No. 20-

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

## PETITION FOR A WRIT OF CERTIORARI


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## QUESTION PRESENTED

Section 116 of title 35 provides that "when an invention is made by two or more persons jointly, they shall apply for a patent jointly." A person who claims to have been improperly omitted from the list of inventors on a patent may bring a cause of action for correction of inventorship under 35 U.S.C. § 256.

The Federal Circuit has held that "to be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention." *Fina Oil & Chem. Co.* v. *Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997).

In this case, in conflict with this Court's guidance and the Fourth Circuit, the Federal Circuit adopted a bright-line rule that the novelty and non-obviousness of an invention over alleged contributions that were already in the prior art are not probative of whether those alleged contributions were significant to conception. App. 13a.

The question presented is:

Whether the Federal Circuit erred in adopting a bright-line rule that the novelty and non-obviousness of an invention over alleged contributions that were already in the prior art are "not probative" of whether those alleged contributions were significant to conception.

## PARTIES TO THE PROCEEDING

Petitioners are Ono Pharmaceutical Co., Ltd., Tasuku Honjo, E. R. Squibb & Sons, L.L.C., and Bristol-Myers Squibb Company, who were the defendants-appellants below.

Respondent is Dana-Farber Cancer Institute, Inc., who was the plaintiff-appellee below.

## CORPORATE DISCLOSURE STATEMENT

Petitioner Ono Pharmaceutical Co., Ltd. has no parent corporation. To the best of Petitioners' knowledge and belief, no publicly held corporation owns 10% or more of One's stock.

Petitioner E.R. Squibb & Sons, L.L.C. is a wholly owned subsidiary of Bristol-Myers Squibb Company.

Petitioner Bristol-Myers Squibb Company has no parent corporation. To the best of Petitioners' knowledge and belief, no publicly held corporation owns 10% or more of Bristol-Myers Squibb Company's stock.

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## INTRODUCTION

Although this Court has decided many patent cases in recent years, it has not decided a case involving issues of joint inventorship in more than 100 years. In that time, joint inventorship has become "one of the muddiest concepts in the muddy metaphysics of patent law." *Mueller Brass Co.* v. *Reading Indus.*, 352 F. Supp. 1357, 1372 (E.D. Pa. 1972), *aff'd*, 487 F.3d 1395 (3d Cir. 1973). The Federal Circuit's decision in this case, which involves a Nobel Prize-winning breakthrough in cancer treatment, adds to that confusion by declaring a critical factor categorically irrelevant to the question of joint inventorship. This conflicts with principles previously articulated by this Court and creates a circuit split. This Court should grant review and reverse.

To be a joint inventor under 35 U.S.C. § 116, the Federal Circuit has held that "an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention." *Fina Oil & Chem. Co.* v. *Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Petitioners appealed a judgment adding Dr. Gordon Freeman and Dr. Clive Wood as inventors on Nobel Prize winner Tasuko Honjo's six patents directed to groundbreaking new treatments for cancer (the "Honjo Patents"). The district court credited Dr. Freeman and Dr. Wood as having made certain significant contributions even though those alleged contributions had already been disclosed in the prior art before Dr. Honjo conceived of the patented methods of treating cancer. The Federal Circuit affirmed the district court's determination by adopting a bright-line rule that the novelty and non-obviousness

of the Honjo Patents over certain contributions by Dr. Freeman and Dr. Wood are "not probative" of whether those contributions were significant to conception. In other words, the Federal Circuit held that whether an individual contributes to what makes an invention *inventive* (i.e., patentable) is not relevant in determining whether an individual is an *inventor*.

The Federal Circuit's bright-line rule conflicts with background principles of patent law, contravenes this Court's precedent, and creates a circuit split with the Fourth Circuit. It is black-letter law that an invention must be novel and non-obvious. 35 U.S.C. §§ 102, 103. Thus, in considering whether a putative co-inventor made a significant contribution to an invention, courts must consider whether the person actually contributed to what makes the concept inventive and thus patentable. Contributions of already-known or obvious ideas, or to ideas that otherwise would be insufficient to warrant a patent are, at the very least, less likely to be significant. By holding that the novelty and non-obviousness of an invention are not probative of whether a contribution is significant, the Federal Circuit's holding conflicts with this Court's decision in *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62 (1853). The Federal Circuit's decision also creates a circuit split with the Fourth Circuit, which has held that "the significance of an alleged joint inventor's contribution … depends on whether that contribution helped to make the invention patentable." *Levin* v. *Septodont Inc.*, 34 F. App'x 65, 72-73 (4th Cir. 2002).

This case presents an important question because the Federal Circuit's bright-line rule will undermine collaboration and create windfalls for individuals who contributed only ideas that are already covered by prior art. Most inventions build on prior ideas, and collab-

oration is an important part of scientific progress. The Federal Circuit's rule will allow individuals who do not contribute to the developments that make an invention patentable over the prior art to claim joint inventorship status for patents, which will allow them to extract full undivided rights to patents. This will discourage collaboration, open the courthouse doors to post hoc claims of joint inventorship, and lead to unjustified windfalls for individuals who receive separate patents on their alleged contributions. In turn, this will undermine the fundamental goal of patent law by stunting "the [p]rogress of … useful Arts." *See* U.S. Const. art. I, § 8, cl. 8.

