**Nos. 2022-2153, 2023-1952**

# United States Court of Appeals
***for the***
# Federal Circuit

SALIX PHARMACEUTICALS LTD., SALIX PHARMACEUTICALS, INC., BAUSCH HEALTH IRELAND LTD., ALFASIGMA S.P.A.,

*Plaintiffs-Appellants*,

– v. –

NORWICH PHARMACEUTICALS INC,

*Defendant-Cross-Appellant*.

On appeal from a final judgment of the
United States District Court for the District of Delaware,
Case No. 1:20-cv-00430
Judge Richard G. Andrews

## CORRECTED BRIEF OF VANDA PHARMACEUTICALS INC. AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANTS AND REVERSAL

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## CERTIFICATE OF INTEREST

1. The full names of all entities represented by the undersigned counsel in this case: *Vanda Pharmaceuticals Inc.*

2. All real parties in interest for the entities: *None*.

3. All parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities: *Amicus has no parent corporation. Blackrock Fund Advisors owns more than 10% of Amicus's stock.*

4. All law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this Court for the entities: *None.*

5. Related or prior cases meeting the criteria of Fed. Cir. R. 47.5(a): *N/A (amicus).*

6. Any information required under Fed. R. App. P. 26.1(b): *None*.

I certify the above information is accurate and complete to the best of my knowledge.

Dated: July 31, 2023

*/s/ Paul W. Hughes*
Paul W. Hughes

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## INTRODUCTION & INTEREST OF THE *AMICUS CURIAE*[*]

Clinical trials are an essential—and typically mandatory—element of the drug development process. Equally essential, and likewise mandatory, is the study sponsor's disclosure of the trial to the National Institutes of Health, which by law must promptly report information about the study publicly on ClinicalTrials.gov. Public reporting of an ongoing clinical trial is as much an element of conducting the study as is developing the protocol, recruiting the subjects, or analyzing the findings. And a sponsor's failure to satisfy this requirement is grounds for criminal liability, including imprisonment and financial penalties, as well as hefty civil fines.

This federally-mandated public disclosure cannot—as some have sought to argue—be a basis to deprive a pharmaceutical innovator of their crucial intellectual property. The congressional determination that drug trials should be subject to certain public disclosures is certainly *not*

[*] Pursuant to Federal Rule of Appellate Procedure 29(a)(2), *amicus* states that plaintiffs-appellants consent to the filing of this brief; defendant-cross-appellant takes no position on Vanda's motion to file. Vanda has filed a motion for leave to file this brief. No party's counsel authored this brief in part or in whole, and no party or party's counsel or person other than *amicus* contributed financially to the preparation or submission of this brief.

a determination that these life-saving innovations are unworthy of patent protection. Properly construed, the patent laws do not establish the mere disclosure of ongoing clinical trials—and, in particular, postings on ClinicalTrials.gov—inform a person of ordinary skill in the art (POSA) about the reasonable likelihood of success in the future, and thus this is no basis to hold a patent invalid.

To begin, clinical trials are far from a sure thing—indeed, most drug trials fail. Accordingly, the mere existence of a clinical study cannot support a POSA's inference that the studied method is reasonably likely to succeed. Simply put, merely describing the design of an experiment in a ClinicalTrial.Gov disclosure tells a POSA nothing about the obviousness of the study's eventual result.

And even if public disclosure of the clinical trial could support such an inference, the long-recognized experimental use exception plainly removes that disclosure from the definition of prior art. The Court has recognized that a clinical study itself is a protected experimental use of the invention. The same result must follow for the public, involuntary disclosure of the existence of the study on a government website. Any other rule—one requiring innovators to hand over their valuable intellectual property in service of the government's public policy ends—would not

only defy statutory text, constitutional principles, and settled precedent but smother innovation that produces lifesaving therapies.

Any rule to the contrary would force drug manufacturers to make impossible choices, either to patent their drug before testing it and thereby risk the patent being invalid for lacking adequate specificity, or else to patent their drug after clinical testing and thereby risk the patent being invalid for being obvious in light of prior art (that is, the contents of the study itself). Such a result would spell disaster for innovation—and the people who depend upon it to access life-saving therapies—and turn patent law on its head.

