

No. 2023-1217

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**United States Court of Appeals For the Federal Circuit**

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US SYNTHETIC CORP.,  
*Appellant,*

v.

INTERNATIONAL TRADE COMMISSION,  
*Appellee,*

AND

SF DIAMOND CO., LTD., SF DIAMOND USA, INC., ILJIN DIAMOND CO., LTD.,  
ILJIN HOLDINGS CO., LTD., ILJIN USA INC., ILJIN EUROPE GMBH, ILJIN  
JAPAN CO., LTD., ILJIN CHINA CO., LTD., INTERNATIONAL DIAMOND  
SERVICES, INC., HENAN JINGRUI NEW MATERIAL TECHNOLOGY CO., CR  
GEMS SUPERABRASIVES CO., LTD., FUJIAN WANLONG SUPERHARD  
MATERIAL TECHNOLOGY CO., LTD., ZHENGZHOU NEW ASIA SUPERHARD  
MATERIAL COMPOSITE CO., LTD., SHENZHEN HAIMINGRUN SUPERHARD  
MATERIALS CO., LTD., GUANGDONG JUXIN NEW MATERIAL TECHNOLOGY  
CO., LTD.,  
*Intervenors.*

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Appeal from the United States International Trade Commission in  
Investigation No. 337-TA-1236

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**BRIEF OF PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA (PhRMA) AS *AMICUS  
CURIAE* IN SUPPORT OF APPELLANT AND REVERSAL**

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

**CERTIFICATE OF INTEREST**

**Case Number** 2023-1217

**Short Case Caption** US Synthetic Corp. v. ITC

**Filing Party/Entity** Pharmaceutical Research and Manufacturers of America

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Date: 05/26/2023

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Name: Richard L. Rainey

| <p><b>1. Represented Entities.</b><br/>Fed. Cir. R. 47.4(a)(1).</p>                            | <p><b>2. Real Party in Interest.</b><br/>Fed. Cir. R. 47.4(a)(2).</p>   | <p><b>3. Parent Corporations and Stockholders.</b><br/>Fed. Cir. R. 47.4(a)(3).</p>  |
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| <p>Pharmaceutical Research and Manufacturers of America</p>                                    |   | <p>See attached page.</p>  |
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Additional pages attached

**4. Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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

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None/Not Applicable  Additional pages attached

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Response to Question No. 3:

PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at [www.phrma.org/about#members](http://www.phrma.org/about#members).

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## STATEMENT OF *AMICUS CURIAE*<sup>1</sup>

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a voluntary, nonprofit association representing the country’s leading research-based pharmaceutical and biotechnology companies.<sup>2</sup> PhRMA’s mission is to advocate for public policies encouraging innovation in life-saving and live-enhancing new medicines. PhRMA’s member companies are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

PhRMA’s members make significant contributions to serve these goals and have led the way in the search for new cures. Since 2000, PhRMA members have invested more than \$1.1 trillion in the search for new treatments and cures, including an estimated \$102.3 billion in 2021 alone. PhRMA members rely on the assurance of patent exclusivity for their innovations when they make these investments and their product development decisions.

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<sup>1</sup> PhRMA submits this brief with the consent of all parties pursuant to Fed. R. App. P. 29(a)(2). *See* Fed. R. App. P. 29(a)(4)(D). No counsel for any party authored this brief in whole or in part, and no party, counsel, or person other than amicus contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

<sup>2</sup> PhRMA’s members are listed at [www.phrma.org/about#members](http://www.phrma.org/about#members) (last visited May 26, 2023).

As inventors, developers, and investors, PhRMA members have a strong interest in clear and predictable rules of patent-eligibility. Many of the medicines developed by PhRMA members involve cutting-edge composition of matter inventions, including innovative drug substances, pharmaceutical formulations, and dosage forms. These medicines have played a central role in transforming the trajectory of many debilitating diseases, resulting in improved health outcomes, and better quality of life for patients.

