UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CORTEVA AGRISCIENCE LLC, PIONEER HI-BRED INTERNATIONAL, INC., and AGRIGENETICS, INC., *Plaintiffs*, v. INARI AGRICULTURE, INC., and INARI AGRICULTURE NV, *Defendants*.	No. 23-cv-1059-JFM

STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA

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INTEREST OF THE UNITED STATES

The United States respectfully submits this statement pursuant to 28 U.S.C. § 517, which permits the Attorney General to direct any officer of the U.S. Department of Justice to attend to the interests of the United States in any case pending in a federal court. The United States, through the Department of Justice Antitrust Division, has a strong interest in protecting competition and promoting innovation in the U.S. economy. The Antitrust Division furthers this interest most often by enforcing the antitrust laws, but also does so through promoting sound interpretation and enforcement of the intellectual property (IP) laws that safeguard patent rights, fuel economic growth, and spur innovation and competition. This interest has led the United States to file numerous statements of interest explaining that the IP laws, properly interpreted, are important to promoting a competitive economy. *See, e.g.*, Statement of Interest of the United States, *Samsung Electronics Co., Ltd. v. Netlist, Inc.*, No. 25-cv-01589, D.I. 37 (D. Del. Apr. 7, 2026); Statement of Interest of the United States, *Radian Memory Systems, LLC v. Samsung Electronics, Co., Ltd.*, No. 2:24-cv-1073, D.I. 52 (E.D. Tex. June 24, 2025).

The United States also has an interest in ensuring that the IP laws are not interpreted to provide greater insulation from competition than necessary, and that the laws incentivize not only large biotechnology firms' innovation, but also that of small businesses and solo inventors. That is because competition benefits from a multiplicity of innovative solutions leading to a wide range of products and services that offer different approaches to addressing the same or similar problems. *Nat'l Soc. of Prof. Eng'rs v. United States*, 435 U.S. 679, 695 (1978) (Congress's "assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain . . . are favorably affected by the free opportunity to select among alternative offers."). These concerns have long extended to the agricultural sector.

See, e.g., Dep't of Justice, *Competition and Agriculture* at 6, 13-14, 23 (May 2012) ("Agriculture Report"), https://perma.cc/D59H-VNXD (documenting market concentration, "especially in the way of conventional corn and soybean varieties," and the potential disruption of IP law's "careful balance" between innovation, competition, and protection); Dep't of Justice, *Antitrust Enforcement and Agriculture* (Aug. 20, 2002), https://atrnet.atr.doj.gov/subdocs/200417.htm.

This case involves claims of infringement of IP rights for agricultural biological material. Although Inari has not asserted an antitrust counterclaim against Corteva,[1] this litigation raises competition concerns because it involves questions of interpretation of the IP laws that impact permissible conduct and may lead to an outcome that "squash[es] nascent, albeit unproven competitors"—a result that would be "inimical" to the goal of promoting innovation and competition. *See United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001). To secure a patent, an applicant is required to adequately disclose the protected material so that the public can access and understand what is protected and the state of the art is expanded to allow follow-on innovation. This disclosure "requirement is to ensure that the scope of the right to exclude . . . does not overreach the scope of the inventor's contribution," and "is part of the *quid pro quo* of the patent grant." *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1353-54 (Fed. Cir. 2010) (en banc) (cleaned up). For entry by a new competitor to be possible in this highly concentrated industry, the established dominant firms must be held to their side of this "patent 'bargain'" by ensuring their invention is brought "'into the public domain through disclosure,' so [it] may benefit all." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 604-05 (2023) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989). The boundaries of permissible

[1] In addition to Corteva Agriscience LLC, the other plaintiffs are Pioneer Hi-Bred International, Inc. and Agrigenetics, Inc. (collectively, "Corteva"). The defendants are Inari Agriculture, Inc. and Inari Agriculture NV (collectively, "Inari").

conduct for the public to access and "read" claimed patented material must be carefully policed to prevent the IP laws from being misused to blunt rather than foster innovation. The United States thus urges the Court to reject any claims of infringement based on a party's access to and use of the deposited material simply to "read" the description of the patented invention. This Statement of Interest does not address what conduct concerning deposits beyond "reading" the description of the patented invention would constitute infringement.

The United States does not take a position on the ultimate application of the law to the facts here.[2] The United States also acknowledges that patent owners are entitled to enforce their exclusive rights under 35 USC §271 during the unexpired term of the patent.