*Amicus curiae* Vanda Pharmaceuticals Inc. knows this firsthand. Vanda is a pharmaceutical company that focuses on the development and commercialization of innovative therapies to address high-priority unmet medical needs. Vanda specializes in acquiring compounds that other companies failed to develop into a useful treatment and, through costly and time-consuming clinical studies, finding novel uses for them in treating patients. Vanda's ability to continue developing new uses for discarded compounds necessitates ensuring that the results of its clinical trials investigating new treatment methods remain patentable. Indeed, Vanda, after devoting years and many millions of dollars to research, development, and regulatory processes, developed a known molecule

(tasimelteon) into the first FDA-approved therapy to treat a rare and debilitating condition called Non-24-Hour Sleep-Wake Disorder, or Non-24.

Yet Vanda's patented method for this previously unknown method of treating Non-24 using 20 mg of tasimelteon one to one-and-a-half hours before bedtime was invalidated based in part on disclosure of what the government compels a sponsor to disclose publicly—the existence of a then-ongoing phase III clinical trial of tasimelteon in Non-24 patients. *See Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, 2023 WL 3335538 (Fed. Cir. May 10, 2023), *pet. for reh'g pending*, No. 23-1247 (Fed Cir. filed June 20, 2023).

The Court should make clear that a drug manufacturer's government-mandated disclosures of ongoing clinical trials necessary to develop the drug and secure FDA approval do not constitute prior art because they do not contribute to a reasonable expectation of success and because an inventor has never been understood to relinquish patent rights by carrying out the experiments necessary to determine that the invention works for its intended purpose in public. Any other conclusion would mean forcing drug innovators to divest themselves of the value of their intellectual property so that the government may put it to the public use through online disclosures of ongoing trials.

## ARGUMENT

### I. GOVERNMENT-MANDATED DISCLOSURES OF ONGOING CLINICAL TRIALS ARE THREATENING PATENT RIGHTS.

Over the past two decades, the government-mandated disclosure of ongoing clinical trials has created a crisis for pharmaceutical innovators. By insisting that innovation take place in the public square, government-mandated clinical trial information has prompted a wave of infringers using those very government-mandated disclosures to attempt to invalidate patents claiming the methods that those trials discovered. While courts to date have reached mixed results on assorted factual records as to whether the disclosure of an ongoing clinical trial actually rendered the method obvious, the fundamental problem remains the same: government mandates are ever more common, and infringers are increasingly invoking those very mandated disclosures to tip the scales against pharmaceutical method-of-treatment patents.

#### A. Federal law compels disclosure of ongoing clinical trials.

Under the Food and Drug Administration Modernization Act of 1997, Congress ordered the National Institutes of Health (NIH) to create a public information resource cataloguing and describing clinical trials involving experimental drugs for patients with serious or life-threatening

diseases or conditions. *See* Pub. L. No. 105-115, § 113, 111 Stat. 2310 (codified at 42 U.S.C. § 282(i)). In 2000, the NIH launched ClinicalTrials.gov to satisfy that mandate. Congress soon expanded those requirements, requiring sponsors to register additional types of trials, publicize more study information, and submit study results under the Food and Drug Administration Amendments Act of 2007. *See* Pub. L. No. 110-85 § 801(a), 121 Stat. 904 (codified at 42 U.S.C. § 282(j)). That law also established serious noncompliance penalties, including withholding of NIH grant funding and monetary penalties of up to $10,000 per day. *See* 21 U.S.C. §§ 331(jj), 333(a). Over time, these statutory requirements, along with FDA's implementing regulations, have steadily increased the scope of mandatory public online disclosures connected to the clinical study of potential new drugs.

