

No. 21-757

**In the Supreme Court of the United
States**

AMGEN INC., ET AL.

Petitioners,

v.

SANOFI, ET AL.,

Respondents.

*ON A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT*

**BRIEF OF THE FYNDER GROUP, INC. d/b/a
NATURE'S FYND AS *AMICUS CURIAE* IN
SUPPORT OF PETITIONERS**

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INTEREST OF *AMICUS CURIAE*¹

Amicus curiae The Fynder Group, Inc. d/b/a Nature's Fynd produces foods from a high-protein fungi-based biomass material grown by a novel fermentation process. Fungi are neither plant nor animal, but rather constitute a separate taxonomic kingdom. Filamentous fungi secrete an array of enzymes to decompose complex biopolymers from organic matter in their environment and consume the decayed matter for nourishment. The thread-like structures that many fungi produce called hyphae together form a mass known as mycelium. Mushrooms are the fruit produced by fungi. In nature, mycelium grows as a dispersed network underground or in organic matter, such as fallen trees. Nature's Fynd has developed a proprietary method to rapidly and efficiently grow mycelium on a variety of diverse feedstocks, from simple liquid media to agricultural waste streams.

Stated with less technical vocabulary, Nature's Fynd is pioneering a fermentation process that cultivates mycelium as a unique high-protein "biomat" that can be used in a wide range of foods. Specifically, the process takes mycelium that, in nature, looks like thin wispy roots (sometimes barely visible to the naked eye) as shown in the following image:

¹ Pursuant to Supreme Court Rule 37.3, Petitioners and Respondents provided written consent to the filing of this brief through their respective letters of blanket consent filed with the Court. Pursuant to Supreme Court Rule 37.6, *Amicus curiae* states that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amicus curiae*, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief.



and grows the mycelium in a manner that forms a unique high-protein biomat (shown below):



which can then be used to make various food products, such as dairy-free cream cheese and meatless breakfast patties:



Nature's Fynd's proprietary protein, known as Fy™, can also be used in exquisite dishes, including those served at Michelin-starred restaurants. For instance, a warm Yukon Gold Potato-Olive-Fy Parfait with a Sauce Vierge and an Apricot Sorbet Chamomile Ice Cream made with Fy cream cheese have both been on the tasting menu at the 3-Michelin-starred Le Bernardin in New York City.²



Nature's Fynd's technological advances are possible only through the commitment of scientists and researchers who have the vision to see what can be. The work of those scientists and researchers is made viable by the U.S. patent system, which encourages investors to support the continued innovation. Without the incentive of an exclusive right, as set forth in the U.S. Constitution, investors are far less likely to support disruptive

² Kate Krader, *Fungus Born of Yellowstone Hot Spring Makes Menu at Le Bernardin*, Bloomberg.com (July 19, 2022), <https://www.bloomberg.com/news/articles/2022-07-19/natures-fynd-fy-a-fungus-from-a-hot-spring-is-now-served-at-le-bernardin>.

sustainable technologies, such as Nature's Fynd's novel fermentation process.

Until the present case, Nature's Fynd has not filed an amicus brief in any legal proceeding, but it is an active user of the U.S. patent system. Nature's Fynd has a strong interest in ensuring that this case leads to a result that continues to protect pioneering innovators, including those developing critical sustainable technologies. A robust and reliable patent system that protects pioneering inventions is critical to ensuring that sustainable technologies are developed and reach wide commercialization and full market potential.

SUMMARY OF THE ARGUMENT

Over 230 years ago, Congress created the U.S. patent system as a *quid pro quo* system in which innovators were encouraged to disclose their inventions and insight in exchange for a time-limited exclusive right to their inventions. Through the decades, the patent system has worked well, encouraging groundbreaking innovations that have opened entire fields of advances. Examples include Alexander Graham Bell's telephone, Samuel Morse's telegraph, Robert Noyce's monolithic integrated circuit chip, and Herbert Boyer and Stanley Cohen's recombinant-DNA technology. Many others exist, of course.

These and similar pioneering inventions fundamentally advanced human society. The inventions earned patent protection that rewarded the inventors (and their supporters) with the exclusive right, as set forth in the Constitution. The inventions also expanded what was considered possible, by making known what was previously unknown. The disclosure of an invention increases the number and types of inventions that will be later developed, either by the same innovator or by follow-on inventors. *Cf. Westinghouse v. Boyden Power Brake*

Co., 170 U.S. 537, 574 (1898) (Shiras, J., dissenting) (“A pioneer patent does not shut, but opens the door for subsequent invention.”).