BACKGROUND

A. IP Laws Reflect a "Carefully Crafted Bargain" that Incentivizes Innovation and Promotes Dynamic Competition

The U.S. Constitution gives Congress 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." U.S. Const. art. I, § 8, cl. 8. Pursuant to that power, Congress enacted the Patent Act, which makes the USPTO responsible for examining and issuing patents for any new, useful, and nonobvious invention. 35 U.S.C. § 1, *et seq*. The Patent Act provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). Infringement liability also attaches for, *inter alia*, actively inducing infringement, or for,

> without authority[,] suppl[ying] or caus[ing] to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that

[2] Most of the filings in this case are under seal, and the United States has no access to them.

> such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States.

35 U.S.C. §§ 271(b), (f).

Securing a patent gives IP-rights holders the "right to exclude others from profiting by the patented invention," *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980), in order "to encourage invention," *Eldred v. Ashcroft*, 537 U.S. 186, 216 (2003). This statutory exclusion is a powerful incentive for inventors to invest in innovation, and strong IP rights promote competition by facilitating market entry and leveling the playing field for small innovative companies. This essential cycle of innovation and competition is crucial to the welfare of the American economy. *See, e.g.*, U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property §1.0 at 2 (2017), https://perma.cc/CH3G-XT6D ("The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare.") ("IP Guidelines"); U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition at 6 (2007), https://perma.cc/BD3B-MCJR (same); *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990) ("[T]he aims and objectives of patent and antitrust laws . . . are actually complementary, as both are aimed at encouraging innovation, industry and competition."); *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) (antitrust law's focus on competition is "*in pari materia*" with IP laws).

Intellectual property laws, however, represent a "carefully crafted bargain" between inventors and the public: in "return" for exclusivity "for a limited period of time," inventors must adequately and timely disclose their invention to the public so as to avoid "unnecessarily stifl[ing] competition." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). Specifically, this

"patent 'bargain'" affords the inventor "a limited term of 'protection from competitive exploitation'" and, "[i]n exchange," the inventor must "bring[] 'new designs and technologies into the public domain through disclosure,' so they may benefit all." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 604-05 (2023) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989)). Such disclosure both permits the public to understand the innovation protected under IP law, thus clearly identifying the invention to avoid infringement, and "secures for the public its benefit of the patent bargain by ensuring that, 'upon expiration of the patent, the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it.'" *Amgen*, 598 U.S. at 605 (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933)); *see also Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014) ("The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention.")

As the Supreme Court has explained, "Congress has exercised this authority . . . from the start," setting out the "*quid-pro-quo* premise of patent law" in the Patent Act of 1790, requiring every applicant to disclose sufficiently detailed information so "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.'" *Id.* at 605 (quoting Act of Apr. 10, 1790 § 2, 1 Stat. 110). The enablement and written description requirements remain in effect today. *Id.* (quoting 35 U.S.C. §§ 111, 112); *see also Universal Oil Prods. Co. v. Globe Oil & Refining Co.*, 322 U.S. 471, 484 (1944) ("[T]he quid pro quo is 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; and the same precision of disclosure is

likewise essential to warn the industry concerned of the precise scope of the monopoly asserted."); Manual of Patent Examining Procedure § 2163 ("Guidelines for the Examination of Patent Applications Under 35 U.S.C. § 112 … 'Written Description' Requirement.").

Adequate access to and understanding of claimed patented material is crucial because "even a valid patent confers no right to exclude products or processes that do not actually infringe." *FTC v. Actavis*, 570 U.S. 136, 147 (2013). Accordingly, "[w]hat is claimed by the patent application must be the same as what is disclosed in the specification." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002); *accord Abbvie Deutschland,* 759 F.3d at 1298 (citing *Festo*). The written description requirement is thus key to both protecting the important patent-related policy of incentivizing innovation and "the patent-related policy of eliminating unwarranted patent grants"—or misinterpretations of the scope of exclusionary rights—"so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification,'" *Actavis*, 570 U.S. at 151 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

B. The Seed Industry

The seed industry, in which this litigation takes place, is highly concentrated with formidable market entry barriers, as "ongoing consolidation has resulted in a global seed industry dominated by just a few companies." U.S. Dep't of Agriculture, *More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs* at 11 (March 2023) ("USDA Report"), https://perma.cc/W9WF-HDG4. Although "[a]vailable public information on levels of concentration in markets for crop seed and biotech traits is quite limited," the USDA has estimated that as of 2020 the top four firms, which include Corteva, hold 84% of the corn market and 79% of the soybean market—an estimate that includes both

conventional and genetically modified seeds. USDA Economic Research Service, *Concentration and Competition in U.S. Agribusiness*, Economic Information Bulletin No. 256, at 11 (June 2023) (Concentration and Competition Report), https://perma.cc/G9Z9-HBLU. And given that "the presence of fewer decision makers may narrow the scope of inquiry and innovation in the market," it is likely that "the increased concentration and economies of scale for dominant companies may pose significant barriers to entry for small and medium-sized enterprises and reduce innovation." USDA Report at 45.