Today, pharmaceutical manufacturers must register most clinical drug studies they perform in the United States with NIH. *See* 42 U.S.C. § 282(j). Generally speaking, a sponsor must submit information about its clinical study within 21 days after enrolling the first trial subject. *See id.* § 282(j)(2)(C)(ii); 42 C.F.R. §§ 11.8, 11.24(a). The information sponsors must provide is extensive; they must describe the study's purpose and design, the primary disease or condition being studied, the drug name

and type, primary and secondary outcome measures, recruitment eligibility and demographic information, and the expected completion date. 42 U.S.C. § 282(j)(2)(A)(ii); 42 C.F.R. § 11.28(a). The law also requires NIH to "ensure that the registry data bank"—*i.e.*, the information submitted by clinical study sponsors—"is made publicly available through the internet." 42 U.S.C. § 282(j)(2)(A)(i). And it must do so within 30 days of a sponsor's submission. *Id.* § 282(j)(2)(D)(i); 42 C.F.R. § 11.35(a).

A sponsor who fails to comply with the ClinicalTrials.gov submission requirements does so at significant peril. The Federal Food, Drug, and Cosmetic Act labels failing to timely submit clinical study information to NIH a "prohibited act" that carries criminal liability , including potential imprisonment and fines. 21 U.S.C. § 331(jj); *id.* § 333(a)(1). And NIH can also impose hefty civil monetary penalties—up to $10,000 per day for an ongoing and uncorrected violation. *Id.* § 333(f)(3)(A)&(B); *see also* FDA, *Civil Monetary Penalties Relating to ClinicalTrials.gov Data Bank*: *Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff* (Aug. 20, 2020), perma.cc/SV5N-3JUF.

### B. Innovators cannot patent methods established in clinical trials until they have trial results.

Although federal law requires the disclosure of ongoing clinical trials, the patent laws often prevent an innovator from seeking patent protection until after it has *results*.

In *Amgen Inc. v. Sanofi*, the Supreme Court reiterated that a drug innovator cannot patent its novel methods without possessing sufficient detail to explain to another the scope of the invention. 143 S. Ct. 1243 (2023). That rule confirms prior Federal Circuit precedent concluding the same. *E.g.*, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1375, 1375 n.20 (Fed. Cir. 2017) (explaining that invention is not ready for patenting where patentee could not satisfy § 112 written description requirement), *aff'd*, 139 S. Ct. 628 (2019). A patent application predating the results of the clinical study necessary to confirm the suitability of the to-be claimed method is thus in many cases doomed from the start.

Indeed, this Court has previously held that certain drug patents predating phase III clinical trials lacked adequate written description. In *Biogen Int'l GMBH v. Mylan Pharms. Inc.*, for instance, the Federal Circuit held that although the patent disclosed a range of effective dosages, "at the time of filing the disclosure—well before the Phase III study even

commenced—a skilled artisan could [not] deduce simply from reading the specification that" one particular dose within that range "would be a therapeutically effective treatment for MS." 18 F.4th 1333, 1344 (Fed. Cir. 2021). Thus, "the inventors were not in possession of a complete and final invention" at that time. *Id*. Similarly, in *In re Omeprazole Patent Litigation,* the Court held that the claimed invention had not been reduced to practice even where the formulation to be studied in Phase III trials had been manufactured and shown to treat gastrointestinal disease because the inventors did not know whether the formulation could achieve the claimed long term, in-vivo stability absent the Phase III study. 536 F.3d 1361, 1373-1375 (Fed. Cir. 2008).

### C. Infringers are increasingly invoking disclosures of the ongoing trial as invalidating prior art.

The combination of the government-mandated trial disclosures and the written-description rules of the patent laws has created a nearly impossible situation for innovators—and a seemingly inadvertent boon for accused infringers. That is because patent law provides only a one-year grace period before a public disclosure is considered prior art. *See* 35 U.S.C. § 102(b)(1). But clinical studies frequently take much longer than a year to complete. *See, e.g.*, FDA, *Step 3: Clinical Research* (Jan. 4, 2018), perma.cc/23ZD-H6FN (describing Phase II trials as taking "[s]everal

months to 2 years" and Phase III trials as taking "1 to 4 years"). Would-be pharmaceutical innovators are thus left with a Hobson's choice—file too early and risk invalidation for lack of written description; file too late and risk invalidation because of the government-mandated disclosure of the ongoing study.