Clear, strong, and predictable patent protection allows PhRMA members and other biopharmaceutical companies to continue making the substantial investments in research and development that yield new and improved medicines and fund additional research. This is particularly true in light of the immense and risky investments required to discover, develop, and deliver new medicines to patients. Indeed, developing a new medicine generally takes between 10 and 15 years of work and costs an average of \$2.6 billion of investment in research and development.<sup>3</sup> Only two of every ten marketed drugs return revenues that exceed or match

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<sup>3</sup> See Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 J. HEALTH ECON. 20, 26 (2016).

that investment.<sup>4</sup> If a company cannot count on the patent system to help protect its research and development, it is unlikely to devote the necessary resources to create new medicines. A weak and unpredictable patent system also leads to uncertainty for investors and inventors in the field, as neither knows which areas to invest their time and money in to secure patentable future inventions. This uncertainty may have a profound impact on the long-term stability of the industry and the availability of lifesaving medicines in the future.

PhRMA submits this brief in the hope that it will assist the Court in the orderly development of law in this important area of patent subject matter eligibility.

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<sup>4</sup> See John A. Vernon et al., *Drug development costs when financial risk is measured using the Fama-French three-factor model*, 19 HEALTH ECON. 1002, 1004 (2010).

## INTRODUCTION AND SUMMARY OF ARGUMENT

Although this case does not involve biopharmaceutical technology or any PhRMA members, PhRMA is concerned with the U.S. International Trade Commission’s troubling expansion of the abstract idea exception to patent eligibility.

This appeal challenges the Commission’s determination that US Synthetic’s patent claims for a “polycrystalline diamond compact”—*i.e.*, a composition of matter—are directed to an abstract idea and nothing more, rendering the claims ineligible for patenting under Section 101.

The Commission’s expansion of the abstract idea judicial exception to render a composition of matter claim patent ineligible is unprecedented and contradicts Section 101’s plain text. Claims to compositions of matter—including chemicals, substances, formulations, and materials—have long been understood to be broadly eligible for patenting. These types of claims are also vital to PhRMA members and the United States biopharmaceutical industry, which rely on such claims to protect innovative medicines.

Composition of matter claims are quintessentially non-abstract, and the Commission’s decision to the contrary is an outlier that presents

a new high-water mark for unpredictability and misguided decision-making in the area of patent eligibility law. If left to stand, the Commission’s decision could negatively impact companies in the biopharmaceutical sector, which have long relied on the stability afforded by composition of matter patents to justify their significant efforts, expenses, and risks associated with bringing innovative new medicines to market.

The Court should take this opportunity to correct the Commission’s error and reverse its decision.

## ARGUMENT

### I. **Compositions of matter have long been held to be patent-eligible inventions.**

For over two centuries, compositions of matter have been expressly identified as statutory subject matter eligible for patenting. The Patent Act of 1793 defined statutory subject matter as “any new and useful art, machine, manufacture, or *composition of matter*, or any new or useful improvement” thereof. Patent Act of 1793, 1 Stat. 318, 319 § 1 (1793) (emphasis added); see *Diamond v. Chakrabarty*, 447 U.S. 303, 308–309 (1980) (discussing same). The same is true today, with Section 101

expressly providing that “any new and useful . . . composition of matter” is entitled to patent protection.

Consistent with the statutory text of Section 101, compositions of matter like US Synthetic’s polycrystalline diamond compacts have consistently been found to be eligible for patenting. *See, e.g., Chakrabarty*, 447 U.S. at 308–309 (holding that a composition claim to a modified bacterium that enabled it to break down various components of crude oil “plainly qualifies as patentable subject matter”); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594–95 (2013) (holding that composition claims to laboratory-synthesized complementary DNA (cDNA) “is patent eligible under § 101”).

PhRMA recognizes that the Supreme Court has held that there are exceptions to patent eligibility. Specifically, “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *see Chakrabarty*, 447 U.S. at 309 (identifying “a new mineral discovered in the earth,” “a new plant found in the wild,” Einstein’s law that  $E=mc^2$ , and Newton’s law of gravity as examples of ineligible material). As the

Supreme Court explained, “monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.” *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 71 (2012).

With respect to composition claims, historically courts have only found such claims to be patent ineligible in rare circumstances where they were directed to naturally occurring products. *See, e.g., Myriad*, 569 U.S. at 591 (holding that composition claims for a naturally occurring “isolated DNA” having a specific genetic sequence were not eligible because merely “separating [a] gene from its surrounding genetic material is not an act of invention”); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948) (holding that a claimed bacteria mixture composition was not patent eligible because the bacteria were not altered from their natural form in any way). The Supreme Court has stated that naturally occurring compositions “are part of the storehouse of knowledge” and are thus “free to all . . . and reserved exclusively to none.” *Id.* at 130.

