Nos. 22-2153, 23-1952

In the 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.

Appeal from the United States District Court for the District of Delaware
No. 20-cv-430, Hon. Richard G. Andrews

CORRECTED BRIEF OF REGENERON PHARMACEUTICALS, INC. AND OCULAR THERAPEUTIX, INC. AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANTS AND REVERSAL

Irena Royzman
Counsel of Record
Christine Willgoos
KRAMER LEVIN NAFTALIS & FRANKEL LLP
1177 Avenue of the Americas
New York, NY 10036
Telephone: (212) 715-9100
Facsimile: (212) 715-8000
iroyzman@kramerlevin.com

Paul Brzyski
KRAMER LEVIN NAFTALIS & FRANKEL LLP
2000 K Street N.W., 4th Floor
Washington, DC 20006
Telephone: (202) 775-4500
Facsimile: (202) 775-4510
pbrzyski@kramerlevin.com

Counsel for Amici Curiae Regeneron Pharmaceuticals, Inc. and Ocular Therapeutix, Inc.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-2153, 23-1952

Short Case Caption Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals Inc.

Filing Party/Entity Regeneron Pharmaceuticals, Inc.; Ocular Therapeutix, Inc.

Instructions:

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Date: 07/27/2023

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Name: Irena Royzman

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☐ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Regeneron Pharmaceuticals, Inc.	N/A	N/A
Ocular Therapeutix, Inc.	N/A	Summer Road LLC

☐ Additional pages attached

4. Legal Representatives. List 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. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☐ No ☑ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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INTEREST OF *AMICI*

Amici are innovator pharmaceutical and biotechnology companies that invent, develop, and commercialize life-transforming medicines. Amici regularly seek and receive patent protection for their many scientific advancements. They also routinely conduct clinical trial experiments—some of which succeed, but many of which fail—as part of the drug development process. Amici are required by law and regulation to publicly disclose a protocol summary of planned and ongoing clinical trials. Accordingly, amici have a strong interest in ensuring that these compelled disclosures are not used to invalidate patents claiming discoveries tested during successful clinical trials. Because the decision below exemplifies a growing negative trend in patent proceedings—using clinical trial protocol summaries to support a finding of reasonable expectation of success—amici file this brief supporting Appellants.[1]

Regeneron Pharmaceuticals is a leading biotechnology company. Its ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all of which were homegrown in Regeneron's laboratories. Regeneron's medicines and

[1] No party's counsel authored this brief either in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person—besides *amicus curiae* Regeneron Pharmaceuticals—contributed money that was intended to fund preparing or submitting the brief.

pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, infectious diseases, and rare diseases.

Ocular Therapeutix, Inc. is a biopharmaceutical company dedicated to the formulation, development, and commercialization of novel therapies for diseases and conditions of the eye. With a focus on advancing its products through Phase 3 clinical trials, Ocular Therapeutix has pioneered a minimally invasive approach to treating eye diseases, achieving continuous drug delivery by integrating medications into a hydrogel platform. Developing much-needed localized and effective treatment options, Ocular Therapeutix is driven to improve the quality of care and quality of life for patients with serious eye conditions.

INTRODUCTION

Research and development should not cannibalize its own success. Yet that is happening with increasing frequency as patent challengers wield mandatory public disclosures of clinical trial protocols against the very inventions being tested during those trials.

Drug researchers are required by law and regulation to publicly share information about their planned and ongoing clinical trials—specifically, to register the trial and disclose information on clinicaltrials.gov, a website hosted by the National Institutes of Health ("NIH") National Library of Medicine. Requirements

for public disclosures of clinical trials, particularly of NIH-funded studies and studies of life-threatening diseases, date back to the late 1990s. In 2007, Congress greatly expanded the number of trials requiring disclosure through the Food and Drug Administration Amendments Act, and the Department of Health and Human Services ("HHS") further expanded disclosure requirements by regulation effective January 2017. As it presently stands, HHS effectively requires disclosure of all interventional clinical drug trials that are beyond Phase I. *See* 42 C.F.R. § 11.22 (2016).

Before the results of a trial are ascertained and disclosed (which often takes years), the information posted to clinicaltrials.gov includes a summary of the clinical trial protocol intended to be used to conduct the study. Disclosure includes, among other details, a brief summary of the experiment, its design, its primary purpose, the measures to evaluate results, the location(s) of the study, and recruitment information.

There is a growing practice among patent challengers of using protocol summary disclosures on clinicaltrials.gov—posted long before any results from the trial are reported—as prior art in obviousness claims. These challengers argue that the invention was obvious in light of the protocol summary on clinicaltrials.gov because the posting allegedly disclosed the method of the ultimately successful

invention—never mind that it was only with hindsight that the challenger knew the clinical trial tested a successful method or dosing regimen.