Accused infringers are taking advantage. With increasing regularity, accused infringers are pointing to the disclosure of the existence of an ongoing trial, including ClinicalTrials.gov postings, as prior art—to varying degrees of success. *See, e.g.*, *Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, 2023 WL 3335538, at *4 (Fed. Cir. May 10, 2023) (affirming invalidity of patent based on existence of ongoing Phase III clinical trial), *pet. for reh'g pending*, No. 23-1247 (Fed. Cir. filed June 20, 2023); *Bausch Health Ireland Ltd. v. Padagis Israel Pharms. Ltd.*, 2022 WL 17352334 (D.N.J. 2022) (finding patent not invalid where ClinicalTrials.gov posting was offered as reference); *Janssen Pharms., Inc. v. Mylan Labs Ltd.,* 2023 WL 3605733, at *18, 20 & n.17 (D.N.J. 2023) (same), *appeal filed*, No. 23-2042 (Fed. Cir. June 20, 2023); *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, 2023 WL 4175334, at *14 (D. Del. June 26, 2023) (finding that mere existence of Phase III trial does not create a reasonable expectation of success).

This case presents the same problem: the district court relied on the existence of an ongoing clinical trial to inform the obviousness analysis—and it tipped the scales. Appx37-41.

## II. THE COURT SHOULD MAKE CLEAR THAT ONGOING-STUDY DISCLOSURES CANNOT BE INVALIDATING PRIOR ART.

The Court should make clear that a drug manufacturer's government-mandated disclosure of ongoing clinical trials necessary to develop the drug and secure FDA approval do not constitute prior art. This is for two reasons.

*First*, such postings cannot inform a POSA's reasonable expectation of success in the claimed method of treatment because clinical trials are, by definition, uncertain. Indeed, most clinical drug trials fail, and thus a POSA cannot, simply by knowing that a clinical study exists concerning an unproven hypothesis, reasonably infer that that hypothesis is correct.

*Second*, in any case, legally required disclosures necessary to conduct a clinical trial are quintessential experimental uses of the invention that fall outside the statutory definition of prior art. For centuries, courts have been clear that an inventor does not relinquish patent rights by carrying out the experiments necessary to determine that the invention works for its intended purpose, even if those experiments occur in public.

Drug clinical trials—typically mandatory tests on human subjects to ensure that the drug works as intended as a medical treatment—are obvious experimental uses of the invention, as this Court and other have repeatedly held. By the same token, the public disclosures necessary to legally conduct those trials are part of the same course of experimental conduct and should be treated the same under patent law. Indeed, treating them any different would mean forcing drug innovators to divest themselves of the value of their intellectual property so that the government may put it to the public use of online disclosure.

### A. Government-mandated disclosure of an ongoing clinical trial cannot provide a reasonable expectation of success.

By definition, a clinical study tests an unproven hypothesis. "[O]nly with the benefit of hindsight" would a POSA have a "reasonable expectation of success in view" of the mere existence of a clinical study. *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019). That is, simply knowing about a clinical study while it is still ongoing "provide[s] no more than hope," which, no matter how "potentially promising" the studied compound, is "not enough to create a reasonable expectation of success in a highly unpredictable art such as" drug development. *Id*. Mandatory disclosures of clinical studies—often, detailing nothing more

than the study's design—simply do not make the results that later come out of that study obvious.

This Court has previously confirmed that a clinical study, by merely existing, lends no support to an inference by a POSA of a reasonable expectation of success. *See, e.g.*, *Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 696 (D. Del. 2016) (finding it "not credible that a POSA would simply read the outline of a future clinical trial and the results of a single post-hoc analysis" to reach a reasonable expectation of success), *aff'd sub nom. Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636 (Fed. Cir. 2017); *see also Novartis Pharms. Corp. v. West-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051, 1061 (Fed. Cir. 2019) (affirming district court's finding of no reasonable expectation of success from positive Phase I study results and entry into Phase II clinical trials).

For good reason. If anything, statistically speaking, the only reasonable expectation for a typical clinical study is failure. The FDA estimates that only a third of drugs move from a Phase II study to Phase III. *See* FDA, *Step 3: Clinical Research* (Jan. 4, 2018), perma.cc/23ZD-H6FN. All told, "[o]nly about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA." Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* at 2 (2021), perma.cc/NEU3-XZHR.

