No. 20-1258

IN THE

Supreme Court of the United States

ONO PHARMACEUTICAL CO., LTD., TASUKU HONJO, E.R. SQUIBB & SONS, L.L.C., AND BRISTOL-MYERS SQUIBB COMPANY,
Petitioners,

v.

DANA-FARBER CANCER INSTITUTE, INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONER

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INTRODUCTION

Dana-Farber's attempts to obscure the clear legal issue in this case are unavailing. The Federal Circuit held that "joint inventorship does not depend on whether a claimed invention is novel or nonobvious over a particular researcher's contribution" and that "[t]he novelty and nonobviousness of the claimed inventions over [Dr. Freeman and Dr. Wood's] provisional application are not probative of whether … each researcher's contributions were significant to their conception." Pet. App 13a. The Federal Circuit thereby categorically refused to consider what made the claims *inventive* as part of the analysis of whether an individual is a joint *inventor*. This case does not present a fact-bound dispute, but rather a fundamental disagreement about the legal standard to be applied in a particularly murky area of patent law that impacts inventorship decisions made every day and that this Court has not addressed for over 100 years. This Court should grant the petition to resolve that important question.

Dana-Farber's own arguments undercut its attempt to downplay the legal issue at the heart of this case. Dana-Farber asserts that the Federal Circuit did not apply a bright-line rule, but simultaneously argues that the Federal Circuit applied "settled law that, for a contribution to be significant, the ideas contributed must not have been *contemporaneously* available to an ordinary skilled artisan *at the time of the contribution*" and that "joint inventorship does not 'depend on' the novelty and nonobvious[ness] of the invention over a particular researcher's contribution." Opp. 21. That characterization of the state of the law in the Federal Circuit aptly illustrates the problem: This bright-line rule that Dana-Farber labels "settled" contravenes

black-letter patent law, conflicts with this Court's precedent, and creates a circuit split. Dana-Farber's assertion that this bright-line rule follows from "settled" Federal Circuit precedent thus provides even more reason to grant the petition and correct the Federal Circuit's misguided precedent.

Beyond contradicting its own characterization of the law, Dana-Farber's attempt to recast the Federal Circuit's decision relies on conflating two distinct portions of the opinion and ignoring the Federal Circuit's plain statement that the "novelty and nonobviousness of the claimed inventions … are not probative." Indeed, neither the district court nor the Federal Circuit ever analyzed the novelty and non-obviousness of the claims of Dr. Honjo's cancer-treatment patents to identify what made the claims inventive. Without such consideration, the district court's factual analysis was legally deficient, and the Federal Circuit's affirmation of that decision—which announced that the refusal to do such an analysis is proper—is incorrect.

Finally, Dana-Farber's attempt to downplay the importance of the question presented ignores that, in addition to the stream of litigated cases, thousands of inventorship decisions with substantial economic consequences are made each day as patent applications are pursued in the shadow of the legal rules articulated by the Federal Circuit. More importantly, scientists and institutions making decisions whether to collaborate with others must now take into account the chilling effect of the Federal Circuit's decision on the ability to collaborate for limited purposes without giving away rights to separate inventions.

This Court should grant this petition to correct the Federal Circuit's mistaken rule.

ARGUMENT

I. DANA-FARBER CONFIRMS THAT THE FEDERAL CIRCUIT APPLIED A BRIGHT-LINE RULE

Dana-Farber repeatedly asserts that the Federal Circuit applied "settled law" to the facts of this case. Opp. 1, 15-24. But Dana-Farber's assertion and articulation of the legal standard merely confirms that the Federal Circuit applied a bright-line rule that conflicts with background principles of patent law and this Court's precedent.

As articulated by Dana-Farber, the rule applied by the Federal Circuit is that "[t]he test for joint inventorship does not 'depend on' the novelty and nonobvious[ness] of the invention over a particular researcher's contributions." Opp. 21. But this rule reads out the most basic requirements for inventorship: acts of alleged inventorship must contribute significantly to an *invention*, and to constitute an invention, what is conceived must be novel and non-obvious. 35 U.S.C. §§ 102, 103; *see* Pet. 16-17. Indeed, the Constitution only authorizes Congress to "secur[e] for limited Times to … ***Inventors*** the exclusive Right to ***their … Discoveries***." U.S. Const. art. I, § 8 (emphases added).

