to show, through expert testimony and other evidence, that a PHOSITA cannot "make and use" the invention without undue experimentation by following the patent's teachings.

Other provisions of the Patent Act impose limits on patentability and contain further guardrails against overly broad genus claims as well. For example, Section 101, 35 U.S.C. § 101, contains an implicit exception that "laws of nature, natural phenomena, and abstract ideas are not patentable." *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 70 (2012) (internal quotation marks omitted); *see also Ass'n for*

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[9] *See Ajinomoto Co. v. Int'l Trade Comm'n*, 597 F.3d 1267, 1273 (Fed. Cir. 2010) ("[D]etermining compliance with the best mode requirement is a two-prong inquiry. First, the court must determine whether, at the time the patent application was filed, the inventor possessed a best mode of practicing the claimed invention. This prong is highly subjective; it focuses on the inventor's own personal preferences as of the application's filing date. Second, if the inventor has a subjective preference for one mode over all others, the court must then determine whether the inventor 'concealed' the preferred mode from the public. In other words, the second prong asks whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention.") (citations omitted).

Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589 (2013).

In addition, the "obviousness" standard of Section 103(a) forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). An overly broad claim that trenches on familiar ground rather than representing a truly pioneering advancement will face challenge under the obviousness standard.

Further, Section 112(a) also contains a "written description" requirement: a patent must contain "a written description of the invention" and "of the manner and process of making and using it." *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002). Thus, Section 112(a) provides another guardrail against overly broad claims that are not adequately described.

In short, the congressionally enacted Patent Act already contains safeguards against overly broad genus claims. There is no need to engraft the "full scope" test on top of the *Wands* factors.

III. THE FEDERAL CIRCUIT'S "FULL SCOPE" TEST IS CONTRARY TO THIS COURT'S LONGSTANDING PATENT PRECEDENT.

The Federal Circuit's "full scope" test upends two centuries of this Court's precedent relating to the enablement requirement. This Court has long

recognized the importance of patent claims that cover more than the particular species or embodiments disclosed by the inventor; in effect, this Court has always recognized the need for genus claiming, particularly with respect to pioneering inventions. And, until now, this Court has upheld patents as sufficiently enabled without regard to whether making virtually all possible variations embodying the claimed invention would have required undue experimentation.

For example, in *Minerals Separation*, 242 U.S. 261, this Court upheld a genus claim relating to "improvements in the process for the concentration" of metallic ores. *Id.* at 263. The Court recognized it was "obviously impossible to specify in a patent the precise treatment" for each of the potentially "infinite[]" variations of the claim. *Id.* at 271. The Court acknowledged that each variation "present[ed] its special problem." *Id.* But this Court held that the claim language was "clearly sufficiently definite to guide those skilled in the art to its successful application," despite "leaving something to the skill of persons applying the invention." *Id.* The patent in *Minerals Separation* thus would have failed the "full scope" test: The "'time and effort'" necessary for skilled artisans "to reach the full scope" of claimed embodiments — the "infinite" variations — would have been significant. Yet this Court held that it was enough that skilled artisans could apply the process to particular ores as needed.

In upholding the claims to Alexander Graham Bell's patent on the telephone, this Court observed that "a patent for such a discovery is not to be confined to the mere means he improvised to prove the reality of his conception." *The Telephone Cases*, 126 U.S. at

539. "It is enough if [the patentee] describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out *some* practicable way of putting it into operation." *Id.* at 536 (emphasis added).

Similarly, in *Tilghman v. Proctor*, 102 U.S. 707 (1880), the Court upheld a genus claim for the separation of oils and fats: "Perhaps the process is susceptible of being applied in many modes and by the use of many forms of apparatus. The inventor is not bound to describe them all in order to secure to himself the exclusive right to the process, if he is really its inventor of discoverer." *Id.* at 728.

In *Mowry v. Whitney*, 81 U.S. 620 (1871), the Court explained that the fact the patent's language leaves "something to the [PHOSITA's] skill in applying the invention" is not fatal. *Id.* at 644. In that case, the Court rejected a challenge to a patent for making cast-iron railroad car-wheels based on the patentee's direction to raise the heat within minimum and maximum limits, where the specific degree was "left to the judgment of the operator," because "it [was] successfully applied in the manufacture of a vast number of wheels" and "failure [was] very rare." *Id.* at 645-46. *See also Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45, 65-66 (1923) (finding enablement where the patent specification described the invention to PHOSITAs such that they "had no difficulty" recreating the invention); *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 380 (1909) ("while no complete mechanism is pointed out in the specifications, [there is] enough to indicate to those skilled in such matters a mechanism whereby the method of the patent can be put into operation").

The "full scope" test is thus contrary to longstanding precedent.

CONCLUSION

The Federal Circuit's judgment should be reversed.

Respectfully submitted.

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