This case presents an ideal vehicle for the Court to clear up joint inventorship jurisprudence and to review the Federal Circuit's bright-line rule. The date on which the inventions were conceived is undisputed. Thus, there is no dispute that many of Dr. Freeman's and Dr. Wood's alleged contributions that were credited as significant to conception were in the prior art before that conception date, meaning that the Honjo Patents had to be novel and nonobvious compared to those background disclosures. In other words, the patents were granted in spite of, not because of, those alleged contributions. Yet, the Federal Circuit categorically dismissed that fact as "not probative," erroneously delinking the question of inventorship from the question of whether a contribution helped to make an invention patentable.

## OPINIONS AND ORDERS BELOW

The Federal Circuit's decision in this case is reported at 964 F.3d 1365 and reproduced at App. 1a-17a. The order denying rehearing and rehearing en banc is unreported and reproduced at App. 19a-20a.

The district court's findings of fact, conclusions of law, and order is reported at 379 F. Supp. 3d 53 and reproduced at App. 21a-109a.

## JURISDICTION

The Federal Circuit entered judgment on July 14, 2020. On October 16, 2020, the Federal Circuit denied Petitioners' timely petition for rehearing and rehearing en banc. App. 19a-20a.

On March 19, 2020, this Court extended "the deadline to file any petition for a writ of certiorari … to 150 days from the date of the lower court judgment, order denying discretionary review, or order denying a timely petition for rehearing."

This Court has jurisdiction under 28 U.S.C. § 1254(1).

## STATUTORY PROVISIONS INVOLVED

Section 116 of the Patent Act, 35 U.S.C. § 116 provides in relevant part:

> (a) Joint Inventions.—When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

## STATEMENT OF THE CASE

### A. Joint Inventorship

A patent confers the right to exclude others from making, using, selling, offering for sale, or importing a claimed invention. 35 U.S.C. § 271(A). A patent's claims define the scope of the invention covered by this right, loosely analogous to the way a deed defines the boundaries of real property. 35 U.S.C. § 112 (each patent "shall conclude with one or more claims particularly pointing out" the subject matter regarded "as the invention").

Claimed inventions cannot be patented unless they are novel and non-obvious. 35 U.S.C. §§ 102, 103. This requires a comparison of the claims to the "prior art," which includes sources such as other patents, printed publications, and public use. 35 U.S.C. § 102.[1] A claimed invention is unpatentable or invalid if it was disclosed in the prior art or would have been obvious over (i.e., compared to) the prior art.

A patent lists one or more inventors, depending on how many people collaborated and made a significant contribution to the invention of the claimed subject matter. The Federal Circuit has recognized the "difficulty of determining legal inventorship." *C.R. Bard, Inc.* v. *M3 Sys., Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998). One court described joint inventorship as "one of the muddiest concepts in the muddy metaphysics of patent law" because the "exact parameters of what con-

[1] The Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011), made some changes to the definition of prior art and the way claims are compared to it as part of the transition to a first-inventor-to-file system. Those changes do not affect the question presented in this petition.

stitutes joint inventorship are quite difficult to define." *Mueller Brass Co.* v. *Reading Indus.*, 352 F. Supp. 1357, 1372 (E.D. Pa. 1972), *aff'd*, 487 F.3d 1395 (3d Cir. 1983); *see In re VerHoef*, 888 F.3d 1362, 1365 (Fed. Cir. 2018) (quoting *Mueller Brass Co.*, 352 F. Supp. at 1372).

"Conception" has been described as "the touchstone of inventorship." *Burroughs Wellcome Co.* v. *Barr Labs., Inc.*, 40 F.3d 1223, 1227 (Fed. Cir. 1994). Conception is "'the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereunder to be applied in practice.'" *Id.* at 1228 (quoting *Hybritech Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986)). In other words, it is "the completion of the mental part of the invention." *Id.* at 1227-1228. The Federal Circuit has explained that "[c]onception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Id.* at 1228.

Section 116 of Title 35 provides that "[w]hen an invention is made by two or more persons jointly, they shall apply for a patent jointly." 35 U.S.C. § 116. The Federal Circuit has interpreted § 116 as including two basic requirements for inventorship: (1) collaboration and (2) contribution. *See CODA Development S.R.O.* v. *Goodyear Tire & Rubber Co.*, 916 F.3d 1350, 1358-1359 (Fed. Cir. 2019) (explaining that "a joint inventor must contribute to the invention's conception" and "there must be 'some quantum of collaboration'" (quoting *Kimberly-Clark Corp.* v. *Procter & Gamble Distrib. Co.*, 973 F.2d 911, 917 (Fed. Cir. 1992))). Collaboration is not the issue in dispute here.

With respect to the level of contribution required, although § 116 "sets no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor," the Federal Circuit has explained that "to be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is *not insignificant in quality, when that contribution is measured against the dimension of the full invention*." *Fina Oil & Chem. Co.* v. *Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997) (emphasis added).

"The line between actual contribution to conception and the remaining prosaic contributions to the inventive process that do not render the contributor a co-inventor is sometimes a difficult one to draw." *Eli Lilly & Co.* v. *Aradigm Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004). For example, "[c]ontributions to realizing an invention may not amount to a contribution to conception if they merely explain what was 'then state of the art,' if they are too far removed from the real-world realization of an invention, or if they are focused solely on such realization." *Id.* (citations omitted); *see Pannu* v. *Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998) (joint inventor must "do more than merely explain to the real inventors well-known concepts and/or the current state of the art").