US Synthetic’s composition of matter claims to polycrystalline diamond compacts do not implicate naturally occurring compositions and

the Commission’s decision does not suggest otherwise. Rather, US Synthetic’s claims are more akin to composition of matter claims that the Supreme Court has held to be patent eligible. *See, e.g., Chakrabarty*, 447 U.S. at 305–306 (discussing the claims at issue in that case); *In re Bergy*, 596 F.2d 952, 970 (C.C.P.A. 1979) (identifying claim 7 at issue in *Chakrabarty* as reciting “[a] bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.”).

**II. The abstract idea exception has never been applied to find a composition of matter patent ineligible.**

Although composition of matter claims have on rare occasions been found ineligible as being directed to naturally occurring products, prior to this case, the abstract idea exception had never been applied to a composition of matter claim. Thus, this Court should look with alarm at the Commission’s decision. Compositions of matter—*i.e.*, “compositions of two or more substances and . . . all composite articles, whether they be the results of a chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids,” *Chakrabarty*, 447 U.S. at 308 (citation omitted)—are necessarily real, physical, and tangible, not abstract. As

such, a physical composition cannot monopolize or preempt “mental processes and abstract intellectual concepts” such that a Court could reasonably find the composition to be directed to an ineligible abstract idea. *See Gottschalk*, 409 U.S. at 67–68.

Indeed, the Commission’s decision is a true outlier. PhRMA is aware of no case finding claims to a composition of matter to be patent ineligible based on the abstract idea exception, and no such case has been cited by the parties or the Commission.

This absence of precedent is instructive, and hardly surprising. Cases involving the abstract idea exception typically involve claims directed to software functionality, mathematical concepts, methods of organizing human activity, and mental processes. *See, e.g., Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. 208, 218–219 (2014) (holding that a claimed “method of exchanging financial obligations between two parties using a third-party intermediary to mitigate settlement risk” were “drawn to the abstract idea of intermediated settlement” and were thus ineligible); *Bilski v. Kappos*, 561 U.S. 593, 599, 609 (2010) (holding that a claimed method and formula instructing “buyers and sellers of commodities in the energy market [how to] protect,

or hedge, against the risk of price changes” was ineligible “because it claims an abstract idea”); *Parker v. Flook*, 437 U.S. 584, 585, 594–95 (1978) (holding that a method involving computing an “alarm limit” value using an algorithm was directed to a mathematical formula and thus was ineligible); *Gottschalk*, 409 U.S. at 65, 71–72 (holding that a claimed method for converting binary-coded decimal numerals into pure binary form was directed to an ineligible mathematical formula). Such claims bear no resemblance to compositions of matter.

There is nothing “abstract” about US Synthetic’s composition claims to polycrystalline diamond compacts, which recite physical elements together with specified measurements describing the properties of the composition. To be sure, courts have noted that “[s]tating an abstract idea while adding the words ‘apply it’ is not enough for patentability.” *Alice*, 573 U.S. at 223 (quotation marks omitted in part); *see also Yu v. Apple Inc.*, 1 F.4th 1040, 1043 (Fed. Cir. 2021) (holding claims to an “improved digital camera” ineligible where “[w]hat is claimed is simply a generic environment in which to carry out the abstract idea.”); *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1292 (Fed. Cir. 2020) (holding a claim to

“[a] method for manufacturing a shaft assembly of a driveline system” ineligible “because it simply requires the application of Hooke’s law to tune a propshaft liner to dampen certain vibrations.”). But unlike the claims in *Alice*, *Yu*, and *American Axle*, the so-called “performance measures and side effects” in the claims that the Commission found “problematic” are not mere concepts, nor can they be achieved in the abstract. Rather, they are measurable properties of the specific compositions recited by the claims. Claiming such features does not catapult an otherwise patent-eligible composition into patent-ineligible territory.

