The Coalition for 21st Century Patent Reform

2023 Agenda for Patent Reform -- Executive Summary

The Coalition for 21st Century Patent Reform ("21C") is a diverse coalition of American companies who rely on patents to protect their inventions. 21C members 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 U.S. patent system is necessary for the health, prosperity, and long-term success of our country. The U.S. patent system, once the envy of the world, no longer compares favorably with systems in Europe and Asia which allow and encourage the patenting of broader subject matters, and in which injunctions are routinely available to encourage voluntary licensing and/or to stop infringement. 21C believes that bipartisan patent reform is needed to level the playing field with China and to protect our domestic manufacturers from foreign imitations of U.S. patented products.

Future U.S. innovation depends upon the willingness of private investors to continue to invest in and develop new inventions here. U.S. government sponsored research alone is simply not enough. Inventions made and patented elsewhere are unlikely to be manufactured in the U.S. and more likely to prevent U.S. products from successfully competing in foreign markets. If done right, U.S. patent reform will fuel the investment, economic development, and job growth that is needed to secure our country and return it to its traditional position as the world's technological leader. With these objectives in mind, 21C proposes that Congress, the USPTO, and the courts focus their attentions on the following priorities:

1. *Make needed changes to USPTO procedures to ensure that granted U.S. patents will enjoy quiet title throughout their statutory terms and will not be taken away from patent owners without due process of law. Such changes should include provisions to reduce serial or duplicate inter partes reviews (IPR), to deny IPR petitions based on the same or substantially same information previously considered by the USPTO or the district courts, and to ensure that all decisions of the PTAB will be effectively reviewed de novo by Article III judges.*

2. *Restore patent eligibility to its traditional, Constitutionally-appropriate scope by abrogating the judicially-created exceptions that now deny patent protection for inventions of processes, machines, manufactures and compositions of matter that have practical utilities, including but not limited to high quality inventions in the fields of diagnostics, biotechnology, and software.*

3. *Ensure that our patent system secures inventors exclusive rights to their inventions for limited periods of time by making injunctions available to stop patent infringement unless the grant of an injunction under the particular circumstances would be clearly contrary to the public interest.*

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

5. *Overturn (a) the Supreme Court's Lexmark decision to restore the right of U.S. manufacturers to use their U.S. patents to sue unlicensed foreign imports and (b) the Supreme Court's Helsinn decision to require that prior art be limited to publicly accessible information, as the AIA intended.*

21C The Coalition for 21st Century Patent Reform

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The Coalition for 21st Century Patent Reform ("21C") is a diverse coalition of American manufacturers who rely on patents to protect their inventions. 21C members develop and manufacture products protected by those 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 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. Past United States Patent and Trademark Office ("USPTO") Directors from both the Obama and Trump administrations, David Kappos and Andrei Iancu, agree that key USPTO functions, such as the post-grant proceedings introduced by the 2011 America Invents Act (AIA), are not working as intended.[2,3] Independent observers, such former Federal Circuit Judges Kathleen O'Malley and Paul Michel agree. Judge O'Malley, for example, points out that U.S. patent rights are now uncertain, and that international observers now see the U.S. IP system as weak:

> I believe that there's a lot wrong with our IP system, and that there are a lot of things that we could try to fix and make it stronger, more robust for everybody, both patent holders and accused infringers, so that people have a more clear sense of what their obligations are or what their rights are. We'd have a stronger position in the international community. I've done a lot of international work and I have a lot of friends in the international space, especially other judges. Their perception is that we've gone from the strongest IP jurisdiction to just about the weakest.[4]

As Chief Judge Michel points out "The assumptions of Congress on point after point [with respect to the AIA's post-grant proceedings] have turned out to be wrong…[Congress] should revisit the entire situation."[5] These views are also reinforced by the Government Accountability

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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

[3] "Kappos at PTAB Masters 2023: The PTAB Simply 'Hasn't Worked Out' as Intended," February 2, 2023, IP Watchdog, Kappos at PTAB Masters 2023: The PTAB Simply 'Hasn't Worked Out' as Intended (ipwatchdog.com)

[4] "Judge Kathleen O'Malley reveals inner thoughts on 101, PTAB reforms, patent injunctions and more" IAM, 11 March 2022, available at Judge Kathleen O'Malley reveals inner thoughts on 101, PTAB reforms, patent injunctions and more - IAM (iam-media.com)

[5] *Id.*

Office (GAO), which found that 75% of the 200+ PTAB judges GAO surveyed said their independence was affected by USPTO officials and PTAB management, thereby underscoring the biased nature of these proceedings.[6]

21C agrees that the importance of restoring high-quality, reliable U.S. patent protection is a foundational part of a successful national innovation policy. It should be a bi-partisan priority deserving immediate attention from 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. Overarching principles to achieve this goal include ensuring that all patents issued by the USPTO be of high quality, that we maintain a unitary system that does not discriminate by technology or inventor/owner identity, and that the procedures for enforcing patents against infringers are fair and efficient.