The Court should therefore confirm that government-mandated disclosures of ongoing clinical trials cannot contribute to a reasonable expectation of success. Anything short of this rule automatically tips the scales against pharmaceutical patents' presumed validity.

### B. Government-mandated disclosure of an ongoing clinical trial falls within the experimental use exception.

Even if information the government requires be disclosed on ClinicalTrials.gov could contribute to a POSA's reasonable expectation of success, the experimental use doctrine, which has "long been a fixture of patent law," should shield these government-mandated public disclosures from being considered prior art. *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1379 (Fed. Cir. 2003). Disclosures on ClinicalTrials.gov are necessary, integral elements of the clinical study to determine whether the drug will serve its intended purpose and thus plainly fall within the heartland of experimental use. Changes to the patent laws under the America Invents Act further clarify this straightforward fact.

#### *1. Ongoing clinical trials are experimental uses entitled to protection.*

Rooted in Supreme Court precedent dating back at least to the late-1800s, the experimental use exception recognizes and protects an inventor's need to test a would-be invention in public to ensure that it works

for its intended purpose. Because posting on ClinicalTrials.Gov is a legally required step for a pharmaceutical company to perform the experiments necessary to test whether the drug is effective (itself a condition for obtaining FDA marketing approval), NIH's publication of the submitted information constitutes part of the inventor's public use excepted from prior art.

The experimental use exception is 175 years old, arising as a necessary carveout from the statute's limitation on patenting inventions in "public use." In 1848—six years before he ultimately obtained a patent for his invention—Samuel Nicholson set out to test his wooden pavement design by laying it down on a 75-foot stretch of Mill-dam Avenue in Boston "by way of experiment." *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 133 (1877). Decades later, when another city attempted to use Nicholson's design without compensation, it defended its infringement by arguing that his "invention was in public use … , with his consent and allowance, for" the six years it lay on the streets of Boston prior to obtaining his patent. *Id*. Recognizing that Nicholson had "constructed the pavement in question by way of experiment, for the purposes of testing its qualities" and to "ascertain its durability," and that such an experiment could not be conducted "satisfactorily except on a highway,

which is always public," the Court held that Nicholson's test was no "public use, within the meaning of the statute." *Id*. at 133-135.

The need for inventors to experiment in public remains just as important today. Thus, under the experimental use exception, "[a]n inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye." *Pfaff v. Wells Elecs.*, 525 U.S. 55, 64 (1998). When an inventor puts her invention to experimental use—even when used in public or even commercially—she "by definition does not abandon the invention to the public." *Lough v. Brunswick Corp.*, 103 F.3d 1517, 1534 (Fed. Cir. 1997) (Rader, J., dissenting).

As this Court has recognized, "[a] use may be experimental if its purpose is: '(1) [to] test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose.'" *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1328 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 869 (2020) (citation omitted). And the Court has promulgated 13 factors a court may weigh when determining whether a use is experimental:

> (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who

> conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

*Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1348-1349 (Fed. Cir. 2018) (citation omitted).

Clinical studies of new drugs or novel uses for existing drugs easily satisfy these parameters. Indeed, to obtain FDA approval, a drug application generally "must contain extensive information on clinical trials [in humans] showing that the drug is safe and effective for its labeled use," all of which the sponsor must disclose to NIH. *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1117 (Fed. Cir. 2021). Those studies often involve complicated protocols surrounding the delivery of the drug to individuals experiencing the target condition. Although non-clinical testing (*e.g.*, animal testing or other laboratory studies) provides useful information about how a drug operates, it is no substitute for conducting a rigorous study in the target population (Factors 1, 3 and 10).