Correctly identifying the inventors of patented claims is important because joint inventors have full undivided rights to the patent, meaning that each inventor "may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, *without the consent of and without accounting to the other*" inventors. 35 U.S.C. § 262 (emphasis added). "[I]n the context of joint inventorship, each co-inventor presump-

tively owns a pro rata undivided interest in the entire patent, no matter what their respective contributions." *Ethicon* v. *U.S. Surgical Corp.*, 135 F.3d 1456, 1465 (Fed. Cir. 1998) (footnote omitted). Those undivided rights include the "power to license rights in the entire patent." *Ethicon*, 135 F.3d at 1466; *see Schering Corp.* v. *Roussel-UCLAF SA*, 104 F.3d 341, 344 (Fed. Cir 1997) ("Each co-owner of a United States patent is ordinarily free to make, use, offer to sell, and sell the patented invention without regard to the wishes of any other co-owner. Each co-owner's ownership rights carry with them the right to license others, a right that also does not require the consent of any other co-owner." (citation omitted)).

Section 256 of title 35 "provides a cause of action to interested parties to have the inventorship of a patent changed to reflect the true inventors of the subject matter claimed in the patent." *Fina Oil*, 123 F.3d at 1471. That section provides as follows:

> (a) Correction.—Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.
>
> (b) Patent Valid if Error Corrected.—The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice

> and hearing of all parties concerned and the Director shall issue a certificate accordingly.

35 U.S.C. § 256. Under 35 U.S.C. § 256, a party may file an action to correct either the failure to name a joint inventor (i.e., "nonjoinder") or the naming of an individual who is not a joint inventor (i.e., "misjoinder"). *See CODA Dev. S.R.O.*, 916 F.3d at 1358 ("Through claims of misjoinder and nonjoinder together, § 256 'allows complete substitution of inventors.'" (quoting *Stark* v. *Advanced Magnetics, Inc.*, 119 F.3d 1551, 1553 (Fed. Cir. 1997))).

### B. Factual Background

Dr. Tasuko Honjo revolutionized cancer treatment and earned the 2018 Nobel Prize for his groundbreaking work using the human immune system to treat cancer. App. 60a.

The human immune system defends the body against disease and infection through a network of specialized cells. App. 23a. When healthy, a person's immune system activates to fight foreign invaders and then deactivates to protect healthy cells from immune attack. App. 24a. T cells are one type of specialized cell in the immune system that works with other cells to protect the body from foreign invaders. App. 23a. T cells have proteins called "receptors" on their surface that can interact with proteins called "ligands" to either stimulate or inhibit immune response. App. 24a.

Dr. Honjo, a professor at Kyoto University's medical school, discovered, isolated, and characterized a receptor on the surface of T cells that he named "PD-1." App. 3a, 30a; C.A.J.A. 5758. Using mice that were genetically engineered to not express PD-1, Dr. Honjo discovered that PD-1 serves as a brake on the immune

system and that the brake is activated when PD-1 binds to certain proteins. App. 3a-4a, 31a. In other words, Dr. Honjo discovered that when PD-1 binds to a ligand, T cells are blocked from protecting the body from foreign invaders. Dr. Honjo submitted his results for publication in April 1999, and they were published in August 1999. App. 31a.

At the time, Dr. Honjo also hypothesized that altering the PD-1 signal could have therapeutic applications for treating cancer. App. 31a. But because this was speculation, he did not seek patent protection for his hypothesis at that time. *Id.* Rather, it was only later, based on subsequent *in vivo* tumor experiments by Dr. Honjo and his Japanese colleagues, that they were able to form the "'definite and permanent idea'" that blocking PD-1 from binding to its ligand could treat cancer—i.e., the invention that led to the Honjo Patents. *See infra* pp. 12-13.

In 1998, Dr. Honjo engaged Dr. Wood, the director of molecular immunology at Genetics Institute, to help identify the ligand that binds to PD-1. App. 4a, 33a-34a. Separately, around that same time, Dr. Gordon Freeman, a professor at Dana-Farber and the Harvard Medical School, located an amino acid sequence he called "292" while searching a publicly accessible database for ligands. App. 4a-5a, 35a-36a. Dr. Freeman was unable to identify any protein ("receptor") to which 292 binds or find 292's function, so he enlisted Dr. Wood's help. App. 36a-37a. Dr. Wood discovered that 292 (later renamed PD-L1) bound to PD-1, and he informed Dr. Honjo that he had identified a ligand for PD-1. App. 5a, 38a-39a. Dr. Wood also ran additional experiments showing that the binding of PD-1 and PD-L1 inhibits immune response. App. 39a. Dr. Honjo ran further experiments that confirmed that the PD-1/PD-

L1 pathway—i.e., the binding of PD-1 and PD-L1—inhibits immune response. App. 5a, 43a-44a.

In November 1999, Dr. Freeman and Dr. Wood filed a provisional patent application with the U.S. Patent and Trademark Office disclosing, among other things, Dr. Freeman's location of 292 in the public database, Dr. Wood's identification of 292 as a ligand of PD-1, Dr. Wood's research regarding the PD-1/PD-L1 pathway, and the concept that antibodies can block the PD-1/PD-L1 interaction. App. 5a, 44a-45a; C.A.J.A. 3502-3505, 3528, 3598, 3607-3612. Dr. Freeman and Dr. Wood's invention built upon Dr. Honjo's PD-1 work, which he also discussed with them at a meeting in October 1999. App. 40a-41a. But their provisional application did not list Dr. Honjo as a co-inventor, presumably because Dr. Honjo had put much of his work in the prior art by publishing it. App. 5a, 31a, 44a. Just as Dr. Honjo's prior disclosures had the effect of putting his work in the prior art for others to build upon, the filing of the provisional patent application ultimately had the effect of putting Dr. Wood's and Dr. Freeman's disclosures into the prior art as of November 1999, before the invention later claimed in the Honjo Patents was conceived.[2]

