No. 2018-1691

United States Court of Appeals for the Federal Circuit

IDENIX PHARMACEUTICALS LLC, UNIVERSITA DEGLI STUDI DI CAGLIARI,

Plaintiffs-Appellants,

v.

GILEAD SCIENCES INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in Case No. 1:14-cv-00846-LPS, Chief Judge Leonard P. Stark

BRIEF OF *AMICUS CURIAE* AMGEN INC. IN SUPPORT OF REHEARING EN BANC

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Dated: January 29, 2020

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Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Idenix Pharmaceuticals LLC **v.** Gilead Sciences Inc.

Case No. 18-1691

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ■ (amicus) ☐ (name of party)

Amgen Inc.

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Amgen Inc.	Amgen Inc.	None.

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:

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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. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

None.

1/29/2020
Date

/s/ Eldora L. Ellison
Signature of counsel

Please Note: All questions must be answered

Eldora L. Ellison
Printed name of counsel

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INTEREST OF AMICUS CURIAE

Amgen is one of the world's leading biotechnology companies, deeply rooted in science and innovation to transform new discoveries and inventions into medicines for patients with serious illnesses. No party, party's counsel, or any person other than the amicus identified herein authored the brief in whole or in part or contributed money that was intended to fund preparing or submitting this brief. *See* Fed. R. App. P. 29(b)(4); 29(a)(4)(E).

ARGUMENT

I. AMGEN ADVOCATES FOR PATENT PROTECTION THAT PROMOTES THE PROGRESS OF SCIENCE

Biologic medicines have revolutionized the treatment of many serious, chronic, and life-threating diseases.[1] Biologics are complex medicines made from living organisms or cells. Examples include vaccines, insulin, hormones, therapeutic proteins, and monoclonal antibodies.[2] These medicines have the ability to dramatically improve the length and quality of life for many patients.[3]

Scientific research and discovery for novel, life-changing medicines is a

---

[1] *See* Amgen Science, https://wwwext.amgen.com/science/; Omudhome Ogbru and Charles Davis, Biologics (Biologic Drug Class), MedicineNet, https://www.medicinenet.com/biologics_biologic_drug_class/article.htm.

[2] *See* Kathlyn Stone, Top 10 Biologic Drugs in the United States, Very Well Health (Dec. 12, 2019), https://www.thebalance.com/top-biologic-drugs-2663233.

[3] *See*, *e.g.*, Nancy Carteron, MD, Phil Mickelson's Story with Psoriatic Arthritis, Healthline (Oct. 30, 2017), https://www.healthline.com/health/phil-mickelson-arthritis#1.

time consuming, expensive, and uncertain endeavor. First, tremendous effort is involved in deciphering the underlying mechanisms of a disease, the potential molecular targets to interdict, and the possible secondary implications of acting on one target over another. Patent protection might be unavailable for much of this foundational work, however, given the doctrine of patentable subject matter.[4] With a fundamental understanding of the pathway or target, the inventor then must assess whether it's possible to create a molecule to activate or inhibit the pathway or target. If the prospects seem promising, to achieve a new medicine, the inventor must generate something that has a structure to precisely bind to the target in its native environment in the body and demonstrate proof-of-principle in laboratory and pre-clinical models. After achieving these goals, methods for repeatable large-scale manufacture and stable formulation of the product must be devised. The product must undergo clinical development and FDA approval: a complex and expensive process with a probability of success of about 10 percent.[5] The average cost of researching and developing one of the few successful medicines is

[4] *See, e.g., Mayo Collaborative Servs. v. Prometheus Labs.*, 566 U.S. 66 (2012).

[5] Thomas et al., Clinical Development Success Rates 2006-2015 (June, 2016), https://www.bio.org/sites/default/files/legacy/bioorg/docs/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

estimated to be $2.6 billion.[6] In the last decade, biopharmaceutical companies "have invested half a trillion dollars" in research and development, "opening the door to entirely new ways to tackle some of the most complex and difficult to treat diseases of our time."[7]

Amgen, and the biotechnology industry in general, must rely on a robust patent system that provides adequate protection for pioneering inventions to ensure that they receive reasonable returns on their investments and appropriate incentives to make future investments in research and development of new medicines. It is therefore critical for innovators like Amgen to obtain patent protection commensurate in scope with their contribution to the advancement of science and medicine.

The pioneering work Amgen performs often warrants patent protection through a genus claim because the inventor has discovered and described how to make and use an entirely new class of therapeutic agents and has shared that invention with the public. In the antibody arts, for example, once the underlying pathways to disease and potential targets have been discovered, and an inventor

[6] The Process Behind New Medicines, Biopharmaceutical Research & Development (2015), http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf

[7] 2019 Biopharmaceutical Industry Profile, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/2019-Profile-Booklet_FINAL_NoBleeds.pdf.

has created and disclosed antibodies capable of precisely binding to a particular target to treat disease, it is usually routine and conventional to make additional antibodies that bind the same target to treat the same disease. Without the protection of genus claims, second-comers could easily appropriate the value of the invention and the investment of the innovator by piggy-backing off the blueprint the pioneer provides through its patent publication and do so with high confidence of success at a much lower cost and no contribution to the advancement of science.