When conducting drug trials, pharmaceutical companies create detailed protocols, submitted to FDA in advance, intended to closely control how a study is performed. *See* 21 C.F.R. § 312.23(a)(6). Those protocols—

which are executed by the investigational sites selected by the study sponsors—detail enrollment criteria, study length, assessment parameters, interventional design. (Factors 2, 4, 8, and 11). *Id*. They also impose substantial record requirements so that data can be analyzed when a study is finished, as good practice typically prohibits a sponsor from obtaining data until the study is completed (Factors 7 and 12). Study investigators are typically held to strict confidentiality agreements (Factor 6). Because of the significant cost associated with conducting a trial, studies are typically run for only so long as is necessary to observe the effect of a drug (Factor 4). From a commercial perspective, manufacturers are prohibited from selling an unapproved drug or marketing an unapproved use (21 U.S.C. § 355(a)), and test subjects do not pay to participate in a study (Factors 5, 9, and 13). *See* Letter from Stephen Rosenfeld, Chair, Secretary's Advisory Committee on Human Research Protections to Alex Azar, Secretary of Health and Human Services, *Attachment A*: *Charging Subjects for Clinical Trial Participation* (Nov. 20, 2019), perma.cc/G67Q-NG37. The conclusion is inescapable: the mine run of clinical trials are experimental uses, and rightly so.

Courts, including this one, have repeatedly recognized as much, often applying the experimental use exception to protect the patent rights of drugs from being invalidated merely because the drugs were used in

clinical trials to ascertain their efficacy. In *In re Omeprazole Patent Litigation*, for example, the generic infringers argued that the pre-AIA § 102(b) "public use" of conducting "four large clinical studies to determine the safety and efficacy of" the innovator's formulation more than a year in advance of the priority date barred the innovator's patents. 536 F.3d 1361, 1371-1375 (Fed. Cir. 2008). This Court found that where "the claimed formulation was not ready for patenting until after the clinical studies were completed," these clinical trials constituted experimental uses. *Id*. at 1372. Likewise, in *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, the Court noted that "the experimental character of" Eli Lilly's clinical studies "negated any statutory bar" to patent protection as a "public use." 471 F.3d 1369, 1381 (Fed. Cir. 2006). Considering how "Lilly tailored its tests to their experimental drug safety and efficacy purpose," the experimental use exception clearly applied. *Id*.[1]

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[1] *See also, e.g., Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 698 (D. Del. 2016) ("[A] clinical trial seeking to test a particular treatment hypothesis seems to be the quintessential experimental use."), *aff'd sub nom. Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636 (Fed. Cir. 2017); *Gilead Scis., Inc. v. Sigma-pharm Labs., LLC*, 2014 WL 1293309, at *7 (D.N.J. March 31, 2014) (finding that sales and purchases "for the purposes of the clinical tests and other studies" and to "develop an FDA-compliant manufacturing practice and protocols to administer the drug to humans in clinical trials" satisfied the experimental use exception). *Accord Janssen Pharmaceutica, N.V. v. Eon Labs Mfg., Inc.*, 134 F. App'x

A rule that would allow an ongoing clinical trial to inform a POSA's expectations of success simply because a drugmaker has declared it on ClinicalTrials.gov would nullify the protection courts have traditionally offered those trials under the experimental use exception. Such postings are an integral—indeed, government-mandated—aspect of conducting clinical studies and thus plainly fall within the exception's purview.

Disclosing a clinical trial on ClinicalTrials.gov is not optional. To the contrary, such disclosure is a mandatory prerequisite to conducting the study in the first place. Failing to promptly do so means paying a hefty civil penalty—up to $10,000 per day—not to mention carries potentially criminal liability piling on more fines still, and even possible jail-time. *See supra* at 2. Posting the study on ClinicalTrials.gov in due course is just as essential to carrying out the study as any other document an experimenter must generate to carry out the experiment, from confidentiality agreements to study protocols.

Simply disclosing the study's existence online—in accordance with federal law—does not make such a disclosure prior art. To the contrary, the necessarily public character of the disclosure is "merely incidental to

425, 431 (Fed. Cir. 2005) (finding that a clinical trial was not a public use).

the primary purpose of experimentation to perfect the invention." *Allen Engineering Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1354 (Fed. Cir. 2002) (quoting *EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1356-57 (Fed. Cir. 2002)). Indeed, in *Allen Engineering,* this Court made clear that even prior commercial marketing is not a bar to later patent rights if the marketing was incidental to the inventor's experimental aims. What matters is "whether the primary purpose of the inventor at the time … was to conduct experimentation." *Id* (quoting *EZ Dock*, 276 F.3d at 1357).