Agricultural economists point to "biotechnology and expanded intellectual property rights" as two of the key drivers that have "spurred [these] structural changes." Concentration and Competition Report at 7. Thus, the dominant seed companies' control of the vast majority of the relevant IP rights raises the fear that they "may leverage their IP rights in combination with [their] market power to create barriers to competition." USDA Report at 41.[3] As relevant to the present litigation, the USDA has estimated that "the top four companies [have] dramatically increased their share of IP ownership since the 1990s," with "the top four (Bayer, Corteva, ChemChina and BASF) own[ing] . . . 95% of corn and 84% of soybean . . . IP," and Bayer and Corteva alone controlling 85% of corn and 76% of soybean IP. *Id.* at 42-43.

If a nascent firm attempts entry with new agricultural products, however, it must be able to accurately identify the extant products and the parameters of their IP protection. While "[i]n other industries, innovators may be able to look at descriptions of inventions described in patent

[3] It is axiomatic that "a patent does not necessarily confer market power upon the patentee." *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 44 (2006); *see also* IP Guidelines, §2.2 at 4 (2017). But the lack of such a presumption does not render a patent holder immune from competition concerns; it simply requires establishing possession of market power through traditional modes of analysis because "a firm or individual may well possess market power derived from the patent." *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013).

applications, then design around the claimed invention," that approach is impossible for "plant varieties and the genetic traits [which] contain [] the product of evolutionary history, domestication, and breeding." *Id.* at 29. Lack of "access to IP-protected seed or other propagation material . . . [and] also the prior innovation that led to its development," thus "limits the ability of other innovators to make follow-on improvements." *Id.* (quoting a customer's observation that "patent disclosures alone do not allow other inventors to benefit from the patented lines when creating new plant varieties"). While the United States "recognizes the critical role that intellectual property rights play in driving innovation and values those rights," it has expressed concerns that an overly expansive interpretation of the IP laws may upset "the careful balance" with competition interests. *Id.* at 23.

C. Factual Allegations and Procedural History

Corteva, which "is one of the world's largest commercial seed and plant producers," "research[es] and develop[s] novel seeds, including for staples such as corn and soybean," and has "obtained patents and Plant Variety Protection ('PVP') certificates on many of its seed lines." Second Am. Compl. ¶¶ 1-2, ¶ 8, D.I. 158 ("Compl.").[4] Inari, a new entrant to this market with facilities in the United States and Belgium, also seeks to "improve the quality of seeds through

[4] Unless otherwise noted, this statement draws its factual discussion from Corteva's Second Amended Complaint. When weighing summary judgment under Fed. R. Civ. P. 56, a court must draw all reasonable inferences in favor of the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-50 (1986). "The rule is no different where there are cross-motions for summary judgment." *Lawrence v. City of Philadelphia, Pa.*, 527 F.3d 299, 310 (3d Cir. 2008); *see also Howland v. Cincinnati Insurance Co.*, 702 F. Supp.3d 335, 340 (E.D. Pa. 2023) ("The standards to be applied in deciding cross-motions for summary judgment are the same as those applied when only one party has filed a summary judgment motion," and "the court must rule on each party's motion on an individual and separate basis."). This statement does not address Corteva's claims based on Massachusetts state law. *See* Compl. ¶¶ 396-405.

genetic modification," and subsequently "seeks patent protection for the resulting modifications." *Id*. at ¶¶ 3, 14-16.

Corteva, in order "[t]o comply with legal requirements for intellectual property protection, [has] deposited samples of its protected seeds with ATCC [the American Type Culture Collection]—a nonprofit organization that collects, stores, and distributes standard reference microorganisms, cell lines, seeds, and other biologic materials . . . in connection with filing applications to obtain patents covering the protected seeds." *Id*. at ¶ 5. Corteva has also obtained certificates of plant variety protection granted under the Plant Variety Protection Act ("PVPA") that "provide[] intellectual property protection to breeders of certain novel plant varieties, and their assignees . . . for a period of twenty years." *Id.* at ¶ 48.

