21C The Coalition for 21st Century Patent Reform

21C's Comments in Response to USPTO's Request for Comments Relating to Patent Eligibility Jurisprudence and Its Impact on Innovation and Investment

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The Coalition for 21st Century Patent Reform ("21C") is pleased to submit the following comments to the questions posed in the USPTO's Request for Comments published in the Federal Register on July 9, 2021.

21C is a diverse coalition of American manufacturers who invest heavily in research and development of inventions that they manufacture and/or market within the United States. These companies routinely patent their inventions, license patent rights to and from others, and, when necessary, assert their patents against infringers and/or defend against patents asserted against them. Members of 21C are thus on both sides of the "v." in litigation. 21C is led by a Steering Committee that includes 3M, Bristol Meyers Squibb, Eli Lilly, General Electric, Johnson & Johnson, Procter & Gamble, and Raytheon Technologies.

21C believes that it is of critical importance to restore patent eligibility to its traditional scope by closing judicially created loopholes that deny some of the best inventions the patent protection they deserve. 21C strongly supports passage of legislation to: i) eliminate judicially created exceptions to patent eligible subject matter; ii) preclude injecting patentability considerations into patent eligibility determinations; iii) clarify the utility requirement of Section 101; iv) require that, in determining patent eligibility, the claimed invention must be considered as a whole; and v) instruct that Section 101 be construed in favor of eligibility.

21C's answers responding to the USPTO's questions are set forth below:

Section I—Observations and Experiences

1. Please explain how the current state of patent eligibility jurisprudence affects the conduct of business in your technology area(s). Please identify the technology area(s) in your response.

> *21C's Answer:* Current patent eligibility jurisprudence in the United States denies patent protection to key inventions in cutting-edge fields such as artificial intelligence, software, diagnostic methods, and biotechnology. Deficiencies in the law discourage inventors from pursuing research and development in these areas, which are critical to the future

health, prosperity, and well-being of the United States. Under the current state of the law, eligibility findings by courts have become unpredictable, making it difficult for businesses to invest in these technology areas, which are susceptible to eligibility attacks in litigation. This increases the potential for companies to divert funds to other industries or to foreign jurisdictions like China and Europe, where eligibility law is more predictable than in the United States.

2. Please explain what impacts, if any, you have experienced as a result of the current state of patent eligibility jurisprudence in the United States. Please include impacts on as many of the following areas as you can, identifying concrete examples and supporting facts when possible: a. Patent prosecution strategy and portfolio management; b. patent enforcement and litigation; c. patent counseling and opinions; d. research and development; e. employment; f. procurement; g. marketing; h. ability to obtain financing from investors or financial institutions; i. investment strategy; j. licensing of patents and patent applications; k. product development; l. sales, including downstream and upstream sales; m. innovation; and n. competition.

21C's Answer as to part a: Patent eligibility jurisprudence has directly impacted patent prosecution strategy and portfolio management for 21C members. For example, some member companies are not pursuing medical diagnostic claims because they are widely considered patent ineligible under current law.[1] This is particularly true for claims associated with "precision medicine," which entail identification of a biomarker in a given patient and subsequent administration of a drug for treatment. In cases where the drug was known, for example, companies may forgo investment altogether given the uncertainty in the law. This is likely unless there is another type of eligible subject matter, such as a composition-of-matter invention, that presents less uncertainty. The resulting opportunity loss of never developing a new use for a known drug is unquantifiable, potentially depriving patients of present and future benefits of precision medicine.

Uncertainty and unpredictability in Section 101 jurisprudence has also increased the risk of disincentivizing many companies in the large equipment manufacturing industry from protecting various commercially viable software and hardware inventions. For example, data-driven inventions, many of which are challenged under Section 101, are used for remote diagnostics, condition monitoring, equipment management, and automation. These inventions enhance machine and fleet performance, among other benefits. But due to the uncertainties in the application of Section 101, companies frequently deploy these inventions in the stream of commerce without the desired patent protection because they often do not meet the current patentable subject matter eligibility standards outlined by the U.S. Patent Office. Without the economic assurance provided by robust patent protection, these companies face the potential risk of competitors reverse

[1] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Moore, J., dissenting) ("Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible.").

engineering their products and losing the competitive advantages of software-based inventions and novel user-interface functionality.

