The Coalition for 21st Century Patent Reform

2019 Agenda for Patent Reform

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

21C believes that a strong U.S. patent system is essential to American innovation and is the key to the future prosperity of our country. 21C agrees with Director Iancu that the importance of restoring high-quality, reliable U.S. patent protection is a fundamental question of national innovation policy that should be a bi-partisan priority deserving of immediate attention amongst all three branches of our government. If done right, patent reforms will stimulate the private sector to invest in innovation, economic development, and job growth.

21C proposes that Congress, the USPTO, and the courts focus their attentions on the following priorities:

1. **Restore patent eligibility to its traditional scope by closing judicially-created loopholes that deny some of our best biotechnology and software inventions the patent protection they deserve.**

2. **Fix the USPTO inter partes review proceedings to create the fair balance Congress originally intended.**

3. **Ensure that our patent system secures for a limited time inventors' exclusive rights to their discoveries by: (a) making injunctions reasonably available to stop continuing U.S. patent infringement, (b) limiting prior art to publicly accessible information as the AIA intended, and (c) providing patentees a reasonable expectation of quiet title to their granted patents.**

4. **Restore the right of patent owners to sue infringers in their home districts.**

5. **Restore the right of U.S. manufacturers to use their U.S. patents to sue unlicensed foreign imports by reversing the Supreme Court Decision in *Lexmark*.**

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An Agenda for Patent Reform

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

21C believes that a strong U.S. patent system is essential to American innovation and is the key to the future prosperity of our country. As Thomas Friedman has written, the country that "endows its people with more tools and basic research to invent new goods and services … is the one that will not just survive but thrive down the road. …. We might be able to stimulate our way back to stability, but we can only invent our way back to prosperity."[1]

Unfortunately, the U.S. patent system has not fared well over the past decade. As current United States Patent and Trademark Office ("USPTO") Director Andrei Iancu explains:

> [T]oday, our patent system is at a crossroads. For more than just a few years, our system has been pushed and pulled, poked and prodded. The cumulative result is a system in which the patent grant is less reliable today than it should be. This onslaught has come from all directions. There has been major reform legislation, and proposed legislation. There have been massive changes brought about by major court cases. And the USPTO itself has taken a variety of actions in an effort to implement these changes. Plus, importantly, the rhetoric surrounding the patent system has focused relentlessly on certain faults in, or abuses of, the system—instead of the incredible benefits the system brings to our nation.[2]

21C agrees with Director Iancu that the importance of restoring high-quality, reliable U.S. patent protection is a fundamental question of national innovation policy that should be a bi-partisan priority deserving of immediate attention amongst all three branches of our government. If done right, patent reforms will stimulate the private sector to invest in innovation, economic development, and job growth.

With these objectives in mind, 21C proposes that Congress, the USPTO, and the courts focus their attentions on the following priorities:

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[1] Friedman, Thomas L., "Invent, Invent, Invent," New York Times, June 27, 2009

[2] "Role of U.S. Patent Policy in Domestic Innovation and Potential Impacts on Investment," Keynote Address, April 11, 2018, https://www.uspto.gov/about-us/news-updates/remarks-director-andrei-iancu-us-chamber-commerce-patent-policy-conference

1. **Restore patent eligibility to its traditional scope by closing judicially-created loopholes that deny some of our best biotechnology and software inventions the patent protection they deserve.**

A quartet of recent Supreme Court decisions (*Mayo, Myriad, Bilski and Alice)* has restricted substantially the scope of patent-eligible subject matter in the United States to far less than that of our major trading partners. This risks decreasing incentives for U.S. investments in research and development in some of our most promising fields, such as artificial intelligence, personalized medicine, and therapeutic biologics.

These developments, which profoundly impact our nation's innovation policies, are created wholly by the judiciary, not by statute. When passed, the House & Senate reports on the 1952 Patent Act were clear in that Section 101, which defines what subject matter is eligible to be considered for patent protection, 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 description) are fulfilled.[3] Nonetheless, in the recent cases mentioned above, the Supreme Court has upset settled law by restricting 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 the judicially-created exceptions to Section 101 – "abstract ideas," "laws of nature," and "natural phenomenon" – and also by conflating the interpretation of Section 101's requirements for patent eligibility with separate patentability requirements of other Patent Act provisions. The result is jurisprudence that is vague, unpredictable, internally inconsistent, and impossible to apply uniformly.[4] As Director Iancu explains:

> [O]ur current law surrounding patentable subject matter has created a more unpredictable patent landscape that is hurting innovation and, consequently, investment and job creation. Recent cases from the Supreme Court – Mayo, Myriad, and Alice – have inserted standards into our interpretation of the statute that are difficult to follow. Lower courts applying these cases are struggling to issue consistent results. Patent lawyers trying to advise their clients are, in turn, struggling to predict the outcome with respect to certain patents. And examiners at the USPTO must spend increased amounts of time addressing this challenging issue. The current standards are difficult for all: stakeholders, courts, examiners, practitioners, and investors alike.[5]

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. As such, 21C joins the IP community at large in calling for legislation to overrule these cases and to substitute 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) now recommend.[6]

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[3] 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).

[4] *See* Proposed Amendments to Patent Eligible Subject Matter Under 35 U.S.C. § 101 available at www.ipo.org

[5] Iancu, Keynote Address, supra.

[6] 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:

2. Fix the USPTO Inter Partes Review proceedings to create the fair balance Congress originally intended.

Created by the American Invents Act (AIA) and having begun in 2012, Inter Partes Reviews ("IPRs") were intended to be faster, lower cost alternatives to district court litigation. The concept was that members of the public could request that the USPTO Director decide whether a newly created board of administrative law judges within the USPTO, the Patent Trial and Appeal Board ("PTAB"), should consider the limited issue of whether a patent's claims were anticipated or made obvious in view of the disclosure(s) of prior patents or printed publications. Congress envisioned that, if and when instituted by the Director, these proceedings would be conducted fairly and inexpensively, be concluded within 12-18 months, and result in avoiding more expensive district court litigation. Importantly, Congress never intended that IPRs would routinely make district court patent cases more protracted, lengthy and difficult to resolve, nor that IPRs would be tilted against patent owners in ways that make it significantly easier to invalidate patents than ever before.

Unfortunately, as implemented by the USPTO, IPRs are frustrating Congress's intentions. Instead of serving as alternatives to district court litigation, about 85% of all filed IPRs are filed as adjuncts to already pending litigation,[7] often extending the course of that litigation by 2 years or more and running up the total cost of patent enforcement and IPR defense to beyond the reach of many patentees. Moreover, instead of having the Director act as gatekeeper to prevent the institution of unnecessary, harassing, and/or duplicative proceedings, as Congress intended, implementing regulations were adopted that bypass the Director altogether – charging the same panel of PTAB judges to decide not only if the proceeding should be instituted, but also its final outcome. Not surprisingly, such panels rarely conclude that their initial determinations were mistaken and thus find one or more of the challenged patent claims to be invalid in about 85% of their final decisions.[8]

As a result, almost four times the number of IPRs have been instituted than were originally projected – most of them duplicating issues that are already being considered by a court or that were previously decided in favor of the patent owner by a court or the USPTO.[9] Even worse, the failure of the USPTO to implement Congress' intended patent owner safeguards, coupled with pro-challenger PTAB procedures,

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(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.

[7] Fitzpatrick Cella, "Just the Stats: Percentage of IPRs With A Concurrent Litigation," https://postgranthq.fitzpatrickcella.com/statistics/percentage-iprs-concurrent-litigation/

[8] "Are More Than 90 Percent of Patents Challenged at the PTAB Defective?", IP Watchdog, June 14, 2017, available at http://www.ipwatchdog.com/2017/06/14/90-percent-patents-challenged-ptab-defective/id=84343/

[9] And as of 6/30/16, of the 5,173 IPR's and CBM's filed, 2,555 (49.3%) were at least second challenges of a patent that was or is already the subject of a prior IPR.

now result in most IPRs being instituted at the request of patent challengers and about 70% of all patents subject to an IPR final decision are being completely invalided.[10]

As a result, IPRs have greatly undermined the reliability of patent rights and the ability of 21C member companies and other innovators to rely on patents to protect the investments needed to turn an invention into a business. Many patent owners simply cannot afford the cost and risk of defending their rights against challenges, which now routinely come from those alleged to be infringing in a concurrent court proceeding, as well as by "patent killing" organizations created to protect those defendants by filing IPRs on their behalf once they are charged with infringement.