The instant case reflects this trend. The IBS-D patents at issue claimed a method of treatment comprising a rifaximin dosage of 550 mg three times per day for 14 days. In its obviousness attack, Norwich asserted as prior art Bausch's[2] own disclosure of a Phase II clinical trial protocol summary posted on clinicaltrials.gov, which was designed to test 550 to 2,220 mg per day of rifaximin, the so-called "RFIB 2001 Protocol." Despite the fact that there were no publicly available results from the RFIB 2001 Protocol or the Pimentel 2006 references for the ***claimed*** method of treatment, which requires 550 mg ***three*** times a day,[3] the court below concluded that "a POSA would have been motivated to combine Pimentel 2006 with the RFIB 2001 Protocol and would have had a reasonable expectation of success." Appx38.

But this trend of using clinical trial protocol summary disclosures for the reasonable expectation of success analysis is not supportable under this Court's established approach to that inquiry. That inquiry is a factual one, and the simple fact is that most clinical trials are unsuccessful. Accordingly, skilled artisans cannot reasonably expect to succeed in achieving the invention based on the protocol

[2] Bausch is the parent company of Salix.

[3] Salix's press release reported only "top-line" results for a dosage of 550 mg ***twice***/day to treat IBS-D; it did not report results for the claimed dosage of 550 mg ***three*** times a day. Appx38.

disclosures. Those disclosures—like the RFIB 2001 Protocol in this case—represent only hypotheses to be tested, and more often than not those tests fail.

Indeed, this Court's decision in *OSI Pharmaceuticals, LLC v. Apotex Inc.*, 939 F.3d 1375 (Fed. Cir. 2019), recognized that high clinical trial failure rates undermine a finding of reasonable expectation of success. The logic of that case applies likewise to the instant one, as it does to all cases where patent challengers claim a reasonable expectation of success that relies on protocol disclosures.

Use of these clinical trial disclosures on clinicaltrials.gov (or elsewhere) to support a finding of reasonable expectation of success is not only factually dubious and inconsistent with this Court's approach to reasonable expectation of success, it threatens research and development ("R&D") efforts by undermining investment. It also creates an incentive to file patent applications early in the process, prior to the mandatory disclosures required by federal regulation to carry out clinical trials.

This Court should put an end to this disturbing trend in patent challenges.

ARGUMENT

I. Clinical trial summary disclosures do not create a reasonable expectation of success.

A. The reasonable expectation of success standard is a factual inquiry, and it is a fact that most clinical trials fail.

"A party seeking to invalidate a patent on obviousness grounds must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Ivera Med. Corp. v. Hospira, Inc.*, 801 F.3d 1336, 1344 (Fed. Cir. 2015). Reasonable expectation of success is a question of fact. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016). The fact is that most clinical trials fail.

Study after study confirms the low success rates of clinical trials. For example, a group of researchers with Biomedtracker measured clinical trial success using a dataset of 4,451 drugs and found an ultimate success rate of 10.4%. *See* Michael Hay, *et al.*, *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40, 40–41 (Jan. 2014). Building on Hay *et al.*'s "landmark study," researchers at Massachusetts Institute of Technology followed up in 2019 with the "largest investigation thus far into clinical trial success rates and related parameters." Chi Heem Wong, *et al.*, *Estimation of Clinical Trial Success Rates and*

Related Parameters, 20 BIOSTATISTICS 273, 274 (Apr. 2019). This research found an overall success rate of 13.8% that "ranges from a minimum of 3.4% for oncology to a maximum of 33.4% for vaccines." *Id.* at 277. *See also* John Arrowsmith, *Phase II Failures: 2008-2010*, Biobusiness Briefs, NATURE (Apr. 2011) ("Analysis by the Centre for Medicines Research (CMR) of projects from a group of 16 companies (representing approximately 60% of global R&D spending) . . . reveals that the Phase II success rates for new development projects have fallen from 28% (2006–2007) to 18% (2008–2009)"). A similar study conducted by industry trade and analytics groups found overall likelihood of FDA approval from Phase I at 9.6%. *See* Amplion, *et al.*, *Clinical Development Success Rates 2006-2015* (June 2016). Notably, in this study, even the aggregate findings on success rates of Phase III trials were only 49.6%. *Id.* at 9. Thus, even when drugs are farthest along in the clinical study process, they still face a less-than-likely chance at success. *See also* U.S. Food & Drug Admin., *The Drug Development Process, Step 3: Clinical Research* (Jan. 4, 2018), https://perma.cc/7XWC-EF3P (estimating that only 25–30% of Phase III trials are successful). Indeed, examples of failed Phase III trials abound.[4]