Innovations in sustainability are the next frontier for pioneering technologies, and they are equally in need of robust patent protection. With the global population reaching eight billion people this year, society needs fundamentally new approaches to providing food, energy, healthcare, and a healthy environment for the world’s growing population. Food production, energy generation, electrification of transportation, capture of carbon emissions from industrial processes and the environment, and the recycling of limited resources all fall within the ambit of sustainability innovation. These technologies will allow billions of people to live within the means of limited global resources and blunt the worst effects of man-made environmental impacts.

Like all pioneering inventions, innovation in the sustainability space needs the support of robust patent protection that will enable those innovators to fully develop their inventions and benefit the public. But the Federal Circuit’s increasingly restrictive approach to the enablement requirement is jeopardizing that necessary patent protection.

The enablement requirement of 35 U.S.C. § 112 must be interpreted and applied in a manner that accomplishes that objective by striking the right balance between rewarding inventors and requiring a written description that enables a skilled person to make and use the invention. The enablement and related requirements form the basis of the *quid pro quo* that is the very essence of the grant of the patent right.

In recent years, however, the Federal Circuit has interpreted the enablement requirement in an unduly burdensome manner that focuses on the “time and effort”

to “reach the full scope of claimed embodiments,” without having to expend “substantial time and effort.” Pet. App. 14a. That standard goes beyond the statute and is inconsistent with this Court’s precedent, as well as earlier Federal Circuit precedent.

The more burdensome standard applied by the Federal Circuit will have detrimental effects on pioneering innovators. They will risk losing patent protection for their inventions, even though they broadly taught the public how to make and use their innovation. Under this standard, instead of focusing on creating more groundbreaking innovation, innovators will have to devote substantial time and resources to produce routine examples premised on their invention—merely to satisfy the Federal Circuit’s concern about the “time and effort” needed to “reach the full scope of the claimed embodiments.” This will impede further innovation and will delay the disclosure of key technological improvements that are critically needed in the sustainability space.

Just as problematically, the risk associated with a higher enablement burden will likely convince many pioneering innovators to maintain their innovation (or key aspects of it) as trade secrets. Trade secret protection has a proper role in enabling innovators to compete, but trade secrets frequently impede innovation because they do not fulfill the patent system’s *quid pro quo*, which encourages dissemination of novel ideas.

ARGUMENT

I. Innovation and Patent Protection are Key to Sustainability

Innovation is the key to the continued advancement of society, and it will lead the way to the development and implementation of sustainable technologies. With the

global population at eight billion people and growing, new sustainable technologies are needed now more than ever.

A. Pioneering Innovation Lies at the Heart of Sustainable Technologies

Population growth, changing climate, economic disruption, and conflict in the world are increasing the need to develop creative solutions for feeding the global population. Some studies estimate that, in 2022, almost 811 million people globally remain hungry at the end of each day, with the number facing acute food insecurity at 276 million.³ The global population is predicted to reach ten billion by 2050, further exacerbating stresses on food production systems. New food sources and new methods for producing sustainable food supplies are needed to address these challenges.

New sustainable food-production technologies are one element in helping to achieve a broader panoply of technological solutions needed for the growing global population. For instance, the Speed & Scale Plan identifies ten targets for global achievement of net-zero emissions by 2050.⁴ Meeting these targets will be possible only with innovation across a spectrum of sustainable technologies, including: electrifying transportation; drastically reducing carbon emissions from electricity generation, agriculture, and manufacturing; protecting nature from deforestation and other impacts; and actively removing carbon dioxide from the atmosphere by carbon capture technologies. In agriculture alone, the world will need to reduce, by 2050, carbon emissions to two gigatons—from the current nine gigatons.

³ *WFP Annual Review 2021*, World Food Programme (June 20, 2022), <https://www.wfp.org/publications/wfp-annual-review-2021> (last visited January 3, 2023).

⁴ Speed & Scale is a global initiative to move leaders to act on the climate crisis. *See* <https://speedandscale.com/>.

As the need for sustainability efforts increases, efforts to mandate changes will become increasingly contentious, if technological solutions are not achieved. This Court has first-hand experience with litigation over environmental issues, including climate-change issues. *See generally West Virginia v. EPA*, 142 S. Ct. 2587 (2022); *Massachusetts v. EPA*, 549 U.S. 497 (2007). Those disputes are certain to increase in number and magnitude if technological solutions are not identified and developed.