21C believes that striking the right balance in USPTO IPR proceedings is a key to their long-term success and to appropriately incentivize American innovation. 21C strongly supports efforts to revise how and when these proceedings are instituted, the standards the USPTO employs during the proceedings, and how the USPTO conducts the proceedings. Many, but not all, of these problems may be corrected by the USPTO itself through rulemaking. A prime example is the USPTO's recent rulemaking conforming claim construction in IPRs to the *Phillips* standard used by the courts.

21C believes that additional rulemakings are needed to address other imbalances in IPR proceedings. The USPTO should ensure that the burden of proof remains on the petitioner throughout the proceeding, as required by statute and Federal Circuit precedent. Moreover, the Director may use his substantial discretion to create a set of factors to be considered when deciding whether an IPR petition should be instituted. A finding of one or more of these factors would provide the presumptive basis to decline to institute an IPR. Examples of such factors include situations where the patent holder (or its licenses) has substantially invested in the technology; the petition is primarily based on evidence not found in a "patent or printed publication;" there is an existing statutory mechanism to adjudicate the patent in question (e.g., the patent is eligible for adjudication via Abbreviated New Drug Application ("ANDA") or Biologics Price Competition and Innovation Act ("BPCIA") litigation); the patent has been subject to a prior IPR or federal court decision; or the petition is based on the same or substantially the same information previously considered by the USPTO in a prior proceeding (which would also improve patent quality by incentivizing applicants to ensure that the best art is before the patent office). An additional appropriate factor to be considered is the length of time over which the patent has been issued without challenge. These reforms, and others, would help address the substantial concerns that stakeholders have expressed with an IPR system that has drifted from the AIA's original intent and undermined confidence in the U.S. patent system.

Other problems with IPR proceedings will require legislation to correct aspects of the America Invents Act that have been proven by experience to have been unwise. One that would benefit from review is the statutory adoption of a lower standard of proof for use in these proceedings than that applicable in the courts, meaning that a patent determined to be valid in the courts – even after years of litigation, including a full trial, and even after appeal to the Federal Circuit – may nonetheless be determined to be invalid in the USPTO.[11] Another is the elimination of the former right of an aggrieved patent owner to seek review from contested USPTO proceedings *de novo* by a district court, where otherwise unavailable evidence may be adduced through discovery and where credibility determinations will be made on the

[10] "Are More Than 90 Percent of Patents Challenged at the PTAB Defective?", *Ibid.*

[11] Congress should review whether the Supreme Court's sanctioned standard of "clear and convincing evidence" should be required in both the USPTO and courts to invalidate a claim of a patent. In addition, the USPTO IPR & PGR proceedings would improve if the standards, presumptions, burdens and ethics applicable in the Federal Courts applied equally to USPTO PTAB judges.

basis of live testimony before an independent Article III judge rather than by administrative patent judges working only off a written evidentiary record.[12] For IPR decisions that are appealed to the Federal Circuit in the first instance, a further needed change is to enhance the scope of appellate review by adopting the "clearly erroneous" standard, rather than the (currently ineffective) "substantial evidence" standard. Finally, changes explicitly protecting patent owners from IPRs brought by parties without standing are needed to curb the rise of "gang tackling" by patent challengers filing multiple petitions against the most valuable patents, as is protection against having a patent attacked more than once in an IPR by the same petitioner or those in privity with that petitioner.

3. Ensure that our patent system secures for a limited time inventors' exclusive rights to their discoveries by: (a) making injunctions reasonably available to stop continuing U.S. patent infringement, (b) limiting prior art to publicly accessible information as the AIA intended, and (c) providing patentees a reasonable expectation of quiet title to their granted patents.

The traditional rights and remedies which attach to a valid U.S. patent, including the right to the entry of an injunction to stop continuing patent infringement, are based on Article I, Section 8 of the U.S. Constitution, which specifies that Congress should "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." Nonetheless, the Supreme Court has largely denied enforcement of the inventor's "exclusive Right" by endorsing the use of limiting equitable considerations to routinely deny injunctions to patentees.[13] Moreover, while long-standing statutes recognize issued U.S. patents as personal property (35 USC 261), Supreme Court has recently endorsed an ill-advised "public franchise" view of patent rights which now facilitates duplicative, harassing attacks on patent validity, dramatically diminishing the value and reliability of U.S. patents.[14] Perhaps most troubling is the Supreme Court's recent *Helsinn* decision, which unintentionally created of a vast new class of worldwide secret "on sale" and "commercial use" prior art never intended by the America Invents Act. *Helsinn*-created prior art now poses the threat of invalidating thousands of U.S. patents based on secret commercial activities that took place anywhere in the world.[15] As a result, the intended incentives to be provided by our patent system have been severely diminished, and inventors may no longer expect that they will ever enjoy quiet title to their U.S. patents.