As with alleged commercial activity in service of "experiment[ing], test[ing], and otherwise engag[ing] in activities to determine if the invention is suitable for its intended purpose" (*Allen Engineering*, 299 F.3d at 1354 (quoting EZ Dock, 276 F.3d at 1357)), so too with publishing on ClinicalTrials.gov in service of readying a drug for clinical study and, hopefully, eventual FDA approval. Without the public posting, there is no trial. And without the trial, there is no method of treating a condition with the drug. The posting serves no purpose other than qualifying the drug for clinical study—that is, to confirm that the drug is "suitable for its intended purpose." *Id*. The court should reject any rule that would hold a drug manufacturer's ClinicalTrials.gov posting against it as prior art.

Indeed, embracing any such rule might well yield disturbing constitutional infirmities. It bears emphasis that drug developers disclose required information to NIH *at pain of criminal prosecution* and for an express public use: for NIH to publicize that information online to foster public confidence in the safety of clinical studies. To be sure, drug innovators share the goal of ensuring that clinical studies are done with the utmost safety. Yet government-mandated disclosures of sensitive commercial information to achieve public-facing regulatory goals—when such disclosure divests the owner of that information of its value—are unconstitutional without just compensation. *See Ruckelshaus v. Monsanto Co.,* 467 U.S. 986, 1010-1016 (1984).

#### *2. The AIA confirms the experimental use exception's application to government-mandated disclosures.*

Changes to the patent laws following the enactment of the America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, also explain why the experimental use exception must extend to disclosures of clinical trials published on ClinicalTrials.gov. The law reflects Congress's desire to treat all forms of prior art uniformly. Accordingly, the experimental use exception applies equally to any publicly available information that may otherwise constitute prior art under the law.

Prior to the AIA, the law's definition of prior art was divided into separate subsections. *See* 35 U.S.C. §§ 102(a)-(b) (2006). But the new § 102 contained in the AIA "enact[ed] a new definition of 'prior art,' … sweep[ing] away a large body of patent law." Joseph Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 449-450 (Mar. 2012). Importantly, the law "combine[d] pre-AIA subsections (a) and (b) into a hybrid definition of 'prior art.'" *Id*. at 450; *see* 35 U.S.C. § 102(a)(1).

That new hybrid definition consolidated the prior art limitation on public disclosures all in one place. It necessarily follows that any exception to the new version of the law's general definition of prior art—including the experimental use exception—applies to all public disclosures. After all, the Congress that enacted the AIA was well aware of the experimental use exception, and it left that doctrine undisturbed when it consolidated the law's definition of prior art all in one place. *See Fluor Corp. & Affiliates v. United States*, 126 F.3d 1397, 1404 (Fed. Cir. 1997) ("Familiar principles of statutory construction teach that Congress is presumed to be aware of judicial interpretations of the law, and that when Congress enacts a new statute incorporating provisions similar to those in prior law, it is assumed to have acted with awareness of judicial interpretations of the prior law.").

In short, the law supplies no basis to distinguish between public knowledge of the purported prior art because of disclosure on ClinicalTrials.gov versus any other public use or disclosure traditionally well-acknowledged to be a part of the experimental use exception, such as other aspects of clinical study, or commercial use incidental to experimentation.

More, confirming that the experimental use exception reaches mandatory clinical trial disclosures is respectful not just of the structure of the AIA but of Congress's objectives in enacting that law as well. As Congress explained in the law, "the patent system should promote industries to continue to develop new technologies that spur growth and create jobs across the country which includes protecting the rights of small businesses and inventors from predatory behavior that could result in the cutting off of innovation." Pub. L. No. 112-29 § 30, 125 Stat. 339. Considering legally mandated disclosures on ClinicalTrials.gov to be prior art under the statute would turn the law on its head. It would convert a policy intended to spur innovation and protect inventors from opportunists into one that leaves drug inventors helpless against would-be infringers simply for doing what the government has ordered them to do. *Cf. C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998) (defenses

to patent infringement "need not be enlarged into an open-ended pitfall for patent-supported commerce.").