[4] *See* Jessica Merrill, *Surprise! It's a Phase III Failure*, Scrip, PHARMA INTELLIGENCE (Aug. 12, 2016) (recounting ten Phase III failures and noting that "the only guarantee when it comes to drug development, is there is no guarantee, even in the final phase"); *see also* Press Release, Janssen to Discontinue Pimodivir Influenza Development Program, PR NEWSWIRE (Sept. 2, 2020); Divya Tirumalaraju, *Sanofi and Regeneron's Kevzara Fails in Phase III Covid-19 Trial*, CLINICAL TRIALS

To prove obviousness, a patent challenger must show reasonable expectation of success by *clear and convincing evidence*. A skilled artisan does not—and cannot—reasonably expect to succeed against such odds.

B. *OSI Pharmaceuticals* recognized that the high failure rate of clinical trials can defeat claims of reasonable expectation of success.

This Court has already held that low clinical trial success rates can be fatal to the reasonable expectation of success inquiry. *See OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1384–85 (Fed. Cir. 2019). At issue in *OSI Pharmaceuticals* was the compound erlotinib—an epidermal growth factor receptor ("EGFR") inhibitor. OSI discovered and patented erlotinib as an effective therapy for treating non-small cell lung cancer ("NSCLC"). *Id.* at 1378. In IPR proceedings, the PTAB concluded that the claims at issue were obvious, relying on the combination of: (1) a prior patent proposing erlotinib as an EGFR inhibitor to treat numerous conditions (including lung cancer); (2) OSI's public disclosure in its 10-K, filed 18 months prior to the invention date, that erlotinib was in Phase II trials as a potential treatment for a number of cancers (including NSCLC); and (3) a review article that identified erlotinib as a drug development target for patients with NSCLC. *Id.* at 1379–81. This third reference—the review article—cited two clinical trials that contained no data regarding erlotinib and NSCLC. *Id.* at 1381.

ARENA (July 3, 2020); Lisa LaMotta, *Regeneron Dumps RSV Drug after Trial Failure*, Dive Brief, BIOPHARMA DIVE (Aug. 14, 2017).

This Court reversed the PTAB, rejecting its finding on reasonable expectation of success. *Id.* at 1384. Two things, in conjunction, doomed the PTAB's finding: (1) lack of clinical efficacy data and (2) low clinical trial success rates. As to the review article, it contained "no data or other promising information regarding erlotinib's efficacy in treating NSCLC." *Id.* "The lack of erlotinib-NSCLC efficacy data or other indication of success [was] significant because of the highly unpredictable nature of treating NSCLC, which is illustrated by the over 99.5% failure rate of [NSCLC] drugs entering Phase II." *Id.*

This Court then (correctly) doubled down on the same logic as to the Phase II disclosure in OSI's 10-K. It admonished the PTAB's failure to "consider OSI's 10-K statement in light of the 99.5% failure rate of the other 1,630 drugs entering Phase II trials for the treatment of NSCLC." *Id.* at 1385. Critically, this Court explained that "[g]iven this high failure rate, a fact finder could not reasonably find that the 10-K statement combined with [the prior-art patent] would have been sufficient to create a reasonable expectation of success." *Id.*

This line of reasoning is spot on. There is no way to know which clinical trials will succeed. In fact, the better bet is on failure. *See supra*, Part I.A. Only with hindsight can one expect success, but hindsight is strictly verboten. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1073 (Fed. Cir. 2012). Given this, it defies logic to conclude that summary

disclosures of intended clinical trials or their protocols provide a skilled artisan with reasonable grounds to expect success. More likely than not, the clinical trial will fail. As this Court correctly held: "[t]hese references provide no more than hope—and hope that a potentially promising drug will treat a particular cancer is not enough to create a reasonable expectation of success in a highly unpredictable art such as this." *OSI*, 939 F.3d at 1385.

OSI accords with *Novartis Pharmaceuticals Corp. v. West-Ward Pharmaceuticals International, Ltd.*, 923 F.3d 1051 (Fed. Cir. 2019). There, the prior art discussed the Phase I results of a related compound and disclosed that a Phase II clinical trial was underway. This Court affirmed the district court's finding of lack of reasonable expectation of success, which rested in large part on the high failure rate of Phase II trials. *Id.* at 1061.