Corteva sued Inari on September 27, 2023, in the District of Delaware. D.I. 1. A Second Amended Complaint was filed on October 15, 2024. D.I. 158. Corteva alleges that Inari "steal[s] Corteva's groundbreaking, patent-protected work" through "unlawful and deceptive conduct [that] violates Corteva's intellectual property rights." *Id.* at ¶ 1. Specifically, Corteva alleges that "Inari's goals ha[ve] been, and will be, to infringe the intellectual property rights of competitors like Corteva by misappropriating their protected seeds, transporting the seeds outside the United States, and then genome-editing or otherwise using those seeds for commercial use," in violation of Corteva's rights under various PVP certificates and patents. *Id.* at ¶¶ 128, 133, 167-370 (Counts I-XVII).

On April 3, 2026, the parties filed cross-Motions for Summary Judgment. D.I. 534 (Corteva) and D.I. 537 (Inari).

ARGUMENT

The Court should not interpret 35 U.S.C. § 271 and related IP laws in a manner that restricts the public's ability to understand a claimed invention. In particular, the Court should not deem any activity to constitute "infringement" if it is a means of accessing and "reading" biological material that the law requires be made publicly available in exchange for a valid patent or other IP protection.[5] In cases where a biological deposit is required to satisfy the written description and enablement requirements of Section 112, that "deposit must be made under conditions that assure that . . . all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent." 37 C.F.R. § 1.808(a)(2). Therefore, activities that amount to accessing and "reading" the deposited biological material cannot be deemed to be "without authority" under Section 271. To hold otherwise would insulate certain products from competition without ensuring the public has received the benefit of the bargain: that the public can ascertain what is thus insulated for the purposes of both avoiding infringement and furthering follow-on innovation.

I. IP Protection for Biological Materials

A. Adequate Disclosure for Biological Materials May Require Use of a Depository

A party seeking IP protection for biological materials must meet the same statutory disclosure requirements that govern all patent claims. Under 35 U.S.C. § 112(a), a patent application must contain

> a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to

[5] Other actions by a party obtaining a seed deposit may constitute infringement, e.g., using deposit seeds to commercially propagate the patented plant in the United States during the life of the patent.

> which it pertains . . . to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

As explained above, this "requirement to describe one's invention is basic to patent law" because "[i]t is part of the *quid pro quo* of a patent"—i.e., "one describes an invention, and, if the law's other requirements are met, one obtains a patent." *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1345 (Fed. Cir. 2010). This disclosure is crucial because it "allows the [USPTO] to examine the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights." *Id.*; *see also Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 56-57 (1938) (disclosure "inform[s] the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not"). Only if these disclosures are adequately made will a patent issue because "exclusive patent rights are given in exchange for disclosing the invention to the public." *Festo*, 535 U.S. at 736.

For agricultural material, Congress has provided several overlapping ways to protect novel plant varieties that include: traditional utility patents, 35 U.S.C. § 101 et seq., so-called "plant patents" for asexually reproducing plants (other than tubers), id. §§ 161-164, and certificates of plant variety protection granted under the Plant Variety Protection Act ("PVPA"), 7 U.S.C. § 2321 *et seq*.[6] Obtaining patent protection for biological materials presents a challenge, however, in meeting the disclosure requirements because "it may be impossible to enable the

[6] PVPA protection includes a research exemption to allegations of infringement. See 7 U.S.C. § 2544 ("The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter"); *see also J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142-43 (2001) (explaining that utility patents require deposit of the biological material for which the applicant seeks protection).

public to make the invention . . . solely by means of a written disclosure." *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988). The IP laws thus provide flexibility and allow the requirements to be satisfied in a way that "varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad Pharm.*, 598 F.3d at 1351.

For biological material, "[o]ne means that has been developed for complying with the enablement [and written description] requirement[s] is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues." *In re Wands*, 858 F.2d at 735 (citing *In re Argoudelis*, 434 F.2d 1390, 1392-93 (C.C.P.A. 1970) (first approving the use of depositories, which were already in use "for over fifteen years," for biological materials to satisfy the written description and enablement requirements to secure a patent, noting the depository would "supply samples to anyone seeking them once the patent issue[d]")). Thus, although a deposit may not be necessary "if [the material] is known and readily available to the public or can be made or isolated without undue experimentation," material that "'cannot reasonably be enabled by a description in written form,'" must instead "be described in surrogate form by a deposit that is incorporated by reference into the specification." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965 (Fed. Cir. 2002) (quoting 37 C.F.R. § 1.802(b)). It is therefore common practice for patent applicants to meet the written description and enablement requirements of 35 U.S.C. § 112 by supplementing (or even replacing) their written disclosures with deposits of biological material in a recognized depository. *See, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345-46 (Fed. Cir. 2000) (explaining that a deposit helps to satisfy the enablement requirement).