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[2] The disclosures in a provisional patent application can help establish an earlier filing date for a full patent application filed within one year of the provisional application. 35 U.S.C. § 119. Moreover, to the extent a published patent application or patent that claims priority to a provisional application is used as prior art against someone else's patent claims, it may qualify as prior art as of the date that the provisional patent application was filed. *Id.* § 102(e) (2011); *id.* § 102(d) (current); *id.* § 119; *In re Giacomini*, 612 F.3d 1380, 1382 (Fed. Cir. 2010) (patent cited as prior art against another patent can have "a patent-defeating effect as of

In 1999 and 2000, Dr. Honjo, Dr. Wood, Dr. Freeman, and sixteen others wrote a journal article documenting their discoveries concerning PD-L1 and the PD-1/PD-L1 pathway. App. 45a-46a; C.A.J.A. 5796. The article published on October 2, 2000. App. 6a, 46a. Among other things, the article disclosed Dr. Freeman's location of 292 in the public database, Dr. Wood's identification of PD-L1 as a ligand of PD-1, the PD-1/PD-L1 pathway's inhibitory effect on the immune system, the expression of PD-L1 in some cancers, and speculation regarding "the possibility that some tumors may use PD-L1 to inhibit an antitumor immune response." App. 45a-46a; C.A.J.A. 5796-5803. Because the article published before the invention claimed in the Honjo Patents was conceived and more than a year before the earliest application for the Honjo Patents, it also qualified as prior art against the Honjo Patents. *See* 35 U.S.C. § 102(a)-(b) (2011).

In early 2000, Dr. Honjo's lab began to run *in vivo* tumor experiments—i.e., tumor experiments in living organisms—to study whether blocking PD-1 from binding to its ligand could be used to treat cancer. App. 50a; C.A.J.A. 1608-1613. Neither Dr. Freeman nor Dr. Wood was involved in those experiments. On September 1, 2000, Dr. Honjo's lab reported results revealing a connection between tumor growth and the PD-1/PD-L1 pathway. App. 52a. On October 27, 2000, Dr. Honjo's lab had results demonstrating that PD-L1 expressing tumors grow less quickly in mice that were genetically engineered to not express PD-1 than in mice expressing PD-1. App. 7a, 54a.

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the filing date of the provisional application to which it claims priority").

It is undisputed that only upon seeing the results from these *in vivo* experiments did Dr. Honjo and his Japanese colleagues conceive of the invention underlying the Honjo Patents on October 27, 2000. App. 80a ("Dana-Farber does not contest this date."). As the district court found, seeing the results of the *in vivo* experiments allowed Dr. Honjo and his Japanese colleagues to form the "'definite and permanent idea' that blocking the PD-1/PD-L1 pathway using antibodies could treat cancer." *Id.*; *see also Burroughs Wellcome*, 40 F.3d at 1227 (defining conception as "'the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention'").

Before those *in vivo* experiments, when it came to treating cancer there was nothing more than speculation—initially by Dr. Honjo before he had any contact with Dr. Wood or Dr. Freeman, App. 31a, and then later by Dr. Freeman, App. 45a-46a. Only with the additional information gleaned through Dr. Honjo's *in vivo* experiments, accounting for the complexity of a living animal, did it become possible for Dr. Honjo and his Japanese colleagues to move beyond speculation to form the definite and permanent idea that blocking the PD-1/PD-L1 pathway using antibodies could treat cancer, as claimed in the Honjo Patents. C.A.J.A. 1977-1978, 2033-2034.

In 2002, Dr. Honjo and Ono Pharmaceutical filed a Japanese patent application claiming methods of treating cancer by blocking the PD-1 receptor from binding to its ligands. App. 7a, 55a. They later filed an international patent application claiming those same cancer treatment methods. App. 55a. The Honjo Patents all claim priority to the filing date of those applications. App. 7a.

Because the disclosures of Dr. Wood's and Dr. Freeman's work in the November 1999 provisional application and the October 2000 article were in the prior art before that conception date, the inventions claimed in the Honjo Patents were required to be novel and non-obvious when compared to that prior art. The Patent Office thus granted the Honjo Patents, the validity of which is undisputed, over those disclosures of Dr. Wood's and Dr. Freeman's work. C.A.J.A. 32, 115, 133, 149, 150, 182, 215, 217, 253, 254, 292, 299, 3043; App. 44a; *see Merck Sharp & Dohme Ltd.* v. *Ono Pharmaceutical Co. Ltd.*, [2015] EWHC 2973 (Pat), ¶ 243 (European Patent (K) 1,573,878 novel over Dana-Farber's international application, which did "not make plausible the specific idea of an anti-PD-1 agent to treat cancer"). In other words, it was the other aspects of the Honjo Patents' claims—in particular, the paradigm shift of taking the brakes off the immune system to *treat cancer*—that made them patentable.

### C. Procedural Background

In 2015, Dana-Farber filed this action, alleging that Dr. Freeman and Dr. Wood should be added as inventors of the Honjo Patents. App. 59a.

Following a bench trial, on May 17, 2019, the district court determined that Dana-Farber had "not produced clear and convincing evidence that Dr. Freeman or Dr. Wood came up with" the idea of blocking the PD-1/PD-L1 pathway as a method of treating cancer, App. 92a, but nonetheless concluded that Dr. Freeman and Dr. Wood were inventors due to what the district court believed were significant contributions to conception, App. 103a-104a.