Of course, the development of technologies to the point of effecting meaningful change entails great risk of time and money. Undertaking that risk can be justified by entrepreneurs and investors only if there is a reasonable expectation of a recoupment of the investment, as envisioned by the patent system. In other words, the incentive-based system devised by the Founders in the Constitution some 235 years ago is the same system that will continue to encourage entrepreneurs and investors to devote their innovative efforts to creating technologies that will provide answers to global climate-change challenges.

B. Nature's Fynd is a Pioneering Innovator of Sustainable Protein Sources

Amicus Nature's Fynd is a key example of a company developing and commercializing a sustainable technology that will revolutionize the food industry. Nature's Fynd and similar innovative companies are the heart of potential innovation that will offer effective climate-change solutions.

Nature's Fynd was founded in 2012, and, like many sustainability-based companies, its technology did not develop in a linear path. The technology created by Nature's Fynd is disruptive and foundational. The company is developing technology that is changing the way we eat and enables the efficient recycling of

agricultural streams for food production in ways that are less burdensome on the environment.

In 2009, co-founder and CSO Emeritus Dr. Mark Kozubal was conducting a NASA-funded study of life in extreme environments in Yellowstone National Park. During that work, he discovered a novel acidophilic fungal organism *Fusarium strain flavolapis* (originally named “MK7”) in the geothermal springs of the Yellowstone Caldera (sometimes called the Supervolcano). Kozubal also discovered that the novel organism had a high protein content. The work initially focused on using the novel organism to manufacture biodiesel, but after several years of research and development, the fungi-based protein was identified as having high potential for use as a new-to-the-world food.

From that work emerged Nature’s Fynd’s proprietary fermentation process that grows the mycelium of fungi on a liquid media. The mycelium, when grown this way in trays, develop in an interwoven fashion to form a fibrous mat-like structure that is similar in texture to muscle fiber. Think of a thin slice of a chicken breast but made of fungi that is highly nutritious and has protein containing all essential amino acids.

This cohesive protein biomass grows in just several days and is the raw nutritional material for Nature’s Fynd’s food products. The cohesive protein biomass is sold under the trademark Fy™.

Fy is a high-protein food ingredient that is about 50% protein and is high in fiber. In contrast to some plant-based materials, Fy is a complete protein supplying all amino acids, including the nine essential amino acids required in the human diet. In other words, unlike some vegan sources of protein, Fy can completely replace meat as a protein source for dietary purposes.

Nature's Fynd's technology leverages the fundamental structure of mycelium and its ability to grow by fermentation in scalable industrial processes. Nature's Fynd's biomanufacturing process can grow *Fusarium strain flavolapis* and a wide variety of other filamentous fungi, without the need for genetic modification. Nature's Fynd's process can be successfully applied to a diversity of naturally occurring filamentous fungi because of the chemical and physical nature of mycelium and how it grows.

Producing Fy does not require fertilizers, pesticides, antibiotics, or hormones—all of which are necessary in current, large-scale plant and animal food production. Fy production, in contrast, does not negatively impact the soil. Fy production at scale emits about 94% fewer greenhouse gases and uses 99% less land and 99% less water than beef production—all with none of the methane emissions produced by cattle. The Fy production process, when grown at scale, can produce more than eight times Fy per acre than chicken and more than ten times Fy per acre than pork. Because Fy is grown indoors, it can be produced in cities and suburbs closer to its consumption sites, thereby lessening transportation-related fuel usage and related costs.

Fy is a versatile food material, and its fibrous texture can simulate the texture of meat when used in food products. One of Nature's Fynd's first products to market is a meatless breakfast patty, introduced in 2021. Fy can also be readily blended with water to form a milk-like product that can be used as an ingredient in a variety of non-dairy-based foods, such as cheese, yogurt, and ice cream. For example, Nature's Fynd's other first product to market is a non-dairy cream cheese. These products are now available in over 550 stores nationwide. The Fy biomass can also be made into a flour-type ingredient and used to make grain-based products, such as pastas and

bread. All these products offer a highly nutritious alternative to their traditional meat and dairy analogs.

Nature's Fynd's sustainable technologies are having positive impacts beyond Earth. In July 2022, Fy was produced in a bioreactor on the International Space Station and returned to Earth, thus successfully demonstrating biomanufacturing of fungi-based biomass in low-gravity environments. The photograph below shows U.S. astronaut Dr. Jessica Watkins with a Fy bioreactor on the International Space Station in July 2022. The attractive attributes of Fy as a food product on Earth make it a highly promising technology for use in space. Minimal water requirements and the ability to grow in closed-loop systems without the need for sunlight make Fy an exceptionally suitable solution for space missions.