Furthermore, as IP rights exist in a global system, U.S. companies can access biological material deposited in foreign depositories and non-U.S. companies can access material deposited

within the United States. *See Feldman v. Aunstrup*, 517 F.2d 1351, 1355-56 (C.C.P.A. 1975) (holding that deposit in "a private foreign depository" was sufficient, so long as "assurance of access []to the microorganism culture by the public upon issuance" is given so that "the public will, in fact, receive something in return for the patent grant") (cleaned up). And just as patented material can be read in the United States, it can be read abroad. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, of which the United States is a signatory, requires the recognition of a deposit with any depository which has been approved by the World Intellectual Property Organization, and contemplates such cross-border access. 32 U.S.T. 1241 at Art. 5 Export and Import Restrictions (Apr. 28, 1977) ("Each Contracting State recognizes that it is highly desirable that, if and to the extent to which the export from or import into its territory of certain kinds of [deposited material] is restricted, such restriction should apply to [the material] deposited, or destined for deposit, under this Treaty only where the restriction is necessary in view of national security or the dangers for health or the environment."). The USPTO's promulgated rules set forth the examining procedures and conditions of deposit that must be satisfied in the event a deposit is required, and which apply to U.S. and non-U.S. entities. *See* 37 C.F.R. §§ 1.801-1.809. The ATCC—in which the seeds here have been deposited, *see* supra, is one such USPTO-qualified depository under 37 C.F.R. § 1.803.

Although a patent applicant need not make their deposited material available to the public during the pendency of their patent application, USPTO regulations provide that such deposits "*must* be made under conditions that assure that . . . all restrictions . . . will be irrevocably removed upon the granting of the patent." 37 C.F.R. § 1.808(a)(2) (emphasis added). To protect

robust competition in the seed industry, "seed deposits serve as part of the disclosure and are intended to be available for continued innovation." USDA Report at 29.

B. "Reading" Deposited Biological Materials May Require Access and Limited Use—And Such Use Is Not "Without Authorization" Under Section 271

While it is easy to read the written descriptions of patent claims submitted with traditional patent applications, "reading" deposited biological materials requires something more. For deposited biological material that is incorporated by reference in a specification, "[a] person of skill in the art" can "read[] the accession numbers in the patent specification [and] obtain the claimed sequences from the ATCC depository by following the appropriate techniques to excise the [patented material] from the deposit[s]. . . ." *Enzo Biochem*, 323 F.3d at 965-66. Forbidding access to deposited material risks upsetting the *quid pro quo* of the patent system because "the public must receive *meaningful* disclosure in exchange for being excluded from practicing the invention for a limited period of time." *Id.* at 970 (emphasis added); *see also Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336 (Fed. Cir. 2006) (same).

Corteva argues that it only deposited seeds with the ATCC "for the purpose of *protecting* Corteva's patent rights." Compl. ¶ 80 (emphasis in original). Corteva is correct that such deposits do protect the applicant—after all, the applicant is not entitled to *any* IP protection and insulation from competition without adequate disclosure. *Amgen*, 598 U.S. at 616. But Corteva disregards the countervailing *public* benefit from disclosure of its patented material to the market. The IP laws demand that this "boundary defining the excludable subject matter must be carefully set: it must protect the inventor, so that commercial development is encouraged; but the claims must be commensurate with the inventor's contribution." *In re Wands*, 858 F.2d at 741 (Newman, J., concurring in part and dissenting in part). Consistent with these principles, USPTO regulations

require that "[a] deposit *must* be made under conditions that assure that . . . *all restrictions* imposed by the depositor on the availability to the public of the deposited material *will be irrevocably removed* upon the granting of the patent." 37 C.F.R. § 1.808(a)(2) (emphasis added).

Through Material Transfer Agreements, patent holders "may contract with the depository to require that" a certain *process* be followed for public provision of the material—e.g., that a request for access be made "in writing" or include specific information such as "the accession number of the deposit. 37 C.F.R. § 1.808(b). But neither patent holders nor depositories should be permitted to construct contractual, extra-statutory encumbrances that extend a patent's boundary. In cases where a biological deposit is required to satisfy the written description and enablement requirements of Section 112, activities that amount to accessing and "reading" biological material—such as ordering and sequencing genetic material—cannot be deemed to be "without authority" under Section 271. To hold otherwise would penalize those who access and use the biological material to understand its specifications, thereby disrupting the carefully crafted balance—protecting competition and innovation—underlying the patent laws.

CONCLUSION

The Court should uphold the carefully crafted bargain set forth in the Patent Act.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 11, 2026, I caused the foregoing to be filed through this Court's CM/ECF filer system, which will serve a notice of electronic filing on all registered users, including counsel for all parties.

/s/ *Shana Wallace*
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