It thus defies black-letter patent law that, where it is contested, a court may assess inventorship without ever actually assessing evidence that is probative of whether a researcher's contribution contributed to what makes the patent claims inventive (i.e., patentable), including whether the claimed invention was patentable (novel and nonobvious) over the researcher's contribution. But that is exactly what happened here, as the Federal Circuit held:

> joint inventorship ***does not depend*** on whether a claimed invention is novel or nonobvious over a particular researcher's contribution. … The novelty and nonobviousness of the claimed inventions over the provisional application are ***not probative*** of whether the collaborative research efforts of Drs. Honjo, Freeman, and Wood led to the inventions claimed here or whether each researcher's contributions were significant to their conception.

Pet. App. 13a (emphases added). Without assessing the underlying inventive concept and determining whether putative co-inventors made a significant contribution to it, the Federal Circuit's rule reads out a key requirement by divorcing the concept of joint *inventorship* from the underlying *invention*.

Dana-Farber attempts to justify the Federal Circuit's bright-line rule by announcing a further bright-line rule, whereby "the ideas contributed" by an alleged co-inventor "must not have been *contemporaneously* available to an ordinary skilled artisan *at the time of the contribution*." Opp. 21. But under Dana-Farber's rigid rule, putative inventors could receive credit as co-inventors for sharing their ideas with a named inventor shortly before publishing a paper on those same ideas, even when the named inventor does not actually conceive of the claimed invention until many years later. This would prevent the named inventor from using ideas that have long since entered the public domain.

Dana-Farber's characterization of the Federal Circuit's bright-line rule as "settled law" further confirms why it is important that this Court grant certiorari. Not only does this Federal Circuit precedent conflict with black-letter patent law, but it also conflicts with

this Court's precedent and the Fourth Circuit's interpretation of "basic principles of patent law." *See* Pet. 17-21.

Dana-Farber attempts to distinguish this Court's decision in *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62 (1853), by asserting that *O'Reilly* "concerned the validity of Morse's patent, not a claim of joint inventorship." Opp. 24-25. But the Court's reasoning in *O'Reilly* connects the concepts of invalidity and inventorship by holding that Morse was an original inventor regardless of whether he "derive[d] his information … from conversation with men skilled in the science." 56 U.S. (15 How.) at 111. In evaluating validity in *O'Reilly*, this Court recognized that assessing Morse's right to be an inventor involved assessing the originality of his contributions over those in the prior art. *Id.*

Similarly, the Fourth Circuit's decision in *Levin* v. *Septodont, Inc.*, recognized that "the significance of an alleged joint inventor's contribution should be assessed by asking whether the contribution helped to make the invention patentable." 34 F. App'x 65, 72 (4th Cir. 2002). The decision in *Levin* leaves no room for the bright-line carve-out the Federal Circuit applies; it describes its rule as a matter of "basic principles of patent law," explaining that it is "implausible to say that a person who contributed only to the non-novel and/or obvious elements of a claim can be called an inventor." *Id.* at 72-73. Dana-Farber argues that *Levin* does not address ideas that are communicated to an inventor before being published. Opp. 26-27. But this is inconsequential; the reasoning in *Levin* makes clear that such an exception would be inconsistent with patent law's "basic principles" because it would permit someone to own the full rights to a patent regardless of whether he

contributed nothing to what made the invention patentable.

II. THE DETERMINATION BELOW WAS NOT FACT-BOUND

Dana-Farber attempts to portray the decision below as "fact-bound" and "case-specific." *See* Opp. i, 1-2, 16-17, 24. But that assertion is contradicted by both the Federal Circuit's explicit language stating the rule it was applying and the district court's decision, neither of which ascribed any probative value to evidence regarding the novelty or nonobviousness of the claimed inventions over Dr. Freeman's and Dr. Wood's prior art disclosures.

As previously explained, the Federal Circuit clearly and unequivocally stated its holding that "joint inventorship does not depend on whether a claimed invention is novel or nonobvious over a particular researcher's contribution" and that "the novelty and nonobviousness of the claimed inventions over the provisional application are not probative of whether … each researcher's contributions were significant to their conception." Pet. App. 13a. In analyzing joint inventorship in this case, it is undisputed that neither the district court nor the Federal Circuit analyzed whether and to what extent Dr. Freeman's and Dr. Wood's alleged contributions were significant to what was inventive—i.e., what was novel and non-obvious over their 1999 provisional application and the 2000 publication.

