No. 21-1566

In The
Supreme Court of the United States

JUNO THERAPEUTICS, INC., et al.,

Petitioners,

v.

KITE PHARMA, INC.,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF CITY OF HOPE AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

City of Hope is a National Cancer Institute-designated Comprehensive Cancer Center and research hospital. Doctors and scientists at City of Hope not only treat patients, but also conduct important biomedical research. Over the years, City of Hope has obtained patents on its groundbreaking inventions, and it has licensed those patents to others in the pharmaceutical industry with the goal of rapidly translating discoveries from the lab to patients. City of Hope's inventions—including those that resulted in patents widely used by others—have benefited not just City of Hope's own patients, but patients throughout the world.

City of Hope submits this *amicus curiae* brief to highlight the ways in which patients may lose out on important future advances in biopharmaceutical medicines as a result of the Federal Circuit's requirement that inventors must do more than disclose the inventive aspects of their claims in order to demonstrate possession of the "full scope" of their invention and thus satisfy the written description requirement.

[1] Pursuant to Rule 37.6 of the Rules of this Court, counsel for amicus certifies that no counsel for any party authored this brief in whole or in part, and that no entity or person other than *amicus* and its counsel made any monetary contribution toward the preparation and submission of this brief. Counsel for all parties received timely notice of *amicus*'s intention to file this brief, and consented to its filing.

SUMMARY OF THE ARGUMENT

Immunotherapies like those involved in this case are among the most promising new treatments for cancer, and City of Hope is at the forefront of research in the area. The availability of dependable patent protection has helped and will continue to help facilitate this innovation. Research hospitals like City of Hope make public their inventions once they have applied for patent protection. They can then license those inventions to the biopharmaceutical companies best equipped to develop the therapeutics for patient benefit. In exchange, they can receive vital licensing payments from the licensees, which can then be used to fund additional research.

The requirements imposed by the Federal Circuit in the opinion below jeopardize future research at City of Hope and other research hospitals, to the ultimate detriment of patients. In order to comply with the Federal Circuit's requirement to show possession of the "full scope" of the claimed invention, inventors may need to delay disclosure of their inventions to conduct testing that is unnecessary to allow the public to benefit from the invention. Notably, in this case, the Federal Circuit presumed that the patent specification enabled a skilled artisan to practice the full scope of the claimed invention with only routine testing. Yet the court nevertheless invalidated the patent because the inventors did not include the results of such routine testing—information that a skilled artisan (and thus the public) does not need to reap the benefits of the patent bargain.

The Federal Circuit's decision leaves City of Hope and like institutions with two bad options: (1) promptly disclose inventions while foregoing patent protection on the full scope of the enabled invention; or (2) delay disclosure in order to conduct routine testing that is unnecessary to allow others to use the invention, solely to meet the requirements imposed by the Federal Circuit. Both options will slow the rate of biopharmaceutical research. Neither option serves patients.

ARGUMENT

I. THE FEDERAL CIRCUIT APPROACH TO WRITTEN DESCRIPTION MAY DELAY THE PUBLIC DISCLOSURE OF INVENTIONS, WITH NO BENEFIT TO THE PUBLIC.

The Federal Circuit's decision focuses on the disclosure of a single claim element—the single-chain antibody variable fragment (scFv), which is "a binding element that specifically interacts with a selected target." Pat. App. 23b (claims 3, 9). The scFv was not the inventive aspect of the claims. The court acknowledged record evidence that scFvs all share the same general structure and were well known in the art. *See* Pet. App. 12a-13a, 15a. Methods for how to make scFvs were admittedly known, and Petitioners point to evidence in the record that scFvs can be generated using those methods. Pet. 13, 16-17.

The Federal Circuit nevertheless determined that to satisfy the written description requirement, "the inventors needed to convey that they possessed the claimed invention, which encompasses *all* scFvs, known and unknown, as part of the claimed CAR that bind to a selected target." Pet. App. 13a (emphasis added). Despite the evidence that scFvs were known and reliable methods for generating new scFvs for essentially any target of interest were also known, the Federal Circuit found the inventors failed to satisfy the written description requirement here because they did not describe "means of distinguishing which scFvs will bind to which targets," a binding experiment that itself was also known. *Id.* (citation omitted).