On July 14, 2020, the Federal Circuit affirmed, holding that "joint inventorship does not depend on whether a claimed invention is novel or nonobvious over a particular researcher's contribution." App. 13a. The Federal Circuit explained that the "novelty and nonobviousness of the claimed invention over [Dr. Freeman's and Dr. Wood's] provisional application are not probative of … whether each researcher's contributions were significant to their conception." *Id.* The Federal Circuit also held that a contribution can be "significant" so as to warrant joint inventorship, even where the information was public knowledge at the time the invention was conceived. App. 13a-14a.

Petitioners filed a petition for panel rehearing and rehearing en banc, and the Federal Circuit denied that petition. App. 19a-20a.

## REASONS FOR GRANTING THE PETITION

### I. THE FEDERAL CIRCUIT'S BRIGHT-LINE RULE CONTRAVENES BASIC PRINCIPLES OF PATENT LAW, CONFLICTS WITH THIS COURT'S PRECEDENT, AND CREATES A CIRCUIT SPLIT

The Federal Circuit created a bright-line rule that the novelty and non-obviousness of an invention over alleged contributions that are in the prior art are "not probative" of whether those contributions were significant to conception. App. 13a. In other words, the Federal Circuit held that what made the claims *inventive* (i.e., novel and nonobvious) is not relevant in determining whether an individual made sufficiently significant contributions to conception to qualify as a joint *inventor*. This bright-line rule contravenes basic principles of patent law, conflicts with this Court's precedent, and creates a circuit split with the Fourth Circuit.

### A. The Federal Circuit's Rule Conflicts With Black-Letter Patent Law

It is black-letter law that an invention must be novel and non-obvious. 35 U.S.C. §§ 102, 103; *see Graham* v. *John Deere Co. of K.C.*, 383 U.S. 1, 13-14 (1966) ("Patentability is to depend, in addition to novelty and utility, upon the 'non-obvious' nature of the 'subject matter sought to be patented' to a person having ordinary skill in the pertinent art."). Thus, a set of previously known concepts does not by itself constitute a patentable invention. However, if one or more novel and non-obvious elements is added to those previously known concepts, or the known concepts are combined in a novel and non-obvious way, the result may be a patentable invention—and whoever was responsible for the novelty is the rightful inventor. *See O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 111 (1853) (Samuel Morse was sole inventor of claims to "combination of different elements" even if he derived knowledge of individual elements "from conversation with men skilled in the science"); *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 418-419 (2007) (invention may consist entirely of elements present in prior art if combination thereof is inventive).

It follows that in assessing whether a putative co-inventor made a "significant" contribution to an invention—as required to establish joint inventorship—courts must consider whether the person actually contributed to that which was inventive. Contributions of already-known or obvious ideas, or to ideas that otherwise would not be sufficient to warrant a patent, are, at the very least, less likely to be significant.

The Federal Circuit denied that basic principle. The Honjo Patents were issued over prior art disclos-

ing many of Dr. Freeman's and Dr. Wood's alleged contributions, including their discoveries concerning the PD-L1 ligand and the PD-1/PD-L1 pathway. C.A.J.A. 32, 115, 133, 149, 150, 182, 215, 217, 253, 254, 292, 299, 3043; App. 44a. The issuance of the Honjo Patents by the Patent Office, in spite of those disclosures, shows that the invention lay elsewhere. *See Merck Sharp & Dohme Ltd.* v. *Ono Pharmaceutical Co. Ltd.*, [2015] EWHC 2973 (Pat), ¶ 243 (European Patent (K) 1,573,878 novel over Dana-Farber's international application, which did "not make plausible the specific idea of an anti-PD-1 agent to treat cancer").

In holding that those alleged contributions were significant to the conception of the invention, the Federal Circuit announced a broad holding that "joint inventorship does not depend on whether a claimed invention is novel or nonobvious over a particular researcher's contribution." App. 13a. Going even further, the Federal Circuit announced that "[t]he novelty and nonobviousness of the claimed inventions over the provisional application are *not probative* of whether" the material disclosed in that provisional application constitutes a significant contribution to the conception of the Honjo Patents. *Id.* (emphasis added).

This holding by the Federal Circuit simply cannot be reconciled with black-letter patent law.

### B. This Court's Precedent Precludes The Federal Circuit's Bright-Line Rule

The Federal Circuit's holding amounts to a bright-line rule that the novelty and non-obviousness of an invention over putative contributions that are in the prior art are *irrelevant* to the significance of that contribution. But this bright-line rule cannot be squared with

this Court's precedent. *See KSR*, 550 U.S. at 401 ("We begin by rejecting the rigid approach of the Court of Appeals."); *Bilski* v. *Kappos*, 561 U.S. 593, 602 (2010) ("This Court has 'more than once cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed."'" (quoting *Diamond* v. *Diehr*, 450 U.S. 175 (1981))).

For example, in *Morse*, this Court held that "inquiries" Samuel Morse made "or the information or advice he received, from men of science in the course of his researches," did not "impair his right to the character of an inventor." 56 U.S. at 111. The Court explained that "it is evident that such an invention as the Electro-Magnetic Telegraph could never have been brought into action without" this information because "a very high degree of scientific knowledge and the nicest skill in the mechanic arts are combined in it, and were both necessary to bring it into successful operation." *Id.* But the fact that Morse "obtained the necessary information and counsel from the best sources, and acted upon it, neither impairs his rights as an inventor, nor detracts from his merit." *Id.*

According to the Federal Circuit's reasoning in this case, however, the fact that Samuel Morse's combination patent for the telegraph was novel and nonobvious over each of the individual elements he combined should have been "not probative" of whether he needed to share inventorship credit. That simply is not the law, as *Morse* shows. If the law were otherwise, as this Court explained in *Morse*, "no patent, in which a combination of different elements is used, could ever be obtained" because "[n]o invention can possibly be made, consisting of combination of different elements … without a thorough knowledge of the properties of each of them, … [a]nd it can make no difference, in this respect,

whether [the inventor] derives his information from books, or from conversation with men skilled in the science." *Morse*, 56 U.S. at 111.