Nature's Fynd is continuing its research and development on fungi-based biomass technologies. It hopes to produce other solutions for the sustainability challenges facing an ever-growing population. To meet these needs, Nature's Fynd is working with the Bill and Melinda Gates Foundation to sustainably adapt its technologies for use in low- and middle-income countries to produce high-protein food materials. These technologies can be used as a platform for food production, anywhere in the world and deployable in disaster-relief situations because edible nutritious food can be grown in a matter of days.

II. Broad, Reliable Patent Protection is Consistent with the Constitution's Objective of Promoting the Useful Arts

The objective of the patent laws, as authorized by the Constitution's Patent Clause, is to promote the progress of "useful arts," *i.e.*, technological innovation. To do so, the enablement requirement of 35 U.S.C. § 112 must be interpreted and applied in a manner that accomplishes that objective by striking the proper balance between rewarding inventors and requiring a written description that enables a skilled person to make and use the invention. An unduly burdensome interpretation of the enablement requirement will harm innovation by imposing undue costs on innovators that do not benefit the public and that disincentivize investment of time and money by innovators who disclose the details of their invention, as part of the *quid pro quo*. Another consideration is that broad patent protection for pioneering inventions encourages further innovation and accelerates follow-on research and development. Reliable patent protection for pioneering innovators in the sustainability space will encourage others to devote their limited resources to solving the toughest sustainability problems. Without a reliable and reasonable

interpretation of the enablement requirement, innovators (including those in the sustainability space) will either commit their resources to lower-risk, lower-return, and less ambitious technology development or resort to trade secrets to protect their intellectual property—an outcome that will slow the dissemination of critical information and delay the development and adoption of crucial advances necessary to achieve global sustainability targets.

A. Broad Patent Protection and a Reasonable Application of the Enablement Requirement Incentivize and Reward Technological Pioneers for Their Creative Efforts

The Constitution provides Congress with the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Art. I, § 8 cl. 8. This provision, which includes the Patent Clause, is one of the most important elements of the original Constitution, and the Founder’s vision, as embodied by Patent Clause, has led to one of the most innovative nations ever to exist.

At the Nation’s outset, George Washington addressed Congress in January 1790 and, excited by the expected societal benefit, urged Congress to pass legislation to put into effect the Patent Clause. President Washington told Congress that “there is nothing which can better deserve [Congress’s] patronage than the promotion of Science and Literature.” President George Washington, First Annual Address to Congress (Jan. 8, 1790).⁵ Within three months of President Washington’s address, Congress established a system to protect

⁵ See Transcript, *January 8, 1790: First Annual Message to Congress Transcript*, University of Virginia, Miller Center, <https://millercenter.org/the-presidency/presidential-speeches/january-8-1790-first-annual-message-congress>.

inventors' rights in their inventions. *See* Act of April 10, 1790, 1 Stat. 109 (1790).

From the beginning, the Patent Act included an enablement requirement. *See id.* (requiring that a patent “specification shall be so particular . . . as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture . . . to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term”). Similar to the first Patent Act, the current statute commands that a patent must “contain a written description of the invention” in “such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” 35 U.S.C. § 112(a).

The enablement and related statutory requirements form the basis of the *quid pro quo* that is the very essence of the grant of the patent right. *See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (“The disclosure required by the Patent Act is ‘the *quid pro quo* of the right to exclude.’” (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974))). The enablement requirement ensures that, once the patentee’s exclusivity has expired, the public may freely practice the invention and reap the full benefits of that advancement. *See Universal Oil Co. v. Globe Co.*, 322 U.S. 471, 484 (1944).

Over the years, this Court has consistently applied the enablement requirement in a manner that does not unduly restrict an innovator’s rights and that is consistent with the *quid pro quo* that advances the Patent Clause’s objectives. The Court has explained, for example, that “a patent for such a discovery is not to be confined to the mere means he improvised to prove the reality of his

conception.” *The Telephone Cases*, 126 U.S. 1, 539 (1888). Expanding on that point, the Court detailed how “[i]t is enough if [the patentee] describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation.” *Id.* at 536.

The purpose of the enablement requirement is not to limit an inventor to the specific embodiments disclosed in a patent but to ensure that the disclosure is commensurate with the granted exclusive right. On numerous occasions, the Court has recognized this principle. Specifically, the Court detailed that “the principle of the invention is a unit, and invariably the modes of its embodiment in a concrete invention may be numerous and in appearance very different from each other.” *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419–20 (1908) (quoting 2 William C. Robinson, *The Law of Patents for Useful Inventions* § 485 (Boston, Little, Brown & Co. 1890)).