To be sure, both *OSI* and *West-Ward* involved cancer drugs, for which clinical trial failure rate is particularly high. But the reasoning of these decisions applies with the same force to other types of drugs. Clinical trials have low success rates across the board. Using the mere existence of clinical trials (even at Phase III) or protocol summaries as evidence of reasonable expectation of success, therefore, is the definition of hindsight. Accordingly, patent adjudicators should not rely on summary clinical trial disclosures as support for a reasonable expectation of success in the obviousness inquiry.

II. Inventions challenged by their own, originating clinical trials undermines investment and exacerbates pressures to file early.

A. Patents are threatened by clinical trial disclosures with increased frequency.

Across a variety of proceedings, patents are being challenged with increasing frequency based on the mere existence of clinicals trials or their protocol summaries like ones disclosed on clinicaltrials.gov. These challenges are not limited to the courts. They are now a recurring feature of IPR proceedings[5] and are being raised by patent examiners as grounds to reject patents.[6]

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[5] *See, e.g.*, *Celltrion, Inc. v. Chugai Seiyaku Kabushiki Kaisa*, No. IPR2022-00579, Paper 9 at 9–10 (P.T.A.B. Aug. 31, 2022) (clinicaltrials.gov posting as the primary prior art reference); *Sun Pharm. Indus. Ltd. v. Aurinia Pharm. Inc.*, No. IPR2022-00617, Paper 9 at 11 (P.T.A.B. Jul. 26, 2022) (same); *Miltenyi Biomedicine GmbH v. Trs. of the Univ. of Pa.*, No. IPR2022-00852, Paper 9 at 5 (P.T.A.B. Oct. 11, 2022) (prior art references included clinicaltrials.gov posting); *Pfizer, Inc. v Genentech, Inc.*, No. IPR2017-1727, Paper 9 at 3–5 (P.T.A.B. Jan. 23, 2018) (clinicaltrials.gov used as principal prior art reference); *Mylan Laboratories Ltd. v. Aventis Pharma S.A.*, No. IPR2016-00712, Paper 99 at 29 (P.T.A.B. Sept. 21, 2017) (Board rejected the argument that "disclosure of a protocol for testing a hypothesis without any evidence of efficacy or safety is insufficient to show that the method itself is useful for the claimed patients.").

[6] *See, e.g.*, *Ex parte Nachiappan Chidambaram*, No. 2023-446, App. No. 16/181,221, at 3 (P.T.A.B. May 4, 2023) (examiner rejected patent as obvious because of clinicaltrials.gov disclosure); *Ex parte John Simard*, No. 2020-4851 App. No. 15/800,407, at 8 (P.T.A.B. Mar. 30, 2021) (rejecting patent application because of clinicaltrials.gov posting); *Ex parte Yoram Yovell*, No. 2019-5415, App. No. 14/345,695, at 6 (P.T.A.B. June 1, 2020) (concluding clinicaltrials.gov posting provided reasonable expectation of success); *Ex parte William Forbes, et al.*, No. 2018-3954, App. No. 14/282,888, at 6 (P.T.A.B. Mar. 18, 2019) (rejecting patent because clinicaltrials.gov posting "discloses the dosage regimen required by Appellants' claimed invention").

Any claim that a skilled artisan can have a reasonable expectation of success based on the existence of a clinical trial or its protocol summary reflects a fundamental misunderstanding of clinical trials as well as the legal meaning of "reasonable expectation of success." A recent decision from the District of Delaware, in particular, illustrates this misunderstanding. *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 18-cv-651 (CFC), 2022 WL 17593282 (D. Del. Dec. 13, 2022). In *Vanda*, the district court relied on the disclosure of Vanda's Phase III trial for the patented drug to support finding a reasonable expectation of success. In particular, the district court relied on an expert's statement that:

> If someone is going to be spending the time and money to do a big Phase 3 trial, all that effort, as well as money, then that would say to me, and to a person of ordinary skill in the art, that clearly there was a reasonable expectation that they are going to succeed. Otherwise, I don't think they would have invested the time and money in the Phase 3 trial.

Id. at *16. Not so. Innovator pharmaceutical companies invest billions annually in projects they know will likely fail on the hope that some small percentage will result in a safe and effective drug.[7] Indeed, about two-thirds of the investment in clinical

[7] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, at 1, 13 (Apr. 2021) ("CBO Report") (reporting annual R&D spending at $83 billion in 2019, and noting that "companies initiate drug projects knowing that most of them will not yield a marketable drug.").

trials is lost to failed experiments.[8] While innovator companies make the investment because the ultimate goal of a marketable drug may be worth it, they do not expect success in any given trial. To the contrary, most trials fail.