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

> *1. Make needed changes to USPTO procedures to ensure that granted U.S. patents will enjoy quiet title throughout their statutory terms and will not be taken away from patent owners without due process of law. Such changes should include provisions to reduce serial or duplicate inter partes reviews (IPR), to deny IPR petitions based on the same or substantially same information previously considered by the USPTO or the district courts, and to ensure that all decisions of the PTAB will be effectively reviewed de novo by Article III judges.*

Created by AIA, *Inter Partes* Reviews ("IPRs") and Post Grant Reviews (PGRs) 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 based on prior art consisting only of the disclosure(s) of prior patents or printed publications. Congress hoped that IPRs and PGRs could then serve as an alternative, not an adjunct, to civil litigation and that, if instituted by the Director, these proceedings would be conducted fairly and inexpensively and be concluded within 12-18 months, such that more expensive district court litigation could be avoided. Congress never intended that IPRs would routinely make district court patent cases more protracted, lengthy and difficult to resolve, nor that IPRs would be implemented in a way that systematically deprives many patent owners of the due process protections that are available to them in the district courts, while making it significantly easier for challengers to succeed in invalidating patents that would otherwise be upheld by the courts.[7]

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[6] *Id., see also* "Patent Trial and Appeal Board: Increased Transparency Needed in Oversight of Judicial Decision-Making," December 22, 2022, available at https://www.gao.gov/products/gao-23-105336

[7] IPR proceedings were established as proceedings that would be instituted entirely at the discretion of the Director of the USPTO with the hope that they would become "quick and effective alternatives to litigation" and provide a "meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court." H.R. Rep. No. 98 Pt. 1, 112th Cong., 1st. Sess. 45, 48 (2011) (House Report).

It also did not foresee the problem that the courts would rule that having these new post-grant invalidity decisions being made by persons who had not been nominated by the President and confirmed by the Senate is unconstitutional.[8]

Congress sought to achieve the objectives of the AIA by authorizing the Director to promulgate regulations governing the conduct of IPR and PGR proceedings.[9] In doing so, the Director was charged with considering "the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted."[10]

A primary concern of Congress was that IPR proceedings, which could be brought by anyone other than the patent owner at any time throughout the life of a patent, would not become tools used by infringers to harass patentees. Accordingly, in the AIA Congress required that regulations be promulgated under 35 USC § 316(a)(6) for IPRs and 35 USC § 326(a)(6) for PGRs "prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding." Congress further expressed its intention that multiple proceedings should be avoided by addressing the relationship that IPRs and PGRs should have to other proceedings or actions, prohibiting institution of a PGR or IPR if the petitioner has already filed a civil action challenging the subject patent, and automatically staying any civil action filed by the petitioner (other than a counterclaim) if the petitioner has previously filed an IPR petition challenging the subject patent.[11]

Unfortunately, the USPTO failed to implement regulations ensuring that IPRs would not be biased against inventors, thereby frustrating Congress's intentions. As a result, instead of serving as alternatives to district court litigation, about 85% of all filed IPRs were filed as adjuncts to already pending litigation,[12] 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 are reluctant to conclude that their initial determinations

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[8] *See Arthrex, Inc. v Smith & Nephew, Inc*, 941 F.3e 1320 (Fed. Cir., 2019) (holding that administrative patent judges who conduct and decide inter partes reviews are acting as principal officers of the United States who must therefore be nominated by the President and confirmed by the Senate, which administrative patent judges are not).

[9] See 35 USC § 316(a) for IPRs and 35 USC § 326(a) for PGRs.

[10] See 35 USC § 316(b) for IPRs and 35 USC § 326(b) for PGRs.

[11] See 35 USC § 315(a) for IPRs and 35 USC § 3256(a) for PGRs. While Congress did make an exception allowing the petitioner to file an IPR petition for up to one year after being "served with a complaint alleging infringement of the patent," it did so subject to the Director's authority to exercise his/her discretion to deny institution of that petition for the reasons mentioned above. See 35 USC § 315(d) for IPRs and 35 USC § 3256(d) for PGRs.