While not binding, the U.S. Patent and Trademark Office’s examination guidance further demonstrates the fundamental mismatch between the abstract idea judicial exception and composition of matter claims. The recently revised Manual of Patent Examining Procedure identifies three “enumerated groupings” of abstract ideas that “are firmly rooted in Supreme Court precedent”: mathematical concepts, certain methods of organizing human activity, and mental processes—none of which involve compositions of matter. *See* MPEP § 2106.04(a) (9th rev. ed., July 2022). Separately, in seeking to provide clarifying guidance to

examiners and stakeholders on eligibility issues, the Office created forty-six example claims based on case law that serve as “a teaching tool to assist examiners and the public in understanding how the Office applies its eligibility guidance . . . across a range of technologies.”<sup>5</sup> None of the examples identified by the Office reflecting “abstract ideas” involved compositions of matter.<sup>6</sup>

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<sup>5</sup> See U.S. PATENT AND TRADEMARK OFFICE, *Subject matter eligibility*, <https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility> (last visited May 26, 2023).

<sup>6</sup> The Office has created an index identifying all 46 examples together with additional information relevant to the Section 101 analysis. See U.S. PATENT AND TRADEMARK OFFICE, *Index of Subject Matter Eligibility Examples (Oct. 2019)*, <https://www.uspto.gov/sites/default/files/documents/ieg-example-index.pdf> (last visited May 26, 2023). The individual examples and accompanying explanation are also available on the Office’s website. See U.S. PATENT AND TRADEMARK OFFICE, *Examples: Abstract Ideas*, [https://www.uspto.gov/sites/default/files/documents/101\\_examples\\_1to36.pdf](https://www.uspto.gov/sites/default/files/documents/101_examples_1to36.pdf) (examples 1–36) (last visited May 26, 2023); U.S. PATENT AND TRADEMARK OFFICE, *Subject Matter Eligibility Examples: Abstract Ideas*, [https://www.uspto.gov/sites/default/files/documents/101\\_examples\\_37to42\\_20190107.pdf](https://www.uspto.gov/sites/default/files/documents/101_examples_37to42_20190107.pdf) (examples 37–42) (last visited May 26, 2023); U.S. PATENT AND TRADEMARK OFFICE, *Appendix 1 to the October 2019 Update: Subject Matter Eligibility–Life Sciences & Data Processing Examples*, [https://www.uspto.gov/sites/default/files/documents/peg\\_oct\\_2019\\_app1.pdf](https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_app1.pdf) (examples 43–46) (last visited May 26, 2023).

**III. The Commission’s Section 101 analysis vitiates other patentability doctrines and is an overreach of Section 101 jurisprudence.**

Congress drafted Section 101 with intentional breadth to encompass a wide range of inventions such that “the patent laws would be given wide scope.” *Chakrabarty*, 447 U.S. at 308. In this way, Section 101 operates as a coarse filter by design that broadly permits patenting of useful subject matter within the enumerated statutory categories. In other words, “[t]he § 101 patent-eligibility inquiry is only a threshold test” that is separate from the patentability conditions of Sections 102, 103, and 112. *Bilski*, 561 U.S. at 602. Issues of novelty, nonobviousness, and sufficient disclosure do not bear on whether a claimed invention falls within the enumerated categories of eligible subject matter. Rather, these issues are properly analyzed under the clearer standards governing Sections 102, 103, and 112.

In extending the abstract idea exception to subsume compositions of matter, the Commission improperly conflated these distinct requirements, merging them all into a single legal determination. For example, in finding US Synthetic’s composition claims to be patent ineligible, the Commission accused US Synthetic of over-claiming, and

held that US Synthetic’s claims would “monopolize every potential structure or way of creating stronger PDCs with the claimed characteristics.” But claim breadth is examined under the principles of Section 112. *See Amgen Inc. v. Sanofi*, No. 21-757, 143 S. Ct. 1243, 2023 WL 3511533, at \*9 (U.S. May 18, 2023). And here, the Commission concluded that US Synthetic’s claims satisfy the enablement requirement, notwithstanding the Commission’s allegations regarding their scope.

The Supreme Court has warned that “too broad an interpretation of th[e] exclusionary principle [against patents directed to judicial exceptions] could eviscerate patent law.” *Mayo*, 566 U.S. at 71; *Alice*, 573 U.S. at 217 (“[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law.”). Unless corrected by this Court, the Commission’s expansive interpretation of what is an “abstract idea” will remain as a misguided and dangerous precedent that could threaten the patentability of many composition of matter patents.

## CONCLUSION

PhRMA respectfully submits that the Court should reverse the Commission's erroneous decision.

May 26, 2023

Respectfully submitted,

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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**Case Number:** 2023-1217

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