No. 2020-1758

United States Court of Appeals for the Federal Circuit

JUNO THERAPEUTICS, INC., SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,

Plaintiffs-Appellees,

v.

KITE PHARMA, INC.,

Defendant-Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA IN NO. 2:17-CV-07639-PSG-KS, JUDGE PHILIP S. GUTIERREZ

BRIEF OF *AMICUS CURIAE* CITY OF HOPE IN SUPPORT OF PETITION FOR REHEARING

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November 10, 2021

CERTIFICATE OF INTEREST

Counsel for CITY OF HOPE certify as follows:

1. The full name of every party represented by us is:

   City of Hope, a California nonprofit benefit corporation.

2. The name of the real party in interest represented by us is:

   City of Hope.

3. All parent corporations and publicly held companies that own 10% or more of stock in the parties represented by us are:

   No person or entity owns stock in City of Hope.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

   None.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal.

   None.

6. The names and information of any organizational victims in a criminal case under Fed. R. App. P. 26.1(b) and the names and information of any bankruptcy case debtors and trustees under Fed. R. App. P. 26.1(c).

   N/A.

Respectfully submitted,

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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 in the fields of cancer, diabetes, HIV/AIDS, and other chronic, life-threatening diseases. Over the years, City of Hope has obtained patents on its groundbreaking inventions, and City of Hope has licensed those patents to others in the pharmaceutical industry with the goal of rapidly translating discoveries from the bench 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 because it believes the Panel's interpretation of the written description requirement will have the unintended effect of jeopardizing the development of biopharmaceutical therapies at City of Hope and other research institutions. Immunotherapies like those involved in this case are among the most promising new treatments for cancer, and City of Hope is

[1] Pursuant to Fed. Cir. R. 35(g), this brief is accompanied by a motion for leave. This brief was not authored in whole or in part by any party or its counsel. Nor did any party or its counsel, or any other person—other than the *Amicus Curiae*, its members, or its counsel—contribute money that was intended to fund the preparation or submission of this brief.

at the forefront of research in the area. Its work includes conducting research across a range of hematologic cancers and solid tumors, partnering with global biopharmaceutical and other companies to make their therapies available to patients, and collaborating with other academic researchers. The availability of dependable patent protection has helped and will continue to help to drive 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.

As explained below, the Panel decision, and its rigid application of the written description test, may threaten or slow City of Hope's ability to continue to bring important new biopharmaceutical advances to patients. City of Hope therefore submits this brief in support of Plaintiffs-Appellees' Petition for Panel Rehearing or Rehearing *En Banc* (the "Rehearing Petition").

ARGUMENT

I. THE PANEL OPINION'S STRICT WRITTEN DESCRIPTION REQUIREMENT MAY DELAY THE PUBLIC DISCLOSURE OF INVENTIONS, WITH NO BENEFIT TO THE PUBLIC

The Panel's decision relies on a single claim element—the single-chain antibody variable fragment (scFv), which is "a binding element that specifically

interacts with a selected target." '190 Patent, claims 3, 9. The scFv was not the inventive aspect of the claims. The Panel acknowledged record evidence that scFvs all share the same general structure and were well known in the art. *See* Op. at 10-11, 13. The Panel decision does not dispute that methods for how to make scFvs were known, and Plaintiffs-Appellees point to evidence in the record that scFvs can be generated using those routine methods. Rehearing Petition at 13-14. The Court determined that to satisfy written description, "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." Op. at 11 (emphasis added). Despite the evidence that scFvs were known and could be generated, the Panel 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." *Id.*

Given the nature of scFvs and other similar biological structures used in therapeutics, the Panel's ruling amounts to a requirement that inventors spend excessive amounts of time conducting routine testing prior to filing for a patent in order to identify specific examples of the claimed invention, if even that will suffice. According to the record here, 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* Op. at 17-18. And there are no currently

understood common structural features specific to particular binding functions. *See id.* at 13. Thus, in order to satisfy the test laid out by the Panel—that the specification "distinguish[] which scFvs will bind to which target" for all scFvs—the applicants would have had to themselves build and test all the potentially relevant scFvs and report them in the specification. *Id.* at 11. The record evidence indicates that no other option would provide the information the Panel required.

Critically, requiring that inventors conduct that additional testing pre-application would serve no purpose and would not benefit the public. Skilled artisans are expected to conduct routine testing in order to practice the full scope of a given patent. *See, e.g.*, *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 982 (Fed. Cir. 2021). And here, the Panel's decision was not based on any apparent lack of an enabling disclosure. Because the Panel did not find the claims to lack enablement, the specification presumptively enables a skilled artisan to practice the full scope of claimed invention with only routine testing. In other words, the artisans to which the patent is directed do not need the specification to contain the detail the Panel required. The invalidation of the patent is thus not due to any failure to teach—and so benefit—the public. As for the inventors, they are presumptively persons of at least ordinary skill in the art and thus could practice the full scope of the invention applying only that same routine skill. What more does it mean to "possess" the invention than to describe its metes and bounds and

be able to practice its full scope? But now, in order to satisfy the requirement that a skilled artisan be able, from reading 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 will be forced to delay filing, publishing, collaborating on, and commercializing an invention that is otherwise ready for disclosure.

That delay can only harm the public's interests in the case like this one where the other requirements of patentability, including in particular the enablement requirement, are presumptively met. 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 swap out the described components with those already known in the art—like the accused product in this case, which uses an "off-the-shelf" scFv. Rehearing Petition at 14 (citing Appx33946-33947). 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'S STRICT WRITTEN DESCRIPTION REQUIREMENT

The above concern is not lessened by the possibility that institutions like City of Hope can choose to disclose their discoveries quickly if they seek only narrow patents—for example, a patent claiming only the particular molecules already in hand, with no genus claims corresponding to and fitting the breadth of the actual innovation. Doing so will leave institutions like City of Hope with patents that cover less than the full scope of the true innovative work. For while some important inventions can be fully claimed through, for example, a so-called picture claim, the law and science both recognize that other important inventions have generic scope. In that situation, a narrow patent does not align with the inventive aspect of the work. And potential licensees, faced with the choice between paying a research institution a royalty or using routine experimentation to identify a non-patented species that can be used royalty-free, will be incentivized to choose the latter option, thereby obtaining access to the inventive work royalty-free.

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 generic 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 serves no other purpose than to satisfy the Panel's strict 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 Panel'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 Panel'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 satisfy the unduly harsh written description requirement discussed in this brief.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a) or Federal Rule of Appellate Procedure 28.1. This brief contains 1,744 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Appellate Procedure 28.1 and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman, 14 point font.

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