21C's Answer as to part b: Patents owned by 21C members have been subject to ineligibility attacks in litigation. For example, in *Neptune Generics, LLC v. Eli Lilly & Co.*,[2] a party attempted to raise ineligibility arguments against a method-of-treatment patent—for the first time—during an appeal from an *inter partes* review (IPR) proceeding. According to the patent challenger, subject matter eligibility was properly before the appellate court, in the first instance, purportedly because it was a question of law with no factual issues to be preliminarily decided. The Court of Appeals for the Federal Circuit ultimately declined to address the ineligibility challenge on the merits, concluding that it was outside the proper scope of an appeal from an IPR.[3] Nonetheless, the patent owner was forced to expend valuable resources defending its novel and nonobvious method-of-treatment claims from an attack portraying the patent as improperly claiming a law of nature. This scenario exemplifies the lengths to which patent challengers will go given the uncertainty in patent eligibility jurisprudence, including for method-of-treatment claims. This uncertainty encourages patent challengers to continue using Section 101 attacks as a sword during litigation, often leaving patent owners with little or no effective shield against those attacks.

21C's Answer as to part c-m: At a minimum, under the current state of patent eligibility jurisprudence, some 21C members have been forced to spend time and resources developing patent strategies in the face of significant uncertainty. These resources could be better spent if focused on research, product development, and improved services to ultimately help customers, including patients.

21C members have traditionally partnered with startups after these have reached a certain milestone in the development of promising patent-protected technology. But uncertainty and unpredictability in Section 101 jurisprudence disincentivizes these startups from pursuing technologies for which eligibility is an obstacle to patentability. Without the economic assurance provided by robust patent protection, these companies may forgo research and development in technology areas that have the potential to otherwise result in groundbreaking advances in, for example, artificial intelligence and treatments for diseases. Left without the ability to license robust patents and/or patent applications, small companies and startups are finding it increasingly difficult to secure the investment necessary to conduct "high-risk, high-reward" research and development.

21C's Answer as to part n: The disproportionate impact that the current state of patent eligibility jurisprudence has on small companies or startups in the diagnostic field will ultimately hurt competition. Without strong patent protection, these companies struggle to stay in business, making it that much harder to enter and compete in the market. Although not directly involving a 21C member, the decision in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*[4] is an apt example. Following this decision in which Sequenom lost its

[2] 921 F.3d 1372 (Fed. Cir. 2019).

[3] *Id*. at 1378.

[4] 788 F.3d 1371 (Fed. Cir. 2015).

diagnostic patent due to ineligibility, the company cut its workforce and closed its North Carolina facility. Ultimately, Sequenom was acquired by another company post-litigation. Such consolidation, spurred in part by patent eligibility jurisprudence, will likely limit competition in the diagnostic market. As such, in the areas of precision medicine and diagnostics, startup and small companies will find it increasingly difficult to engage business partners, which will ultimately result in lost opportunities to advance much needed care for patients.

3. Please explain how the current state of patent eligibility jurisprudence in the United States impacts particular technological fields, including investment and innovation in any of the following technological areas: a. Quantum computing; b. artificial intelligence; c. precision medicine; d. diagnostic methods; e. pharmaceutical treatments; and f. other computer-related inventions (e.g., software, business methods, computer security, databases and data structures, computer networking, and graphical user interfaces).

21C's Answer as to part a, b, & f: Some 21C members have an interest in investing in technological fields such as quantum computing, artificial intelligence, and other computer-related inventions. But the uncertainty surrounding Section 101 jurisprudence, which appears to have expanded its reach well beyond these cutting-edge technologies, makes that decision increasingly risky. Although not involving 21C members directly, 21C views with grave concern the outcome in *American Axle & Manufacturing. v. Neapco Holdings*[5] in which certain patent claims directed to a method of manufacturing an automotive drive shaft assembly were found invalid as purportedly being directed to ineligible subject matter. As the dissent in *American Axle* noted, the patent at issue "is the type of traditional manufacturing patent of automotive parts which has been eligible for patent protection since the invention of the car itself."[6] In 21C's view, *American Axle* constitutes "a vast expansion" in Section 101 jurisprudence, which is "bound to cause confusion in future cases."[7]

21C's Answer as to parts c, d, & e: In the areas of precision medicine, diagnostic methods, and pharmaceutical treatments, there have been rapid and significant advances in correlating biomarkers to specific drug treatments or regimens to improve patient outcomes. These advances move away from the traditional "one-size-fits-all" approach for the treatment of diseases toward a targeted approach that matches the best therapy to a particular disease state. For example, diagnostic methods and pharmaceutical treatments may take advantage of the human genome—which is well known in its natural state and thus unpatentable—to target a disease with precision. Yet uncertainty in patent eligibility discourages investment in these areas of technology for fear that courts will deem them laws of nature, natural phenomena, or otherwise patent ineligible subject matter. Furthermore, 21C members note the surge of promising research in technologies that seek to employ endogenous biological mechanisms in innovative drugs and treatments, such as

[5] 967 F.3d 1285 (Fed. Cir. 2020).

[6] *Id.* at 1305-06 (Moore, J. dissenting).