[12] "2020 Analysis on PTAB Contested Proceedings," at www.PostGrantHQ.com, Venable-Fitzpatrick , page 13, reporting that 87.2% of IPRs are involved in concurrent district court proceedings. Available at https://www.venable.com/-/media/files/publications/2020/11/2020-analysis-on-ptab-contested-proceedings.pdf?

were mistaken and thus find one or more of the challenged patent claims to be invalid about 80% of the time.[13]

For independent inventors, startups, universities and small businesses, the filing of just one IPR petition against one of their patents may itself inflict economic hardship on the patent owner, as IPR defense is expensive, costing in the range of $500,000 to $1 million or more per IPR. Because there is no standing requirement to bring an IPR, anyone can bring an IPR against any patent, even if the patentee is in the early stages of product development, and may never have asserted its patents against anyone. Under these circumstances, some challengers have come to recognize that settlements forcing the patentee to compensate them with licenses or other consideration can be obtained just by threatening to file an IPR petition. If that doesn't work, such "reverse trolls" can and often do proceed with their IPR petitions under the not-unreasonable expectation that because the patent owner can't afford to defend, settlement will sooner or later be forced on the defending patentee. And indeed, the USPTO's statistics continue to show that approximately one quarter to one third of all IPR proceedings never progress to a decision on the merits due to settlements.[14]

USPTO filing statistics also confirm that IPR petitions have most often been brought by large entities. In 2021, for example, the largest filers of IPRs were Samsung (133), Apple (66), Google (51), Intel (30), Dell (29) and Microsoft (27). Six of the top twenty IPR filers were foreign companies (four of them being Chinese). The seventh most prolific IPR filer was Unified Patents (23), which is a subscription-based membership organization that brings IPRs to benefit its members by challenging patents of non-practicing entities (NPEs) in certain identified technology zones.[15]

At least four times the number of IPRs are now being instituted than the USPTO 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.[16] The failure of the USPTO to implement Congress' intended patent owner safeguards, coupled with pro-challenger institution procedures, results in about two thirds of the requested IPRs being instituted. Of those IPRs that are instituted, PTAB panels end up affirming the validity of all challenged claims in only 8% of the cases.[17]

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[13] As of October, 2020, for example, of 434 Final Written Decisions entered in the previous 10 months, 247 (57%) found all claims unpatentable, 94 cases (22%) found some claims unpatentable, and only 93 cases (21%) found no claims unpatentable. See "Final FY 2020 PTAB Statistics Posted," Jones Day PTAB Litigation Blog, available at https://www.jdsupra.com/legalnews/final-fy-2020-ptab-statistics-posted-56588/ ; see also "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/
Data for more recent years is consistent with these findings. *See footnotes below.*

[14] USPTO statistics for fiscal years 2018 to 2022 reflect that on average 27% of all IPRs end in settlements, *See* "PTAB Trial Statistics FY22 End of Year Outcome Round IPR, PGR" at slide 11. Available at https://www.uspto.gov/sites/default/files/documents/ptab__aia_fy2022_roundup.pdf

[15] See www.unifiedpatents.com

[16] *See* Venable-Fitzpatrick, *Ibid* at note 7. *See also* Carlson & Schultz, "Tallying Repetitive Inter Partes Review Challenges," September 14, 2018 IP Law360, reporting that the IPR petitions of the top five IPR filers are duplicative in that they challenge at least one claim that is the subject of attack in another of their petitions in percentages of 56% for Apple, 38% for Samsung, 38% for Google, 59% for Microsoft and 34% for LG Electronics.

[17] In FY 2020, final dispositions by patent were rendered by the PTAB on 1,348 cases. IPRs final written decisions ended up being rendered in 425 (38%) of the cases. Institution was denied in 382 (34%) and 227 (20%) were settled. Of the 425 patents that were the subjects of final

The net effect is that IPRs undermine 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 patent rights against challenges, which routinely came from those alleged to be infringing in a concurrent court proceeding, as well as by "patent killing" organizations created to protect their "members" by filing IPRs on their behalf once they are charged with infringement. [18]

Recognizing these problems with the USPTO's original implementation of IPR procedures, during the last administration the USPTO implemented policies intended to: (a) improve the fairness of IPRs by repealing the original, USPTO-created presumption favoring patent challengers at the initial stage of an IPR or PGR, (b) ensure that the burden of proof remains on the challenger throughout IPR proceedings, (c) adopt the "Phillips" claim construction standard used in the federal courts, (d) endorse procedures to "take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office" (35 USC 325(d)), (e) provide meaningful opportunities for inventors to amend their challenged claims as the AIA had intended, (f) improve the consistency of internal precedents guiding the decisions of the Patent Trial and Appeal Board ("PTAB"), (g) establish a set of factors to be considered when deciding whether a potentially duplicative IPR petition should be instituted and (h) employ the discretionary power given by the AIA to the Director to deny institution of IPRs in certain circumstances to preserve the economy and integrity of the patent system and to protect inventors from abusive, duplicative challenges. Unfortunately, none of these policies were promulgated as regulations (nor have they been codified), and some, particularly those relating to discretionary institution denials, have now been dialed back, underscoring the need for the certainty that appropriate legislation could achieve.