To ensure that the full potential and rapid pace of biological advancements in science and medicine are realized, innovators must have confidence that they will receive a breadth of patent protection that is meaningful in the marketplace; in this example, protection on the entire genus of antibodies that act on the defined target to successfully achieve a therapeutic benefit. Otherwise, innovators will not be able to justify the enormous and long-term investments necessary to decipher the enigmatic nature of human disease and create, develop, and bring to market innovative medicines.

II. THE PANEL OPINION IN *IDENIX* HAS THE POTENTIAL TO NEGATE GENUS CLAIMS, HARMING BOTH INNOVATORS AND THE PUBLIC

A. Litigants Are Already Pressing an Interpretation of *Idenix* That Would Require Unreasonable Numbers of Examples for Genus Claims

The quid pro quo of the Patent Act requires "disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired." *Universal Oil Prod. v. Globe Oil & Ref.*, 322 U.S. 471, 484 (1944). Litigants are already pressing an interpretation of *Idenix* as focusing on how many working examples the specification must disclose or how much experimentation would be required to make "each" and every embodiment of a genus invention. Op. at 16-17. Such a reading would clearly be in tension with precedent.

This Court has previously held that an enabling disclosure that allows ordinary artisans "to practice the full scope of the claimed invention" does ***not*** require the patent to "describe how to make and use every possible variant" of the invention. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). That conforms with Supreme Court precedent holding that, to be enabling, the specification must only "guide those skilled in the art to" the invention's "successful application." *Minerals Separation, Ltd. v. Hyde,* 242 U.S. 261, 270-71 (1916).

In *Minerals Separation*, the invention was applicable to "a large class of substances," and the "composition of ores" to which it applied "varies infinitely." *Id.* Because the patent did not set forth the "precise" treatment for those variations, the precise formulations for the "infinit[e]" compositions were left to skilled practitioners in the field. *Id.* But the Court held that the patent was enabled nonetheless. In *In re Angstadt*, this Court endorsed *Minerals Separation* as "aptly" rejecting the notion that enablement requires more than "guid[ing] those skilled in the art" to successful application of the invention. 537 F.2d 498, 503 (C.C.P.A. 1976) (quoting *Minerals Separation*, 242 U.S. at 271).

Broad statements in the *Idenix* opinion could be read to require a patent holder to exemplify or demonstrate *each species* within its genus claim to meet section 112:

> [E]ach of these [many thousands of] compounds would need to be screened in order to know whether or not they are effective against HCV…
>
> [N]otwithstanding the fact that screening an individual compound for effectiveness was considered 'routine,' we concluded as a matter of law in *Wyeth* that the claim was not enabled because there were 'at least tens of thousands of candidate compounds' and 'it would be necessary to first synthesize and screen each candidate compound…'

Op. at 21-22. Indeed, defendants are already arguing that *Idenix* prohibits any claim scope broader than the specific examples disclosed as a matter of law. *See Juno Therapeutics Inc., v. Kite Pharma Inc.*, No. 2:17-cv-7639-SJO-KS21, Dkt

659 at 21 (C.D. Cal. Jan 21, 2020) ("Where, as here, a POSITA must screen a large number of compounds to find the active species, the full scope of the claims is not enabled as a matter of law."); *id.* at 24 ("Even if the synthesis and testing was so easy that a 'dishwasher' could do it . . . the mere fact that those steps are required . . . means that the full claim scope is not enabled"). *Idenix* and other recent cases are therefore "significant" insofar as they are construed to "reduce the analysis down to . . . *how many working examples have been provided*, how much experimentation is necessary, how broad the claims are."[8] Such a trend in enablement would narrow the available scope of patent protection for breakthrough innovations to the point where it fails to provide the marketplace protections necessary to support the large investments associated with such inventions and the early public disclosure that defines the patent bargain.

B. *Requiring Endless and Excessive Number of Examples Threatens Innovation for Patients*

It is not only an enabling disclosure, but a prompt one, that defines the public benefit of the patent system. *See Eldred v. Ashcroft*, 537 U.S. 186 (2003) ("*[I]mmediate* disclosure is not the objective of, but is exacted from, the patentee. It is the price paid for the exclusivity secured.") (emphasis added). Prompt disclosure and publication of patent applications is a catalyst to further innovation.

[8] *See* Matthew Bultman, Drug Cos. May Rethink Patent Strategy After Fed. Circ. Ruling, Law 360 (Nov. 13, 2019) https://www.law360.com/articles/1219542 (emphasis added).

Some competitors may seek to develop a different modality to interdict a validated target or pathway disclosed in a patent publication, to design around that intellectual property.[9] Others may seek to develop improvements on the innovator's molecules and obtain their own patents, thus leveraging the knowledge gained from the innovator's disclosure and promoting the progress of science.[10] Impediments that delay patent filings and public disclosure of inventions must be critically scrutinized because they directly undermine these public benefits the patent bargain seeks to achieve.