[7] *Id.* at 1319.

gene therapies and mRNA vaccines. Investment in these critical technologies, however, carries undue risk because of the lack of clarity in subject matter eligibility jurisprudence.

4. Please explain how your experiences with the application of subject matter eligibility requirements in other jurisdictions, including China, Japan, Korea, and Europe, differ from your experiences in the United States.

21C's Answer: Foreign jurisdictions such as Japan and Europe, among others, have a more liberal view of subject matter eligibility than the United States. This creates opportunities for foreign companies to exploit those laws and obtain patent protection in their home jurisdictions. In contrast, American companies seeking that same protection in the United States are unable to do so for technologies that have become patent ineligible under the current state of the law. This places U.S. companies at a disadvantage. On the one hand, foreign competitors are free to enter the U.S. market. On the other, those same competitors retain the ability to keep U.S. companies from entering their foreign markets due to more expansive patent protection in those jurisdictions.

5. Please identify instances where you have been denied patent protection for an invention in the United States solely on the basis of patent subject matter ineligibility, but obtained protection for the same invention in a foreign jurisdiction, or vice versa. Please provide specific examples, such as the technology(ies) and jurisdiction(s) involved, and the reason the invention was held ineligible in the United States or other jurisdiction.

21C's Answer: 21C member companies report that they have not been denied patent protection on the basis of subject matter eligibility in foreign jurisdictions; however, 21C is concerned that the United States' leadership position as a strong advocate for robust intellectual property rights is weakened by the current uncertainty in patent eligibility jurisprudence. For example, a patent owned by a 21C member with claims directed to a method for detecting skin defects was the subject of a Section 101 attack in litigation in the United States.[8] As a result, claims of that patent were held invalid as patent ineligible.[9] Notably, however, the foreign counterparts of that patent remain intact in their respective foreign jurisdictions, including, for example, in China and Europe. But the disparity in treatment in the United States vis-à-vis foreign jurisdictions is not limited to 21C member companies. For example, even though the claims of a patent directed to a diagnostic method were held to be patent ineligible in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,[10] the claims of the Australian counterpart were recently held patent eligible by the Australian court that reviewed them.[11]

6. Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to modify or shift investment, research and development activities, or jobs from the

[8] *See, e.g., Procter & Gamble Co. v. QuantifiCare Inc.*, 288 F.Supp.3d 1002, 1006 (N.D. Cal. 2017).

[9] *Id*. at 1030.

[10] 788 F.3d 1371 (Fed. Cir. 2015).

[11] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* [2021] FCAFC 101 (Austl.).

United States to other jurisdictions, or to the United States from other jurisdictions. If so, please identify the relevant modifications and their associated impacts.

> *21C's Answer:* The current state of patent eligibility jurisprudence all but forecloses patent protection for the development of new precision medicines from known drugs, where the patent is directed to a diagnostic method-of-treatment reciting a diagnosis step followed by a treatment step. Accordingly, in many instances, 21C member companies are no longer seeking patents directed to diagnostic methods in the United States, negatively impacting the development of new precision medicines in the United States.

7. Please explain whether the state of patent eligibility jurisprudence in the United States has caused you to change business strategies for protecting your intellectual property (e.g., shifting from patents to trade secrets, or vice versa). If so, please identify the changes and their associated impacts.

> *21C's Answer:* In the life sciences, companies working on transformational early-stage treatments for new diseases, or new mutations of old diseases, are either not pursuing patent protection or keeping ideas as trade secrets. This trend is due in great measure to concerns or beliefs that those ideas are too fundamental and will fall outside of patent protection as abstract ideas, natural phenomena, or laws of nature. Similarly, in large equipment manufacturing and deployment, trade secret protection has become the primary mode of protection given the confusion in patent eligibility law. Foregoing patent protection has a devastating impact on the future pipeline of products across industries, including medical treatments, sometimes with life or death consequences for the American people.

8. Please explain whether you have changed your behavior with regard to filing, purchasing, licensing, selling, or maintaining patent applications and patents in the United States as a result of the current state of patent eligibility jurisprudence in the United States. If so, please describe how you changed your behavior.

> *21C's Answer:* 21C members have had to change their patent filing practices in the United States as a direct result of the current patent eligibility jurisprudence. Some companies are no longer pursuing certain categories of patent protection (e.g., medical diagnostics claims) in the United States because they have been generally deemed patent ineligible under the law. Similarly, some companies in the large equipment manufacturing industry that use data-driven inventions to enhance machine and fleet performance are forgoing patent protection for certain innovations because of the uncertainties stemming from the existing patent eligibility law.