Unfortunately, the trend in Federal Circuit caselaw has led to an unduly burdensome interpretation of the enablement requirement. In numerous cases, the court of appeals has placed an undue focus on the supposed number of embodiments covered by the claim at issue. *See, e.g., Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1162 (Fed. Cir. 2019), *cert. denied*, 141 S. Ct. 1234 (2021).

In the decision at issue, the Federal Circuit unduly focused on “time and effort” to “reach the full scope of claimed embodiments” without having to expend “substantial time and effort.” Pet. App. 14a. That standard goes beyond the statute and “raises the bar,” as the Federal Circuit noted, by imposing “high hurdles in fulfilling the enablement requirement.” *Id.* at 12a–13a.

Contrast that approach to this Court's interpretation of the enablement requirement in *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261 (1916). There, the Court addressed the validity of a patent directed to a process of concentrating powdered ores containing various "metal and metallic compounds." *Id.* at 264. This Court held that the claims at issue "satisf[y] the law" even though "the process is one for dealing with a large class of substances and the range of treatment within the terms of the claims." *Id.* at 271. "[T]he composition of ores varies infinitely," the Court recognized, "each one presenting its special problem, and it is obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case." *Id.*

The Court's reasonable approach in *Minerals Separation* was reflected in the Federal Circuit's older case law, where a patent's guidance combined with the knowledge of those skilled in the art would enable the claimed invention, without undue experimentation. *See, e.g., Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). Nor was there a need to include information that was well known in the art. *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1457 (Fed. Cir. 1984) ("[T]he specification need not disclose what is well known in the art." (citing *In re Myers*, 410 F.2d 420, 424 (C.C.P.A. 1969))). It was also long recognized that a broad genus claim could include some embodiments that were not operative; one of skill in the art could apply some experimentation, using the patent's written description, to determine which embodiments worked. *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening.").

Along similar lines, the Federal Circuit's predecessor—the Court of Customs and Patent

Appeals—rejected the idea that, even in unpredictable technologies, a patent application needed to provide complete disclosure of every species covered by a claim because “[t]o require such a complete disclosure would apparently necessitate a patent application or applications with ‘thousands’ of examples or the disclosure of ‘thousands’ of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides.” *In re Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976). “More importantly,” as the appeals court recognized, “such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments.” *Id.* That rejected, unreasonable requirement would “discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed.” *Id.*

B. Broad Patent Protection Encourages Follow-On Innovators to Invent

Another consideration is the reality that broad patent protection for pioneering inventions both encourages further innovation and accelerates the development of follow-on innovation. Too often, the critique about a broad pioneering patent is that it will hinder further development or will harm competition. That view, quite simply, is incorrect, and that view perpetuates a mistaken understanding of the innovation cycle and the role of the disclosure incentive of the patent system.

In rapidly developing disruptive technologies such as those being driven by the need to address climate change, the disclosure through the patent application publication process allows industry participants to learn of the innovations as early as eighteen months after a patent application is filed—when the application is published,

often long before a patent is even issued. *See* 35 U.S.C. § 122(b). This public access drives innovation of new technology as others try to improve upon the published technology or “invent around” others’ technologies. This cycle of innovation is the intended benefit of the patent system and contrasts with the alternative of companies maintaining technology as trade secrets.

In many industries, the timeline to commercialize products—where they can be reverse engineered by competitors or those unwilling to invent—is longer than the eighteen-month patent publication period, and many innovations are not susceptible to being reverse engineered and thus remain secret indefinitely. Broad patent rights to inventors that are supported by the enablement standard proposed by Petitioner Amgen avoid biasing the technology protection system too far in the direction of trade secrets and stifling the cycle of public patent disclosure leading to further innovation.

The Cohen-Boyer patents⁶ on recombinant DNA technology exemplify a pioneering foundational technology being protected by broad patent claims that spurred society-changing innovations. The Cohen-Boyer patents broadly claimed methods of genetically engineering living cells, as well as claiming compositions of matter of engineered cells, *e.g.*, bacteria transformed with DNA from another organism to produce a protein encoded by the foreign DNA. This foundational technology enabled the efficient production of a human protein in bacteria in large enough quantities that the protein could be used therapeutically. The Cohen-Boyer patent claims were broad genus claims, not limited to specific microorganisms or specific genes being engineered into microorganisms.

