July 26, 2021

The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear President Biden:

The Coalition for 21st Century Patent Reform ("21C") is a diverse coalition of American manufacturers who rely on patents to protect their inventions and the products based on those inventions. 21C members invent, develop and manufacture products protected by patents, license patents to and from others in furtherance of their business activities, and, when necessary, assert their patents against infringers and/or defend against patents asserted against them.

21C believes that a strong, predictable U.S. patent system is necessary to the health, prosperity, and long-term success of our country. Unfortunately, however, our patent system is now denying patents to cutting-edge inventions that are routinely granted protection in China, Europe and elsewhere. It is imperative, as a matter of national economic competitiveness in the technologies of the future, that the availability of high-quality, reliable U.S. patent protection be restored.

Accordingly, we join with the many organizations, individuals and others who have recently written to you in supporting strengthening our patent system through patent eligibility reform. This reform is desperately needed to ensure consistent and predictable application of the laws regarding patent validity and restore patent eligibility to its traditional scope by closing judicially-created loopholes that deny some of our most important and cutting edge U.S. technology innovations the patent protection they deserve. A quartet of recent Supreme Court decisions (*Mayo, Myriad, Bilski and Alice)* has not only substantially restricted the scope of patent-eligible subject matter in the United States to far less than that of our major trading partners, but has created enormous uncertainty as to what subject matter is or is not eligible for patenting. This has seriously decreased the incentives for U.S. investment in research and development in some of our most promising fields, such as artificial intelligence, personalized medicine, therapeutic biologics and advanced diagnostics.

This impact to our nation's innovation policies has been engineered by the judiciary, not by statute. The statute itself describes what is eligible in very clear and concise terms:

> …any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof…[1]

And when it was passed, the House & Senate reports on the 1952 Patent Act were clear in that Section 101 was intended to be broad, encompassing "anything under the sun that is made by man," provided the other conditions for patentability (such as novelty, non-obviousness, enablement, and sufficient written

[1] 35 U.S.C. §101.

description) are fulfilled.[2] Nonetheless, in the recent cases mentioned above, the Supreme Court has restricted patent eligibility for a wide range of software, computer implemented, medical diagnostic, and biotechnology inventions. The Court has done so by stretching its interpretation of three judicially-created exceptions to Section 101 – "abstract ideas," "laws of nature," and "natural phenomenon" – and also by conflating Section 101's requirements for patent eligibility with separate and distinct patentability requirements of other Patent Act provisions. The result is jurisprudence that is vague, unpredictable, internally inconsistent, and impossible to apply uniformly.

Lower courts trying to apply this muddled case law are struggling to produce consistent results. Patent lawyers trying to advise inventors and innovators are, in turn, struggling to counsel on what technologies are patent eligible. The current standards are difficult for all: stakeholders, courts, examiners, practitioners, and investors alike. These cases have confounded the USPTO's job of examining patents, as well as the lower courts' ability to distinguish clearly and consistently between those inventions that are directed to patent-eligible subject matter from those that are not. The burdens of uncertainty ultimately fall upon those we need the most: the inventive community that fuels our nation's innovation ecosystem. And while the constitutional mandate for the patent system -- to "promote the progress of science and useful arts"[3] is being undermined in fields that are becoming more and more important as the 21st century progresses their counterparts in other countries face no such obstacles and work on inventing the future

To remedy this critical problem, the undersigned organizations join the IP community at large in calling on your Administration to support legislation to undo this judicially created morass and to return to a simple, more objective, and more straightforward approach to defining patentable subject matter, as all three of the major U.S. IP bar associations (AIPLA, ABA-IPL and IPO) recommend.[4]

Respectfully submitted,

Phillip S. Johnson
Chairman, 21C Steering Committee

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[2] The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S Rep. No 1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep. No. 1979, 82d Cong., 2d Sess., 6 (1952). Cited with approval in *Diamond v* Chakrabarty, 447 U.S.309 (1980).

[3] U.S. Const. Art. I, § 8, cl. 8.

[4] Both the IPO and AIPLA have proposed similar, straight-forward language to solve this problem. AIPLA's text would revise 35 USC 101 to read:

> **(a) Eligible Subject Matter.—**Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title.
>
> **(b) Sole Exceptions to Subject Matter Eligibility.—**A claimed invention is ineligible under subsection (a) only if the claimed invention as a whole exists in nature independent of and prior to any human activity, or can be performed solely in the human mind.
>
> **(c) Sole Eligibility Standard.—**The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to the requirements or conditions of sections 102, 103, and 112 of this title, the manner in which the claimed invention was made or discovered, or whether the claimed invention includes an inventive concept.