9. Please explain how, in your experience, the status of patent eligibility jurisprudence in the United States has affected any litigation for patent infringement in the United States in which you been involved as a party, as legal counsel, or as another participant (e.g., an expert witness). For example, please explain whether this jurisprudence has affected the cost or duration of such litigation, the ability to defend against claims of patent infringement, the certainty/uncertainty of litigation outcomes, or the likelihood of settlement.

21C's Answer: In the last several years, patent owners in the United States, including 21C members, have faced increased attacks based on patent eligibility.[12] The disarray in Section 101 jurisprudence creates an incentive for accused infringers to challenge patent eligibility throughout litigation. But the lack of certainty in outcomes makes it difficult for parties on either side of the "v." to predict with a reasonable degree of certainty whether such attacks are likely to succeed. As such, Section 101 jurisprudence introduces inefficiencies in the patent litigation system.

Section II—Impact of Subject Matter Eligibility on the General Marketplace

10. Please identify how the current state of patent eligibility jurisprudence in the United States impacts the global strength of U.S. intellectual property.

21C's Answer: Uncertainty in patent eligibility jurisprudence weakens the standing of the United States' leadership as an advocate for robust intellectual property rights. This jurisprudence is eliminating entire categories of patents, including, for example, diagnostic methods.[13] Importantly, foreign jurisdictions look to the United States as a leading signatory of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) to serve as a model for meeting the requirements set forth in the agreement. But because certain categories of inventions have been deemed patent ineligible in the United States, foreign jurisdictions are emboldened to categorically deny patents in contravention of TRIPS.

11. Please identify how the current state of patent eligibility jurisprudence in the United States impacts the U.S. economy as a whole.

21C's Answer: By eliminating entire categories of patentable subject matter, current eligibility law in the United States disincentivizes companies from pursuing research and development in areas of technology that may prove critical to the continued growth of the U.S. economy. For these affected technologies, which include diagnostic methods, precision medicine, and computer-related inventions, effective patent protection is often necessary to secure investment. Thus, removing the uncertainty that currently plagues patent law eligibility is of critical importance.

12. Please identify how the current state of subject matter eligibility jurisprudence in the United States impacts the global strength of U.S. intellectual property and the U.S. economy in any of the following areas: a. Quantum computing; b. artificial intelligence; c. precision medicine; d. diagnostic methods; e. pharmaceutical treatments; and f. other computer-related inventions (e.g., software, business methods, computer security, databases and data structures, computer

[12] *See, e.g., Procter & Gamble*, 288 F.Supp.3d at 1006 (dismissing-in-part patent infringement lawsuit due to invalidity of claims under Section 101).

[13] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1352 (Moore, J., dissenting) ("Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible.").

networking, and graphical user interfaces). In responding to this question, please provide concrete examples and supporting facts when possible.

> *21C's Answer as to part a, b, and f:* Many U.S. companies, including 21C members involved in equipment manufacturing, have a strong interest in investing in emerging technologies such as autonomous vehicles, connectivity, machine learning, artificial intelligence, and electrification, among others. The uncertainty in Section 101 jurisprudence, however, makes this investment decision significantly more challenging. At its core, algorithms are the backbone of these applications, but when deemed ineligible for patent protection, companies must decide whether to spend additional resources to implement other technologies and patent around that roadblock, often requiring proprietary hardware components.

> *21C's Answer as to part c, d, and e:* Current jurisprudence has all but eliminated certain categories of patent protection in the life sciences—most notably, diagnostic methods. Lack of patent protection may stifle the incentive for innovation in this field. But diagnostic methods have an outsized impact on the U.S. economy, with potentially significant resources being spent on unnecessary services and other inefficiencies that could be avoided with improved methods of diagnosis.

13. Please identify how the current state of patent eligibility jurisprudence in the United States affects the public. For example, does the jurisprudence affect, either positively or negatively, the availability, effectiveness, or cost of personalized medicine, diagnostics, pharmaceutical treatments, software, or computer-implemented inventions?

> *21C's Answer:* A patent regime that does not protect innovations in diagnostic medicine likely stifles the development of those innovations, leading to significant reductions in their availability for the general public. The lack of early diagnoses for otherwise treatable conditions, in turn, increases the cost of personalized medicine at a time when the cost of healthcare is a pressing concern for Americans. Additionally, almost all economic sectors rely on computers and software to maintain a high level of productivity. A failure to protect these inventions may discourage further innovation, with potential ripple effects throughout the U.S. economy. Finally, we should not forget the purpose of the patent system. The right to exclude others from practicing the patented invention for a limited period of time is granted not only to reward inventors for their contributions, but also so that these technical advances will later enter the public domain and be shared with the public for all to use once the patent expires. With such uncertainty in the eligibility of certain inventions for patenting, innovators will keep inventions as trade secrets whenever possible, thus frustrating the constitutional purpose of the patent system.