Thus, contrary to Dana-Farber's repeated assertions, the Federal Circuit made clear that its decision was not based on the "context of the evidence in this case," Opp. 23 (emphasis omitted), but on the Federal Circuit's bright-line rule.

III. DANA-FARBER CONFUSES THE ISSUE BY MISCHARACTERIZING PETITIONERS' ARGUMENTS AND FOCUSING ON THE WRONG SECTION OF THE FEDERAL CIRCUIT'S OPINION

Dana-Farber attempts to confuse the question presented by focusing on a portion of the Federal Circuit's decision that discussed a different argument made below, not the one being made here.

In the litigation below, Petitioners argued that (as the Federal Circuit described it) "research made public before the date of conception of a total invention *cannot* qualify as a significant contribution to conception of the total invention." Pet. App. 13a (emphasis added); *see* Opp. 18, 21-22. In rejecting this rule, the Federal Circuit stated that "publication of a portion of a complex invention does not necessarily defeat joint inventorship of that invention, and it does not here." Pet. App. 14a.

Dana-Farber repeatedly relies on this quotation and takes it out of context to suggest that the Federal Circuit never pronounced a bright-line rule about contributions to conception that are in the prior art. Opp. 2, 18, 22. Instead, Dana-Farber asserts that the Federal Circuit "simply rejected BMS's now-abandoned argument that if the ideas contributed enter the prior art before the date of conception, they are disqualified, *as a matter of law*, from consideration in the inventorship determination." *Id.* at 18. Dana-Farber even relies on that statement by the Federal Circuit to assert that "BMS fails to acknowledge, let alone challenge, this articulation of the correct legal rule or its fact-bound application here." *Id.* at 2.

But Dana-Farber misconstrues the Federal Circuit's opinion and the question presented here. Petitioners raised multiple issues before the Federal Cir-

cuit. The Federal Circuit articulated the bright-line rule raised in the Petition in a paragraph that precedes the one on which Dana-Farber focuses. There, the Federal Circuit addressed Petitioners' argument "that the Honjo patents were issued over Drs. Freeman and Wood's 1999 provisional patent application, so the latter contributions were thus not significant to the dispute over inventorship of Dr. Honjo's patents." Pet. App. 13a. The Federal Circuit rejected this argument, holding that "[t]he novelty and nonobviousness of the claimed inventions over the provisional application *are not probative* of whether … each researcher's contributions were significant to their conception." *Id.* (emphasis added). Only after announcing and applying this legal rule did the Federal Circuit address the different argument made by Petitioners below in favor of a rule that public disclosure of a contribution is a bar to joint inventorship. *Id.* at 13a-14a.

The only categorical rule relevant to the petition is the Federal Circuit's holding that the novel and nonobvious aspects of an invention *need not* be considered when evaluating the significance of an inventor's contribution (i.e., when evaluating whether a contribution rises to the level of joint inventorship).

IV. DANA-FARBER INCORRECTLY ASSUMES THAT THE DISTRICT COURT'S DECISION WOULD BE THE SAME IF IT HAD DONE THE PROPER ANALYSIS

Dana-Farber challenges this case as a vehicle for review of the Federal Circuit's erroneous legal rule by assuming that the case would come out the same way even if the district court were to compare Dr. Freeman's and Dr. Wood's alleged contributions to what made the patented inventions novel and nonobvious over the prior art. But Dana-Farber's assumption is

based on its incorrect characterization of the Federal Circuit's holding.

Dana-Farber asserts that "[t]he district court found, and the Federal Circuit agreed, that Dr. Freeman and Dr. Wood made significant contributions to each patent's conception that were *not* disclosed in either the 1999 provisional or the Freeman 2000 paper." Opp. 30. But neither the district court nor the Federal Circuit made such an independent finding, and the Federal Circuit said the issue was "unclear." Pet. App. 13a.