⁶ U.S. Patent No. 4,237,224 (Dec. 2, 1980); U.S. Patent No. 4,468,464 (Aug. 28, 1984); U.S. Patent No. 4,740,470 (Apr. 26, 1988).

It would have been impossible for Drs. Cohen and Boyer and their team of scientists to satisfy the Federal Circuit's current "full scope" test by running thousands of experiments with all cell types and genes for all types of proteins that could be produced with their technique.⁷ Nonetheless, the Cohen-Boyer patents launched the modern biotechnology industry. It has been reported that the patents were licensed to over 450 companies, leading to over 2,400 commercialized products developed from the patented technology, including drugs for the treatment of heart disease, anemia, cancer, HIV-AIDS, and diabetes. Commercial sales of recombinant DNA products over the life of the patents exceeded \$35 billion.⁸

For many years, the Federal Circuit and its predecessor court applied the enablement requirement in a manner consistent with the statute. For instance, in *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986), the appeals court considered a challenge to patents directed to an immunometric assay using monoclonal antibodies having an affinity for the antigenic substance of at least about 10⁸ liters per mole. *Id.* at 1370. The court, in an opinion written by Judge Rich, rejected the infringer's enablement challenge as "utterly baseless." *Id.* at 1384. The court explained that enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly excessive." *Id.*

Other decisions, including many in the biotechnology field, conform to the correct application of the statute.

⁷ See *Bertram Rowland and the Cohen/Boyer Cloning Patent*, GW Law, <https://www.law.gwu.edu/bertram-rowland-and-cohenboyer-cloning-patent> (last accessed Dec. 28, 2022).

⁸ Rajendra K. Bera, *The Story of the Cohen-Boyer Patents*, 96 *Current Sci.*, 760, 760 (2009).

See, e.g., PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (“The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation ‘must not be unduly extensive.’” (quoting *Atlas Powder*, 750 F.2d at 1576)); *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988) (“A specification may, within the meaning of 35 U.S.C. § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.”); *In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971) (reversing a rejection that was based on “nothing more than a concern over the breadth” of the claim); *In re Robins*, 429 F.2d 452, 456–57 (C.C.P.A. 1970) (“[R]epresentative samples are not required by the statute and are not an end in themselves.”); *In re Borkowski*, 422 F.2d 904, 908 (C.C.P.A. 1970) (explaining that “a specification need not contain a working example” and reversing enablement rejection of claims including broad limitation of “hydrocarbon”).

Consideration of these prior decisions highlights two flaws in the Federal Circuit’s current interpretation and application of the enablement requirement. *First*, the Federal Circuit’s enablement standard punishes pioneering innovators who first identify and share their breakthrough technologies which, by their nature, are often broad in scope. This punishment, of course, provides no corresponding benefit to the public. For instance, the Federal Circuit’s analysis in its present case focused on the “quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the full scope of the claim,” concluding that the Amgen claims were not enabled because “‘substantial time and effort’ would be required to reach the full scope of claimed embodiments.” *See* Pet. App. 14a. Moreover, a follow-on

innovator would rarely need or want to make every single embodiment within the scope of a broad claim; the time and effort needed to accomplish this laborious task are therefore not relevant to assessing whether a patent teaches others how to practice a claimed invention. The appeals court also “raise[d] the bar” by using § 112 to invalidate a patent simply because “substantial time and effort” might be required to develop further embodiments within the claimed genus. *See id.*

Since breakthrough inventions are fundamentally broad, the Federal Circuit’s current “full scope” doctrine will force innovators to spend significant time and money on filling patent applications with as many examples within a genus as possible—most of which will be routine examples in view of the patent specification’s guidance. The resources required to produce routine examples will be diverted from more productive work that would further innovation and offer new advances to the public.

Innovators frequently make discoveries that create and open many new lines for future development. Those who first discover rarely can perform every experiment that will follow from the breakthrough innovation. Imposing a standard that forces innovators to spend time generating rote data—in excess of that needed to teach skilled persons to practice claimed inventions—is counter to the intended goal of the patent system to encourage the early dissemination of that innovation