The court should not misconstrue ClinicalTrials.gov to require inventors to give over their claims to exclusivity as the price of doing their part to achieve the public purpose of safe and effective scientific development through clinical study—instead, the AIA only further confirms Congress's intent that these disclosures are part and parcel of experimenting and excepted from prior art.

## III. TREATING GOVERNMENT-MANDATED DISCLOSURES OF ONGOING CLINICAL STUDIES AS PRIOR ART WILL CHILL INNOVATION.

In seeking to develop innovative therapies while protecting their investment, drug companies face an impossible choice. On the one hand, seeking a patent *before* clinical study would make those patent rights vulnerable to attack for lacking sufficient detail. On the other, filing for a patent *after* clinical study could mean seeing patent rights washed away due to public disclosure. Facing threats to their intellectual property regardless of which lane they choose, inventors of life-saving and life-improving therapies, wary of making enormous investments of time and resources only to be left with nothing to show for it, will have little incentive to continue innovating.

Presciently, *amici* supporting the petition for certiorari to the Supreme Court in *Biogen Int'l GmbH v. Mylan Pharms. Inc.* warned that "forcing pharmaceutical innovators to wait until successful clinical evidence is in hand before they file their patent applications will effectively prevent patenting of their innovations," as "pharmaceutical innovators are required to publicly disclose details of their clinical investigations and results of their clinical trials before the FDA approves their products." Brief of Pharmaceutical Research and Manufacturers of America & Biotechnology Innovation Organization as Amici Curiae Supporting Petitioners at 8-9, *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 143 S. Ct. 112 (2022) (mem) (cert. denied). That is, the *amici* warned, "requiring pharmaceutical innovators to wait for clinical evidence could result in denial of their patent applications *in light of their own compelled public disclosures*." *Id*. at 9 (emphasis in original). Commentators have also raised the alarm regarding the threat to patent rights posed by mandatory disclosures of clinical data. *See* Darpan Patel, *Clinical Trial Data Reporting: Breaking Free of a Prisoner's Dilemma*, 76 Food & Drug L.J. 101, 118-119 (2021); Michelle Mello, et al., *Preparing for Responsible Sharing of Clinical Trial Data*, 369 New Engl. J. Med. 1651, 1654 (Oct. 2013).

These fears are all coming to pass, as infringers increasingly invoke government-mandated information disclosures as invalidating prior art.

Undercutting the good-faith efforts of drug developers to comply with federal laws directed towards preserving public safety, all so second-movers can prematurely extinguish hard-earned intellectual property rights, perverts patent law. It also flies in the face of the core constitutional principle undergirding it that "[s]acrificial days devoted to such creative activities deserve rewards commensurate with the services rendered." *Mazer v. Stein*, 347 U.S. 201, 219 (1954) ("The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in 'Science and useful Arts.'").

The Court should take this opportunity to clarify—as precedent, statutory text, and constitutional principles require—that a drug company does not throw away its stake in the very innovation it means to create by fulfilling the congressional mandate to conduct clinical study in public view.

## CONCLUSION

The Court should make clear that government-mandated disclosures of ongoing clinical trials cannot be considered in evaluating obviousness and should reverse the conclusion otherwise against plaintiffs-appellants.

Dated: July 31, 2023

Respectfully submitted,

/s/ *Paul W. Hughes*
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## CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I hereby certify that this brief:

(i) complies with the type-volume limitation of Rule 29(a)(5) and Circuit Rule 29(b) because it contains 5,731 words, excluding the parts of the petition exempted by Rule 32(f) and Circuit Rule 32(b)(2); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Word for Microsoft 365 MSO and is set in New Century Schoolbook LT Std in 14 point font.

Dated: July 31, 2023 /s/ *Paul W. Hughes*

## CERTIFICATE OF SERVICE

I hereby certify that on August 30, 2023, I electronically filed the foregoing petition with the Clerk of this Court using the CM/ECF system, and counsel for all parties will be served by the CM/ECF system.

Dated: August 30, 2023 /s/ *Paul W. Hughes*