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[12]Prior to the AIA, 35 USC 146 allowed aggrieved parties in contested USPTO proceedings, such as interferences, to appeal first to a district court, where additional evidence could be adduced through discovery. Patent owners in USPTO IPR & PGR proceedings have very little right to any discovery, and no ability to compel witnesses to testify on their behalf. Experience has shown that these time-honored rights are important to ensuring the fairness of the outcomes in IPR & PGR proceedings. In addition, as such appeals will dispose of many IPRs at the district court level, the very large number of IPR appeals now going directly to the Federal Circuit will be reduced.

[13] *eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006)*

[14] *Oil States Energy Services v Greene's Energy Group,* __U.S. ___(2018).

[15] *Helsinn Healthcare v Teva Pharma*, __ U.S. __ (2018); *see* Sauer, " Why Helsinn v. Teva Creates Inscrutable Uncertainty About the Scope of Prior Art Instead of Confirming Longstanding Law" available at http://www.ipwatchdog.com/2019/02/05/helsinn-v-teva-creates-inscrutable-uncertainty-scope-prior-art-instead-confirming-longstanding-law/id=105953/#.XFrAvGw0EwQ.email.

4. Restore the Right of Patent Owners to Sue Infringers in their Home Districts.

For the first time in decades, the recent decision in *TC Heartland* now restricts venue in patent infringement cases to those cases brought in districts where the defendant resides or has a regular and established place of business and has committed acts of infringement.[16] In doing so, *TC Heartland* overly restricts venue to preclude patent owners from bringing patent actions in their home districts.

The one-sided, defendant-only perspective on venue in patent cases (above and beyond the statutory and constitutional protections defendants already have under personal jurisdiction requirements to ensure that they are not forced to litigate in locations that would be unfair or inconsistent with due process) that the *TC Heartland* decision reflects threatens the ability of all patent owners to seek relief from infringement in their home districts. The defendant-focused imbalance goes well beyond what is needed to prevent venue "gamesmanship" by some patent owners and is unfair to the majority of patent owners who sometimes must bring suit to protect their investments in R&D, products, and businesses built upon their patented inventions from infringement. Even for patent owners who have made enormous R&D and manufacturing investments in their home districts, they often will not be able to seek judicial protection of those investments where they are located and will be forced to bring suit where the infringer resides. This undermines legitimate patent owner interests in seeking relief from infringement in their home districts, even when that is where relevant business activities, witnesses and evidence, and the harm from the infringement are all focused. Protection of a defendant's interests is and should be accomplished through personal jurisdiction law, not venue. Sound venue law and policy should focus instead on ensuring that litigation takes place in a convenient forum, and in determining convenience, it is neither fair nor good policy to ignore the interests of all innovators and patent owners.

Accordingly, 21C supports expanding patent venue to authorize U.S. patent owners (a) to assert their patents in venues where technological activities relating to the invention that led to the application for the patent(s)-in-suit – such as inventing, substantial research and development, or manufacturing – have taken place or (b) where a plaintiff or a subsidiary has a regular place of business, not operated primarily for the purpose of creating venue, that is engaged in substantial: (i) management of research and development or manufacturing activities for a product or process related to the patent or patents in dispute; (ii) research and development of a product or process related to the patent(s) in dispute; or (iii) manufacturing activities of a product or process related to the patent(s) in dispute.[17]

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[16] *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017).

[17] This proposal has broad cross-industry support, having been adopted as a resolution by the IPO in 2015, worded as follows:

> **[Venue in Patent Suits]** — *RESOLVED*, that IPO confirms its support for legislation to limit venue in patent suits in order to curb forum shopping by patent owners and, specifically, IPO supports an amendment to 28 U.S.C. § 1400(b) to limit venue to a judicial district as follows:
>
> (A) In a patent infringement action brought by a patent owner against an accused infringing defendant, venue should be limited to a judicial district:
>
> 1. where the defendant has its principal place of business or is incorporated, or if the defendant is an individual, where the defendant resides;
> 2. where the defendant has committed acts of infringement and has a regular and established physical facility where defendant's acts of infringement have occurred;
> 3. where technological activities relating to the invention that led to the application for the patent(s)-in-suit – such as inventing, substantial research and development, or manufacturing – have taken place;
> 4. where a plaintiff or a subsidiary has a regular place of business, not operated primarily for the purpose of creating venue, that is engaged in substantial: (a) management of research and development or manufacturing activities for a product or process related to the patent or patents in dispute; (b) research and development of a

5. Restore the right of U.S. manufacturers to use their U.S. patents to sue unlicensed foreign imports, by reversing the Supreme Court Decision in *Lexmark*.