Suggesting a requirement of greater numbers of working examples for a broad genus that encompasses "thousands and thousands" of species—which may often be the case in biological and chemical genus claims—could pressure innovators to withhold their disclosures until they have amassed an excessive number of working examples. "To require such a complete disclosure," the *Angstadt* court explained, would "necessitate a patent application [] with 'thousands' of examples . . . . [S]uch a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual

[9] *See* Wheeler, George F., *Creative Claim Drafting*, 3 J. Marshall Rev. Intell. Prop. L. 34, 43 (2003).

[10] *See* Scotchmer, Suzanne, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. Economic Perspectives 29 (Winter 1991).

experiments." 537 F.2d at 503. Such a requirement would also be disproportionately biased against not-for-profit entities with fewer resources.

Moreover, the rote disclosure of additional embodiments does not promote the progress of science; it is the innovator's disclosure of the groundbreaking research and discovery of a new medicine that does. When a disclosure contains sufficient instruction—whether through working examples or otherwise—for the ordinary artisan to make additional claimed embodiments, it should counsel in favor of enablement. Even where rote repetition of routine techniques is required to catalog each embodiment, that is not undue experimentation. It may simply indicate that the full scope of the genus contains more compounds than any skilled artisan would need or desire to create. *See In re Wands*, 858 F.2d 731, 740 (Fed. Cir. 1988) (finding that undue experimentation does not turn on the number of embodiments never screened).

Any delay in patent filings in an attempt to compile an exemplification of each embodiment to support a genus claim, delays the prompt disclosure of the invention that sits at the heart of the public benefit of the patent bargain.[11] Resources that the entire industry will now feel forced to devote to synthesizing and screening such cumulative examples will be resources unavailable to discovering the next breakthrough medicine. And without the scope of protection

[11] *See* Bultman, *supra*, at note 8.

afforded by genus claims, innovators will have less incentive to take the risk on making the substantial investment in research and development necessary to invent and bring to market new medicines. Amgen thus shares industry-wide concern that if this pendulum swings too far, as the *Idenix* decision portends, it will have a crippling effect on the pace and breadth of scientific advancement in medicine in the United States.

III. SECTION 112 REQUIRES A FLEXIBLE AND FACT-BASED INQUIRY

Section 112 precedent should not overlook a key element—flexibility—especially as applied to biotechnology inventions. Insofar as *Idenix* is read to posit a rigid legal inquiry into the time or burden required to make "each" potential embodiment, such a reading fails to square with precedent.

The Supreme Court and other circuit courts have recognized that enablement is a context-specific, "question of fact" to be decided by a jury. *Battin v. Taggert*, 58 U.S. 74, 85 (1854); *Wood v. Underhill*, 46 U.S. 1, 5-6 (1847); *Gasifier Mfg. v. General Motors*, 138 F.2d 197, 198-99 (8th Cir. 1943); *Schumacher v. Buttonlath Mfg.*, 292 F. 522, 532 (9th Cir. 1920). Similarly, this Court has warned that "each case involving the issue of written description, 'must be decided on its own facts.'" *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991)). Despite this history, modern

Federal Circuit cases like *Idenix* treat the enablement question as primarily a question of law. *See* Op. at 4.

Section 112 had traditionally been applied in a flexible, context-specific manner, for both written description and enablement. In *Capon v. Eshhar*, for example, the court articulated a multi-factor inquiry, recognizing that "[t]he 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge." 418 F.3d 1349, 1358–59 (Fed. Cir. 2005).

To a great extent, the *Capon* test tracks this Court's test in the enablement context. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). In comparing the *Capon* and *Wands* factors, Judge Linn observed that the *Capon* factors for written description "mirror the *Wands* factors for enablement." *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1368 (Fed. Cir. 2010) (Linn, J., dissenting). Indeed, these factors *should* mirror each other when applied correctly.

The *Capon* factors effectively collapsed both inquiries into a single test as the statutory text requires. There is not a single, dispositive factor under *Capon's* test; rather, weight is accorded to each relevant factor depending on the circumstances of each case. *See id*. The standard of Section 112, whether called "written description" or "enablement," should be applied as it was in *Capon* and *Wands*: in a flexible, context-specific manner, with consideration paid to all

relevant factors in each case. Indeed, in *Wands*, the quantity of experimentation and number of working examples were just two of *eight* factors the Court used to determine if the patent met the disclosure requirements of Section 112(a). Unduly rigid application, or giving undue weight to just one or two factors to assess enablement, is inconsistent with the flexible and context-specific approach this Court and the Supreme Court have long applied. *See Wands*, 858 F.2d at 737.

Like the rigid tests the Supreme Court rejected in *KSR* and *Bilski*, *Idenix*'s examination of the number of working examples and quantity of experimentation may have "captured a helpful insight," *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), or provided "a useful and important clue," *Bilski v. Kappos*, 561 U.S. 593, 604 (2010). But "[h]elpful insights . . . need not become rigid and mandatory formulas." *KSR*, 550 U.S. at 419. Section 112 should not be converted from a practical inquiry about what the patent teaches into a pointless numbers game.

CONCLUSION

The Court should grant the petition for rehearing *en banc*.

Respectfully submitted,

Dated: January 29, 2020

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