### C. The Federal Circuit's Bright-Line Rule Conflicts With The Fourth Circuit's Interpretation Of "Basic Principles Of Patent Law"

The Federal Circuit's bright-line rule also conflicts with the Fourth Circuit's interpretation of "basic principles of patent law." As the Fourth Circuit explained based on a "[r]eflection on the basic principles of patent law, … a person does not qualify as an inventor simply because his contributions to an invention appear in the claims of the patent." *Levin* v. *Septodont Inc.*, 34 F. App'x 65, 72-73 (4th Cir. 2002). The plaintiff in *Levin* asserted that "whether a contribution counts as 'significant' … for joint inventorship depends on the extent to which the contribution makes the invention patentable by making it novel (as required by 35 U.S.C. § 102) or non-obvious (as required by 35 U.S.C. § 103)." *Id.* at 72. The Fourth Circuit agreed. Although "[a] patentable invention need not be novel and non-obvious in every respect," the court explained 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 73. As a result, "the significance of an alleged joint inventor's contribution … depends on *whether that contribution helped to make the invention patentable*." *Id.* (emphasis added).

The Federal Circuit's holding in this case allows such an "implausible" result. While the Fourth Circuit correctly held that "the significance of an alleged joint inventor's contribution … depends on whether that contribution helped to make the invention patentable,"

the Federal Circuit reached the exact opposite conclusion.[3]

Here, the Honjo Patents issued in spite of the prior art disclosures of Dr. Freeman's and Dr. Wood's contributions. In other words, because some of Dr. Freeman's and Dr. Wood's alleged contributions were disclosed in a prior-art provisional application and a prior-art publication, the Honjo Patents issued only because the claimed inventions were novel and non-obvious over those disclosures.

The Federal Circuit has thus "entered a decision in conflict with the decision of" the Fourth Circuit "on the same important matter." *See* Sup. Ct. R. 10(a). And multiple courts have approvingly cited the Fourth Cir-

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[3] Although the Federal Circuit has "exclusive jurisdiction over 'an appeal from a final decision of a district court'" that "'aris[e]s under any Act of Congress relating to patents,'" *Christianson* v. *Colt Indus. Operating Corp.*, 486 U.S. 800, 807 (1988) (quoting 28 U.S.C. § 1295(a)(1); 28 U.S.C. § 1338(a)), that does not mean that it has exclusive jurisdiction over all questions of patent law. *See Gunn* v. *Minton*, 568 U.S. 251, 258 (2013) ("[S]tate legal malpractice claims based on underlying patent matters will rarely, if ever, arise under federal patent law for purposes of § 1338(a)."). For example, in *Levin*, the Fourth Circuit examined whether a patent underlying a breach-of-contract claim was invalid for failure to name a joint inventor. 34 F. App'x at 66-67. Further, although the Fourth Circuit primarily cited Federal Circuit precedent, it did not purport to be bound by that precedent. But even if it had, the conflict would still illustrate the confusion the Federal Circuit has created. *See infra* § II.C.

cuit's decision in *Levin*. *See, e.g.*, *Horizon Medicines LLC* v. *Alkem Labs. Ltd.*, __ F. Supp. 3d. __, 2020 WL 7022591, at *8 (D. Del. Nov. 30, 2020) (putative inventor "did not contribute to the purported novel aspect of the … patent, and thus he is properly not named an inventor on the patent"), *appeal pending* No. 21-1480 (Fed. Cir.); *Rothschild* v. *Cree, Inc.*, 711 F. Supp. 2d 173, 203 (D. Mass. 2010) ("The significance of an alleged joint inventor's contribution may be assessed by asking whether the contribution helped to make the invention patentable."); *Coca-Cola Co.* v. *Pepsico, Inc.*, 2004 WL 4910334, at *41 (N.D. Ga. Sept. 29, 2004) (holding that "the limitation recited in the Coca-Cola Patents" that was purportedly the idea of a putative inventor "did not assist in the obtainment of the relevant patents, and for this additional reason, the Court concludes that [the putative inventor] cannot be said to be the joint inventor of the patented invention").

## II. THE FEDERAL CIRCUIT'S BRIGHT-LINE RULE RAISES QUESTIONS OF SUBSTANTIAL IMPORTANCE THAT WILL IMPACT THE INCENTIVES FOR COLLABORATION, CREATE WINDFALLS, AND AFFECT INVENTORSHIP JURISPRUDENCE MOVING FORWARD

### A. The Patent System Should Encourage Collaboration

Patent law is designed to promote innovation and scientific progress. *See* U.S. Const. art. I, § 8, cl. 8 (granting Congress the power "[t]o promote the [p]rogress of … useful Arts, by securing for limited [t]imes to … [i]nventors the exclusive [r]ight to their respective … [d]iscoveries"). But innovation does not occur in a vacuum. Instead, most inventions build on prior ideas. *KSR*, 550 U.S. at 401 ("Inventions usually rely upon building blocks long since uncovered and

claimed discoveries almost necessarily will be combinations of what, in some sense, is already known."); *Morse*, 56 U.S. at 111 ("No invention can possibly be made, consisting of a combination of different elements … without a thorough knowledge of the properties of each of them, … [a]nd it can make no difference, in this respect, whether [the inventor] derives his information from books, or from conversation with men skilled in the science.").