More importantly, neither court analyzed whether and to what extent Dr. Freeman's and Dr. Wood's alleged contributions were significant to what made the claims inventive—i.e., novel and non-obvious over the 1999 provisional application, the 2000 publication, and other prior art. *See supra* p. 6. Dana-Farber identified two particular contributions that it alleges Dr. Freeman and Dr. Wood made beyond those disclosed in the prior art. Opp. 30-31. But nowhere in either the Federal Circuit's or the district court's decisions is there a finding that the two contributions identified by Dana-Farber, in their own right, are significant contributions to what was novel or nonobvious over Dr. Freeman's and Dr. Wood's previously disclosed ideas. And although this Court need not consider any factual issues in analyzing the Federal Circuit's bright-line rule, Dana-Farber ignores that the underlying ideas behind both alleged contributions—the concept that antibodies can block the PD-1/PD-L1 interaction and the expression of PD-L1 on tumors—were in fact in the prior art before the date of conception. *See* Pet. 11; Pet. App. 6a. Moreover, the district court held that Dr. Freeman's alleged contribution regarding certain tumors expressing PD-L1 was not enough—standing alone—to support a finding of joint inventorship. Pet. App. 103a; *see*

Pet. 28-29. Dana-Farber cannot assume, as it does, that the district court's determination would be the same if it had considered in its analysis the evidence that the claimed inventions were novel and nonobvious over those contributions. This Court should reverse the Federal Circuit's legal error so the correct legal framework is applied.

V. THE FEDERAL CIRCUIT'S RULE WILL CAUSE CONFUSION AND DISCOURAGE COLLABORATION

In addition to fashioning a bright-line rule that conflicts with black-letter patent law and this Court's precedent, the Federal Circuit's rule further muddies inventorship jurisprudence and stifles, rather than encourages, collaboration. *See* Pet. 21-28.

Dana-Farber offers no reassurance that the Federal Circuit's rule can be applied without muddying inventorship jurisprudence. For the more than 600,000 patent applications filed every year,[1] naming the correct inventors is crucial for determining rights that can be extremely valuable. *See* Pet. 7-8, 23-25. In response, Dana-Farber asserts that there is approximately one lawsuit over inventorship every year—a figure that represents only those cases identified in the parties' appellate briefs. Opp. 32. This is not an insignificant amount of litigation, as Dana-Farber seems to contend, especially given the high stakes in many patent disputes. More importantly, it does not come close to approximating the magnitude of the impact of the Federal Circuit's rule given the number of unlitigated patents issued annually

[1] USPTO Patent Technology Monitoring Team, *U.S. Patent Statistics Chart, Calendar Years 1963-2019*, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (visited May 3, 2021).

for which an inventorship determination needs to be made in the shadow of the Federal Circuit's rule.

The Federal Circuit's rule also discourages collaboration. It creates a risk, for example, that any person who shares pre-publication research with a co-author—which is an inevitability when coauthors share drafts and discuss ideas—can bring a claim to share an undivided interest in any of her co-author's subsequent patents that follow from that initial research, regardless of whether such person made a significant contribution to what made the later invention patentable.

Dana-Farber contends that this rule will not chill collaboration because collaboration still gives researchers "a valuable head-start." Opp. 33. But Dana-Farber's rule creates what could be an unending obligation for inventors to name others as coinventors simply because the inventor received unpublished information from them at some point, and even though the inventor's patent had to be inventive over prior art disclosing the same ideas. *See* Pet. 23-24. The other inventors would have the right to prevent licensing decisions and demand royalties for patents that were granted despite, not because of, their contributions.

Implicit in Dana-Farber's argument is the idea that allowing people who share their results pre-publication to take credit for those ideas twice-over incentivizes sharing. That argument ignores the other side of that equation—that the recipient of those unpublished ideas may not seek to hear it. If an inventor can avoid sharing the rights to her own future work by waiting to learn of others' results and ideas until they are published, many will wait. Dana-Farber also ignores the unfairness of such a rule, including the opportunities it

creates for opportunistic claims of inventorship after a patent has issued.

CONCLUSION

This petition presents an ideal vehicle to address the Federal Circuit's legally erroneous bright-line rule. The Federal Circuit's rule carves out an exception from basic patent law principles for joint inventorship claims. This Court should grant this petition to reverse that decision and reject that rule.

Respectfully submitted.

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