Second, the Federal Circuit’s approach fails to recognize that the inventor’s own disclosure will inevitably increase the storehouse of knowledge leading to further innovation. Consider again the pioneering cases noted above, such as the Cohen-Boyer patents. At the time of the invention, recombinant DNA technology was unknown. But the disclosure of the invention led to countless innovations. That technology became the

foundation of the biotechnology industry, which created some of the most significant advances in the history of human health care, such as the recombinant production of biopharmaceuticals, *e.g.*, human insulin, as well as gene therapy techniques to treat genetic diseases. Recombinant DNA technology also led to breakthroughs in agricultural production, chemical manufacturing, and the food and beverage industry. The subsequent innovation and development of Cohen-Boyer's pioneering recombinant DNA technology is precisely what is intended by the patent system. But further experimentation and further knowledge-generation do not mean that the original patents were not enabled. To the contrary, the follow-on explosion of biotechnology-based innovation since the first Cohen-Boyer patent issued in 1980 confirmed that the Cohen-Boyer patents were a springboard to an entire industry, as that disclosure taught those skilled in the art how to develop further embodiments within the scope of their pioneering patents.⁹

Some mistakenly criticize when multiple patents might cover a single innovative product, but that criticism rests on a fundamental misunderstanding of the exclusive right associated with patents that fails to appreciate how pioneering patents and future improvements can be cross-licensed. By opening the field with the pioneering invention, the first patent is rewarded with the exclusive

⁹ This Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), paved the way for the success of the Boyer-Cohen inventions. In *Chakrabarty*, the Court upheld the patent eligibility of broad claims to man-made, genetically engineered bacterium, designed to degrade petroleum. *Id.* at 310. The Court issued its decision in June 1980, and the U.S. Patent and Trademark Office later granted the Cohen-Boyer patents, starting in December 1980, including one patent that issued in April 1988 with broad claims covering genetically engineered prokaryotic cells.

right to that broad invention. Improvements may later be developed and patented by others, and those later innovators can obtain separate patents for their distinct improvements, even though they fall within the scope of the earlier pioneering patent. But the later innovator must obtain a patent license from the pioneering innovator to use the improvement, just as the pioneering innovator would need a license from the later innovator to use the improvement.

The nature of their respective exclusive rights recognizes that the subsequent improvement invention would not have been created but for the work of the pioneer. It should not, however, be a basis to invalidate the earlier pioneering patent.

C. Reliable Patents Protecting the *Quid Pro Quo* Encourage Investments in Sustainable Technologies

Reliable patent protection for pioneering innovators, including in the sustainability space, will encourage others to devote their finite resources to developing further innovation. That positive result will lead to further new sustainable technologies—some that the original pioneering inventors could have hardly conceived and others that the pioneering inventor would not have had time to develop.

Nature's Fynd and companies like it invest and dedicate an astounding amount of time and money to research and development that will improve society, all the while knowing the statistical chances of success in their ventures are slim. Often, the founders of early-stage companies work for years without salaries—depending on savings, a spouse's income, or a second job—while focused on pushing the technology forward. Investors assume the risk of receiving little to no return on their investments. To incentivize the commitment of resources needed to

make the changes required to develop sustainable technologies that will facilitate a growing global economy, the patent system must offer a reasonable economic justification for taking the risk. Inventors and investors in technologies having the potential to effect meaningful change need broad patent rights commensurate with their contributions. That reasonable justification can be realized by adopting the enablement standard offered by Petitioner Amgen, which incentivizes innovation and enables practice of the invention.

The road for Nature's Fynd has not been easy. The founders devoted years of work into the company on the bet that it would be successful, despite knowing that most start-ups fail in a short time frame. Nature's Fynd successfully developed its technology, its commercial potential, and its patent portfolio to create a value proposition that attracted substantial venture capital funding to fuel further innovation. The company is now expanding capacity to continue development and expand its product line. Even at the venture capital stage, the success rate of funded companies is low, with only about one in ten becoming successful in the long term.

If innovators such as Nature's Fynd devote extraordinary resources to developing sustainable technologies, only to be later told that their patents are not valid because of an unduly harsh enablement requirement, then those innovators are far less likely to be able to continue to finance the commercialization process. Other innovators, moreover, will be less likely to pick up the mantle and continue with further developments in the technology first identified by the pioneering innovator. Such outcomes are contrary to the objective of the Patent Clause.

III. Imposing an Unduly Burdensome Enablement Standard Will Impede Innovation by Encouraging Innovators to Resort to Trade Secrets

The Federal Circuit's current, unduly demanding enablement standard will likely lead to another unwanted outcome in the sustainability space: Increased reliance on trade secrets. Such an outcome would adversely impact the sharing of technical advances and would almost certainly delay the development of critical technologies.

As noted above, a patent specification serves the role of requiring the inventor to disclose the details of the invention so as to enable the public to practice the invention once the patent expires. This exchange is the *quid pro quo*.