As a result, the exchange of ideas is essential for scientific progress. *See* Sung, *Collegiality and Collaboration in the Age of Exclusivity*, 3 DePaul J. Health Care L. 411, 438 (2000) ("Scientific progress depends upon the ability of individual researchers to engage in the exchange of information free from proprietary concerns."). Collaboration has become increasingly important as technology has become more complex and individuals have specialized. *See* Dreyfuss, *Collaborative Research: Conflicts on Authorship, Ownership, and Accountability*, 53 Vand. L. Rev. 1161, 1162-1163 (2000) ("In many fields—biotechnology is one example—the intensity of specialization makes it nearly impossible for any one researcher to know enough to work alone; interdisciplinary investigation is essential if the frontiers of knowledge are to be pushed forward.").

As a result, it is imperative that the patent system creates an environment that encourages such collaboration. *See* Sung, 3 DePaul J. Health Care L. at 422 ("The U.S. patent laws, which are designed to promote innovation, should facilitate and not hinder the vehicles for progress, such as collegiality and collaboration.").

### B. The Federal Circuit's Bright-Line Rule Will Chill Collaboration, Lead To Windfalls, And Invite Litigation

The Federal Circuit's legal errors blur the line between collaboration and co-inventorship in a way that makes it difficult for parties to collaborate for a limited purpose without opening the door to claims of joint inventorship directed to their separate work. This will chill cooperation across laboratories, lead to windfalls, and invite future litigation.

Given the ever-increasing complexity of biopharmaceutical research, the ability to collaborate freely ensures that the best science is applied to address serious unmet medical needs. If collaborators contribute significantly to an inventive concept, they deserve to be co-inventors of any resulting patent. The Federal Circuit's decision, however, disconnects the significance of a contribution from its contribution to inventiveness and thereby eliminates an important safeguard against an unending stream of purported co-inventors laying claim to patent rights that turn out to be valuable.

Moreover, because joint inventors share equally in the value of the invention no matter how small their relative contributions, the law will deliver a windfall to individuals who make contributions that do not help make a claim patentable. Not only will those individuals be able to receive their own patents—as Dr. Wood and Dr. Freeman eventually did here from inventions disclosed in their provisional application—but the Federal Circuit's decision will require that they be named as joint inventors of other patents that build on their earlier work. In the case of Dr. Wood and Dr. Freeman, they not only have their own patents issued from their provisional application, but the Federal Circuit's

holding will also allow them to have full undivided rights to the Honjo Patents, including the right to sell and license those patents.

By categorically denying the "probative" value of an invention's novelty and non-obviousness over alleged contributions, the Federal Circuit opened the courthouse door to post hoc claims based on mere collaboration, even though collaboration is just one part of the test for joint inventorship. *See* Okuley, *Resolution of Inventorship Disputes: Avoiding Litigation Through Early Evaluation*, 18 Ohio St. J. Disp. Resol. 915, 923 (2003) ("Because of the difficulty in determining who can correctly be identified as an inventor, and because researchers commonly are uneducated regarding inventorship law (especially regarding how inventorship is differentiated from academic authorship), inventorship disputes are common in collaborative research.").

Indeed, the impact of the Federal Circuit's decision will be felt beyond the courtroom. Companies and individuals make decisions every day on whom to list as inventors on patents. *See* Okuley, 18 Ohio St. J. Disp. Resol. at 923-924 ("A patent attorney may initially solicit information from potential inventors and interested parties, and then use that information to make a preliminary inventorship determination."); *id.* at 931 ("Because authorship disputes are apparently resolved without litigation, it is likely that many disputes over inventorship are similarly resolved."). With more than half a million patent applications filed per year, the Federal Circuit's decision thus has the potential to lead to an influx of new inventorship disputes both because of a flood of inventorship claims and the confusion in joint inventorship jurisprudence. *See U.S. Patent Statistics Chart Calendar Years 1963-2019*, PTO, https://

www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (updated Apr. 2020); Krul, *The 'Four Cs' of Joint Inventorship: A Practical Framework for Determining Joint Inventorship*, 21 J. Intell. Prop. L. 73, 82-83 (2013) ("[I]n 1970, roughly 60% of patents issued had one inventor, compared to roughly 35% of patents issued in 2010—approximately a 50% decline.").

Ultimately, if "[c]ollaboration and concerted effort" alone give rise to joint inventorship, as the Federal Circuit indicated, App. 13a, scientists may reduce or avoid collaborations for fear that collaborating on one subject may inadvertently lead to shared credit for other achievements. This could stunt "the [p]rogress of … useful Arts." *See* U.S. Const. art. I, § 8, cl. 8.

### C. The Federal Circuit's Bright-Line Rule Further Muddies Joint Inventorship Jurisprudence

Although the Federal Circuit's decision creates a bright-line rule, the decision will actually create even more uncertainty as to joint inventorship jurisprudence. As explained above, the Federal Circuit has recognized the "difficulty of determining legal inventorship," *C.R. Bard*, 157 F.3d at 1352, and one court has described joint inventorship as "one of the muddiest concepts in the muddy metaphysics of the patent law" because the "exact parameters of what constitutes joint inventorship are quite difficult to define," *Mueller Brass*, 352 F. Supp. at 1372.