In its recent decision in *Impression Products v. Lexmark*,[18] the Supreme Court decided that the sale outside of the United States of a product or process that happens also to have been patented within the United States exhausts all of the U.S. patent owner's U.S. patent rights for the product sold. As a result, a foreign manufacturer who is licensed by an innovator to sell a product in a given foreign country under the innovator's foreign patent in that country now also exhausts the innovator's U.S. patent in the product sold, even if the seller is not licensed to sell those products in the U.S. This remains true even if the innovator has given an exclusive license under its U.S. patent to a different party, which means that patent owners may no longer effectively enter into agreements protecting regional licensees from unlicensed cross-border competition. This interpretation turns decades of patent precedent on its head and places U.S. patent owners and their businesses at a severe worldwide competitive disadvantage.

For decades, it has been common to directly export and/or license foreign entities to market goods and services in specified regions, allowing them to set prices for these products to meet local demand. Many factors influence the value of products in different markets, including the local value of the product, its utility, the value of the local currency and funding to purchase the product, and the nature of local competitive alternatives. It is therefore advantageous to allow local suppliers to adjust product pricing to foster widespread adoption of their product offerings and widespread adoption of the patented technology.

Patents have long aided businesses in establishing such market price differentiation and have fostered U.S. competitiveness by allowing the down-pricing of products in markets which otherwise would not support the same pricing as elsewhere. By licensing foreign suppliers in a given market under the local patents applicable in the respective jurisdiction, those suppliers are encouraged to invest in developing their market through advertising, training, customer service, product support, and other commercialization activities without fear that others not licensed to sell in that region will attempt to piggyback on their efforts by engaging in unauthorized cross-border competition.

The Supreme Court has now upset countless licensing arrangements dealing with the manufacturing, supply, distribution, and sale of thousands of products and processes covered by U.S. patents. While some appear to think that the Supreme Court's decision will lead to the lowering of U.S. prices for those products, in fact, the opposite is most likely. U.S. manufacturers and their licensees will now find it more difficult to down price their products in foreign countries to meet local demand for fear that local

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product or process related to the patent(s) in dispute; or (c) manufacturing activities of a product or process related to the patent(s) in dispute;

5. where the defendant has agreed or consented to be sued in the instant action; or
6. where, for foreign defendants that do not meet any of the above, venue would be proper according to 28 U.S.C. § 1391(c)(3).

(B) In a declaratory judgment action brought against a patent owner, venue should be determined according to 28 U.S.C. § 1391.

(C) In considering a motion to transfer venue involving a retailer that sells consumer products alleged to infringe the patent(s)-in-suit, the location of such retail sales should be afforded no weight in deciding the transfer motion if they occur in all of the judicial districts under consideration.

[18] 581 U.S. 1523 (2017).

purchasers will then simply buy them for shipment into the U.S. or other higher priced markets. Without the ability to down price in foreign markets, foreign sales will be discouraged. As a result, the capital investment made in R&D and manufacturing infrastructure will need to be amortized over the smaller sales base remaining in the U.S. (and other countries where the products can be comparably priced). This increased amortization will add to the costs of goods sold in the remaining markets, tending to drive prices up, not down. The net result is also likely to be the loss of jobs in U.S. manufacturing organizations as the overall demand for U.S. patented goods falls overseas.

Fortunately, the fix for this problem is straightforward: reversal of the Lexmark decision by adopting a statutory provision providing that the first sale of a product outside of the United States, whether or not made or authorized by a United States patentee, shall not exhaust that patentee's United States patent rights in the product sold. The statute could simply state that a "sale of a product outside of the United States, by a United States patent owner or its parent, subsidiary, affiliate, or authorized licensee, shall not exhaust the patent owner's United States patent." Of course, consumers and other end users may be protected by providing that "end-use consumers who purchase a product when they are outside the United States shall be permitted to continue their non-commercial uses of that product within the United States."