In exchange, the patent accomplishes its innovation-incentivizing role primarily through the force of the exclusive right contemplated by the Founders and specified in the Constitution. *See* 35 U.S.C. § 154 (“Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention . . .”). This Court has recognized the same. *E.g., Horne v. Dep’t of Agric.*, 135 S. Ct. 2419, 2427 (2015) (stating that a patent “confers upon the patentee an exclusive property in the patented invention” (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882))). The right to exclusivity is what ultimately enables a patentee to reap the full reward of his or her innovative efforts and to prevent free riders from adopting the technology without incurring the costs and expenses associated with research and development.

As a tool to encourage and promote innovation, the exclusive right of a patent and its “boundaries should be clear,” as this Court explained in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730–31 (2002) (citing *Bonito Boats, Inc. v. Thunder Craft Boats,*

Inc., 489 U.S. 141, 150 (1989)). The Court continued and observed:

This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not. . . . [I]nventors . . . rely on the promise of the law to bring the invention forth, and the public . . . should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights.

Id. Indeed, the original Patent Act embodied Thomas Jefferson's philosophy that "ingenuity should receive a liberal encouragement." *Diamond v. Chakrabarty*, 447 U.S. 303, 308–09 (1980) (quoting 5 Writings of Thomas Jefferson 75–76 (Washington ed. 1871)).

This *quid pro quo* breaks down, however, when the enablement requirement is interpreted in a manner that is disadvantageous to the pioneering innovator. When misapplied, the enablement requirement creates situations, as in the present case, where a pioneering innovator teaches the full scope of the invention, only to have a patent later invalidated—even though the patent specification provides the blueprint for creating further embodiments and follow-on innovation. When that occurs, innovators lose confidence in the bargained-for exchange, and they will eschew the patent system, turning instead to trade secrets.

Trade secrets can be extremely important for protecting intellectual property. They can be, in certain circumstances, more powerful than patents. But trade secrets carry with them a major disadvantage for the public—they are secret. The public never learns the innovative elements of the trade secret, so follow-on innovators remain in the dark on where to start. They

must undertake duplicative efforts, with the hope of reverse engineering a technological advance. Cf. Andrea Contigiani & David H. Hsu, *How Trade Secrets Hurt Innovation*, Harv. Bus. Rev. (Jan. 29, 2019) (“Overall, our study suggests that, while firms lobby for a strengthened trade secrecy environment, this may ultimately backfire in the long run by leading to lower innovation.”).¹⁰

Not so with patents. In rapidly developing, disruptive technologies, such as those being driven by the need to address climate change, the public disclosure through the patent process facilitates the early disclosure of new ideas and inventions. As noted, patent applications are typically published within eighteen months from the patent application’s filing date, 35 U.S.C. § 122(b), and this early access accelerates the innovation cycle and can encourage the needed financial investment. See, e.g., Ali Mohammadi & Pooyan Khashabi, *Patent Disclosure and Venture Financing: The Impact of the American Inventor’s Protection Act on Corporate Venture Capital Investments*, 15 Strategic Entrepreneurship J. 73, 75 (2021) (concluding that “the mandatory public disclosure function of IP systems can directly improve the investment relationship in the startup financing market”).

At the same time, however, the early disclosure of pioneering innovation through the publication of patent applications is likely to impose risks on the pioneer. During the period between publication of the patent application and the subsequent issuance of the patent, the innovator has essentially no rights in the innovation. Economic studies suggest, not surprisingly, that this forced early disclosure may be detrimental to the innovator but beneficial to its competitors. See, e.g., Jinhwan Kim & Kristen Valentine, *The Innovation Consequences of Mandatory Patent Disclosures*, 71 J. of

¹⁰ <https://hbr.org/2019/01/how-trade-secrets-hurt-innovation>.

Accounting & Econ., Apr. 2021, Article No. 101381, at 1, 1 (observing that, in the context of early patent publication, “forcing firms to share proprietary information can be privately costly but beneficial to other firms”).

In sum, the patent system embodies a balanced tradeoff, which can increase social welfare more effectively than any other incentive-based legal regime. The tradeoff will only work, however, if the patent system’s constitutional *quid pro quo* is respected. Broad patent rights to inventors that are consistent with the enablement standard proposed by Petitioner Amgen avoid biasing the technology protection system too far in the direction of trade secrets and stifling the cycle of public disclosure that leads to further innovation.

CONCLUSION

For the foregoing reasons, *Amicus* respectfully requests that this Court reverse the court of appeals.

Respectfully submitted,

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