That ruling will require inventors to conduct extensive and time-consuming routine testing prior to filing for a patent in order to generate a plethora of specific examples of the claimed invention. According to the record here, scFvs have no currently understood common structural features specific to particular binding functions. *See* Pet. App. 15a. As a result, the only way to determine whether a particular scFv will bind to a selected target when incorporated into a CAR is to test each individual structure. *See id.* at 19a-21a. Thus, for the patent in this case to satisfy the test laid out by the Federal Circuit—that for all scFvs, known and unknown, the specification "distinguish[] which scFvs will bind to which targets"—the applicants presumably would have had to generate and test all the potentially relevant scFvs and report the results of that

testing in the specification. *Id.* at 13a. The record evidence discloses no other option that would provide the information the Federal Circuit required in this case, where the Federal Circuit overturned a jury finding that the applicants *had* complied with the written description requirement.

Requiring that inventors conduct that additional testing pre-application would serve no purpose and does not speed up the benefit to the public where, as here, there is no live dispute that the invention was enabled. That a skilled artisan may need to conduct routine testing in order to practice the full scope of a given patent is, with respect to the enablement requirement, not disqualifying. *See, e.g.*, *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 982 (Fed. Cir. 2021) (reiterating rule that a patent does not fail the enablement requirement where the skilled artisan must fill in gaps between embodiments using routine experimentation). Because the Federal Circuit did not dispute that the specification in this case contained such an enabling disclosure, it necessarily follows that the artisans to whom the patent is directed do not need more details to make use of the full scope of the invention.

The invalidation of the patent in this case is thus not due to any failure to teach—and so benefit—the public. But now, in order to satisfy the Federal Circuit's requirement that a skilled artisan be able, from reading the prior art and the specification *alone*, to identify each species of the claimed invention, inventors will

need to devote time and resources doing additional routine testing to fill the specification with information *unnecessary* for the intended audience. As a result, inventors may delay filing, publishing, collaborating on, and commercializing inventions that are otherwise ready for disclosure.

That delay can only harm the public's interests. Where the inventors have upheld their end of the patent bargain and taught skilled artisans how to practice the full scope of the invention, there is no additional benefit to requiring the inventors to identify and list innumerable individual embodiments of it. Indeed, some of those embodiments may simply replace the specifically-described components with those already known in the art—like the accused product in this case, which uses an "off-the-shelf" scFv. Pet. 30. In the context of enablement, all of this detail could safely be omitted, as "a patent need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (citation omitted). The written description requirement should not insist that time and resources be wasted filling the specification with detail that the person of skill can herself routinely obtain.

II. INSTITUTIONS LIKE CITY OF HOPE MAY BE HARMED BY THE PANEL OPINION.

The above concern is not lessened by the possibility that institutions like City of Hope can disclose their discoveries quickly if they choose to seek only narrow

patents—for example, a patent claiming only the particular molecules already in hand. Doing so will leave institutions like City of Hope with patents that cover less than the full scope of the true innovative work. Where an invention has broad applicability, a narrow patent does not align with the inventive aspect of the work. Potential licensees, faced with the choice between paying a research institution a royalty or using routine experimentation to identify a royalty-free non-patented variation, may be incentivized to choose the latter option, thereby depriving research institutions like City of Hope of compensation for the use of their inventive contributions.

This loss of patent protection will be particularly harmful for an institution like City of Hope that does not typically commercialize patented inventions, but instead relies on commercial partners to develop therapies and bring them to patients. The revenue City of Hope receives from licensing its patents is vitally important to furthering City of Hope's mission. Although City of Hope is a nonprofit corporation, it must house, supply, employ, and otherwise pay for the substantial expenses associated with laboratory research. To meet these needs, all sources of revenue are important, including from licensing its patents.

The combination of these factors will leave City of Hope with a choice: disclose its broadly-applicable inventions rapidly but in a form that covers less than the full scope of the true innovative work, or spend time and resources on additional routine testing that is

unnecessary to allow others to use the invention, solely to satisfy the Federal Circuit's strict "full scope" written description requirement so that it can obtain patents that match the scope of its invention. Both options harm patients. If City of Hope is slowed in its ability to bring innovations forward to commercialization partners because it must meet an unduly onerous written description requirement, that will be to the detriment of patients who depend on rapid translation of innovative therapies. Or, if City of Hope's ability to earn and reinvest licensing revenue in new research is impeded, that too will be to the detriment of patients who depend on City of Hope to continue to innovate. The practical effect of the Federal Circuit's decision will thus be to slow the pace of biopharmaceutical research at institutions like City of Hope.

CONCLUSION

Amicus Curiae City of Hope respectfully submits that, under the Federal Circuit's decision, patients will lose. Immunotherapy is an area of research that has shown immense therapeutic promise, particularly in cancer treatment. It should be pursued with vigor, not stunted by the need to fill the specification with the

information that the Federal Circuit insisted on in this case.

Respectfully submitted,

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