The Federal Circuit's decision further muddies joint inventorship jurisprudence. The Federal Circuit created a bright-line rule that the novelty and non-obviousness of an invention over alleged contributions that are in the prior art are "not probative" of whether

those contributions were significant to conception. App. 13a. It is impossible to reconcile that rule with background principles of patent law. And it is difficult to reconcile that bright-line rule with prior joint-inventorship decisions of the Federal Circuit, including the Federal Circuit's repeated pronouncement that "[a] contribution of information in the prior art cannot give rise to joint inventorship because it is not a contribution to conception." *Eli Lilly & Co.* v. *Aradigm Corp.*, 376 F.3d 1352, 1362 (Fed. Cir. 2004).

For example, in *Board of Education ex rel. Board of Trustees of Florida State University* v. *American Bioscience, Inc.*, 333 F.3d 1330 (Fed. Cir. 2003), two scientists had contributed to the claimed anti-cancer compounds by making compounds with similar properties and conceiving of a method to synthesize the chemical used to create the claimed compounds. *Id.* at 1334, 1341. But the scientists had a separate patent on their analogous compounds, and that patent was treated as prior art. *Id.* at 1334 n.4, 1335. The Federal Circuit rejected the joint inventorship claim, explaining that the "grant" of the new patent over those prior disclosures "itself supports the conclusion that the claimed … compounds … were novel and nonobvious over the prior art, and hence not the invention of" the putative co-inventors. *Id.* at 1335, 1340.

Likewise, in *Garrett Corp.* v. *United States*, 422 F.2d 874 (Ct. Cl. 1970), the Federal Circuit's predecessor rejected a co-inventorship claim based on an idea that the Court determined "to be obvious in view of the prior art." *Id.* at 881. The court thus appeared to treat the obviousness of a putative inventor's contribution as probative of whether that contribution was significant to the conception of an invention.

There are many other examples of the Federal Circuit's apparent contradiction. *See, e.g.*, *Maatuk* v. *Emerson Electric, Inc.*, 781 F. App'x 1002, 1006 (Fed. Cir. 2019) (holding that contributions were not significant where they "were disclosed in the prior art when" the named inventors "conceived" of the patent invention); *Nartron Corp.* v. *Schukra U.S.A. Inc.*, 558 F.3d 1352, 1357-1359 (Fed. Cir. 2009) (holding that individual was not co-inventor where alleged contribution was insignificant "not just because it was in the prior art, but because … including it as part of the claimed invention was merely the basic exercise of ordinary skill in the art"); *Tavory* v. *NTP, Inc.*, 297 F. App'x 976, 979-980 (Fed. Cir. 2008) (consultant failed to prove he was an inventor where he did not establish that the interface switch he contributed "was not in the prior art"); *Hess* v. *Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 981 (Fed. Cir. 1997) (engineer was not coinventor where he did "nothing more than explain[] to the inventors what the then state of the art was and supply[] a product to them for use in their invention"); *Sewall* v. *Walters*, 21 F.3d 411, 416 (Fed. Cir. 1994) (plaintiff was not joint inventor where prior art patent disclosed his contribution).

The uncertainty regarding how the Federal Circuit's most recent pronouncement can be reconciled with its prior decisions is likely to only exacerbate the "difficulty of determining legal inventorship." *See C.R. Bard*, 157 F.3d at 1352. In turn, this uncertainty will also likely intensify the flood of litigation that will result from the Federal Circuit's decision.

* * *

Because the Federal Circuit's legal errors involve questions of substantial importance that will disincen-

tivize collaboration and impact inventorship decisions and jurisprudence going forward, this Court should grant this petition for a writ of certiorari to correct them.

## III. THIS CASE IS AN IDEAL VEHICLE FOR THIS COURT TO CONSIDER THIS IMPORTANT LEGAL QUESTION

This case is an ideal vehicle for this Court to weigh into joint inventorship jurisprudence and clear up the problems created by the Federal Circuit's bright-line rule. The question presented in this petition was presented below and squarely addressed by the Federal Circuit. App. 13a.

Moreover, there is an undisputed conception date of October 27, 2000. App. 80a ("Dana-Farber does not contest this date."). As explained above, "conception" has been described as "the touchstone of inventorship." *Burroughs Wellcome Co.*, 40 F.3d at 1227. An undisputed conception date means that there is no dispute that many of Dr. Freeman's and Dr. Wood's alleged contributions were in the prior art before conception. As a result, there can be no dispute that both the district court and the Federal Circuit credited as significant certain contributions that were disclosed in the prior art.

Although Dana-Farber may assert that Dr. Freeman and Dr. Wood were credited with other contributions that were not part of the November 1999 provisional application or October 2000 publication, that is beside the point. The Federal Circuit did not hold that any contributions not disclosed in the prior art were enough for Dr. Freeman and Dr. Wood to be joint inventors of the Honjo Patents. Indeed, with respect to at least Dr. Freeman, the district court held that his

alleged contribution regarding certain tumors expressing PD-L1 was not enough—standing alone—to support a finding of joint inventorship. App. 103a (explaining that "this dependent claim limitation does not by itself render Dr. Freeman a joint inventor of the patent").

Here, there is a clean legal issue where the Federal Circuit held that "[t]he novelty and nonobviousness of the claimed inventions over the [prior-art] provisional application are *not probative* of whether" the material disclosed in that provisional application constitutes a significant contribution to the conception of the Honjo Patents. App. 13a (emphasis added). In light of the undisputed conception date of October 27, 2000, it is clear that the Federal Circuit credited as significant certain prior art contributions. Therefore, this case presents an ideal vehicle for this Court to consider the Federal Circuit's bright-line rule.

## CONCLUSION

For the foregoing reasons, this Court should grant the petition for a writ of certiorari.

Respectfully submitted.

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