This Court affirmed the *Vanda* district court, *see Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, No. 23-1247, 2023 WL 3335538 (Fed. Cir. May 10, 2023), but nothing in the nonprecedential opinion prevents this Court from properly curbing the use of protocol summary disclosures in the reasonable expectation of success inquiry following full scrutiny of the issue. For example, although the opinion states that it was not error to use the fact of an ongoing clinical trial to support an obviousness determination, *id*. at *4, the decision did not grapple with the reality of low clinical trial success rates or explain how use of the summary clinical trial disclosures like the ones on clinicaltrials.gov could be squared with this Court's factual approach to reasonable expectation of success. At a minimum, nothing in this Court's *Vanda* decision approved the above-quoted passage from the district court, which fails to grasp (or even consider) the incentives and behaviors of drug researchers like amici.

[8] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, at 15 (Apr. 2021) ("CBO Report") (estimating that $1,065 million is spent on clinical trials per approved new drug, and explaining that "$690 million (of the $1,065 million in average total spending on clinical trials) reflects companies' contemporaneous spending on drugs that failed in clinical trials or were otherwise set aside").

Encouragingly, patent adjudicators are not uniformly accepting clinical trial disclosures as a basis for expectation of success. Some decisions have correctly given them little or no weight, or rejected their use in the reasonable expectation of success analysis. *See, e.g.*, *Janssen Pharms. Inc. v. Teva Pharms. USA, Inc.*, 571 F. Supp. 3d 281, 310–11 (D.N.J. 2021) (court rejected challenge based on disclosure of Janssen's first (ultimately failed) Phase III trial, given the unpredictable nature of clinical trials), *appeal filed*, No. 22-1288 (Fed. Cir. Dec. 14, 2021); *Sanofi v. Lupin Atl. Holdings S.A.*, 282 F. Supp. 3d 818, 841 (D. Del. 2017) (rejecting obviousness challenge that relied on a disclosed clinical trial because trials are "[h]ypotheses not guaranteed to be true"). But the decision below and this Court's recent affirmance of the district court in *Vanda* will serve as a springboard for additional challenges based on clinical trial summaries that lack adequate factual or legal basis.

B. The current trend undermines investment and pressures researchers to file patent applications early.

A mandated disclosure of a clinical trial should not destroy a patent claiming the drug or method being tested. As referenced above, an average of $1.07 billion is invested "in clinical trials per approved new drug (more than twice the amount spent in the preclinical research phase)." CBO Report, *supra* n.7, at 15. Of this amount, $690 million is lost to failed clinical trials. *Id*. This does not even consider the billions that companies sink into pre-clinical R&D. Regeneron alone spent $2.9 billion dollars in R&D in 2021. All of that investment is cannibalized when the

mandated disclosure of the clinical trial is later used to attack a patent arising from that same investment.

In addition to lost investment, the ability to use in obviousness challenges the mere existence of a clinical trial or the summary disclosures on clinicaltrials.gov distorts incentives around the timing of patent applications. It pressures innovator drug companies to file patent applications earlier in the process, before being compelled to disclose their planned clinical trials, and before the invention tested may have been shown to not work in those clinical trials. The inevitable consequence of such earlier filings is an increase in the volume of patents and further strain on the patent system, all of which is bad for innovation and the already overburdened courts, PTAB, and patent examiners.

CONCLUSION

This Court should use this opportunity to eliminate or at least dramatically curb the use of the mere existence of clinical trials or summary clinical trial protocols as a basis for finding a reasonable expectation of success.

Dated: July 27, 2023

Respectfully submitted,

/s/ Irena Royzman
Irena Royzman
Christine Willgoos
KRAMER LEVIN NAFTALIS & FRANKEL LLP
1177 Avenue of the Americas
New York, NY 10036
Telephone: (212) 715-9100

Facsimile: (212) 715-8000
iroyzman@kramerlevin.com

Paul Brzyski
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
2000 K Street NW, 4th Floor
Washington, D.C. 20006
Telephone: (202) 775-4500
Facsimile: (202) 775-4510
pbrzyski@kramerlevin.com

Counsel for Amici Curiae Regeneron Pharmaceuticals, Inc. and Ocular Therapeutix, Inc.

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 29(a)(5) and Federal Circuit Rule 29(b). Exclusive of the items excluded by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2), this brief contains 3,598 words. It has been prepared in proportionally spaced typeface using Microsoft Word for Office 365 in 14-point Times New Roman font. I have relied on the word count feature of this word processing system in preparing this certificate.

Dated: July 27, 2023

/s/ Irena Royzman
Irena Royzman

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This brief was electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

Dated: August 30, 2023

/s/ Irena Royzman
Irena Royzman