Not included within these, but still needed, are a variety of additional reforms to improve the fairness of the system, including guaranteeing that decisions of the PTAB will be reviewed by Constitutionally appointed principal officers such as District Court judges, by ensuring the same patentability standards and laws that are applied in the federal courts will be applied in PTAB proceedings, and limiting the scope of IPR proceedings to ensure that IPRs may not be used to overrule prior court decisions.

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written decisions on the merits, 267 (63%) found all claims unpatentable and another 90 (21%) found some of the claims to be unpatentable. Accordingly, only 8% of the originally challenged patents (16% of the patents for which final written decisions were rendered) had the patentability of all their claims confirmed by the PTAB. USPTO FY20 End of Year Outcome Roundup, Slide 14, available at https://www.uspto.gov/patents/ptab/statistics

FY 2022 statistics are similar, with 1,320 IPR petitions filed, 769 petitions instituted (67%), 339 settlements (174 before institution and 165 after). PTAB AIA FY 2022 roundup (uspto.gov) (Slide 10). Of the 464 proceedings reaching a final written decision (FWD) in FY22, 305 (66%) found all of the challenged patent claims invalid, 74 (16%) some of the challenged claims invalid, and only 85 (18%) fully valid. (*Id.* at Slide 11). Viewed on a patent claim by patent claim basis, in FY22, 77% of the patent claims subject to an FWD were found invalid. (*Id.* at Slide 13). Of the 20,614 patent claims challenged in FY 22, only 1,653 (8%) were confirmed as valid. (*Id.).*

More recent USPTO filing statistics indicate that institution rates by patent are rising, from 64% in FY 2020 to 69% in FY 22, to 72% for FY 2023 through November 30. PTAB AIA Statistics Nov 2022 (uspto.gov)

[18] *See* the Testimony of Philip S Johnson before the Subcommittee on Courts, the Internet, and Intellectual Property of the Committee on the Judiciary, House of Representatives, November 7, 2017 at pages 11-12, describing "*IPR Patent Trolling,"* available at www.republicans-judiciary.house.gov/hearing/sovereign-immunity-intellectual-property-system/ *See also* footnote 8.

With hindsight, additional stability could have been provided in 2012 through the adoption of more appropriate regulations. But 21C believes that codification of the USPTO's recent improvements would be a good first step to assure the innovation community that it can rely on the progress made to date. Codification is needed because the key to the long-term success of the IPR system depends not only how the inventor community (and its investors) currently perceives its fairness, but also upon whether they can rely upon IPRs to provide just results over the long term. So while some progress has been made to improve IPR fairness, little has been done to assure the inventor community that this progress is not temporary, or that it won't be reversed based upon the changing priorities of USPTO leadership. Codification will provide that assurance.

21C believes that legislation is also needed to address other aspects of IPR proceedings that have turned out to be unwise. While the AIA created a procedure allowing third parties to bring prior art that is relevant to a pending U.S. patent application to the Examiner's attention before the patent is allowed, the availability of IPRs discourages third parties from doing so by allowing them to rely on that prior art, if need be, at a later date. Accordingly, to enhance the incentive to have all relevant prior art brought to and considered by the USPTO during a patent's original examination, IPR petitions should be prohibited from relying in whole or in part upon prior art and arguments that are the same or substantially same as those that have been previously considered by the USPTO.

Experience has also shown that the statutory adoption of a lower standard of proof for use in IPR proceedings than is applicable in the courts was unwise. As a result, under current law 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 later be determined to be invalid by a panel of PTAB judges on a comparatively scant, written record.[19]

The AIA's elimination of the former right of an aggrieved patent owner to seek review from contested USPTO proceedings *de novo* by a district court has also proven to be unwise. Without this right patentees are precluded from introducing probative evidence that is routinely available to patentees in district court. For example, because patentees cannot subpoena witnesses in PTAB proceedings, patentees are now foreclosed from adducing important third party evidence that is routinely gained in district court discovery. They are also deprived of having important fact and expert witness credibility determinations made on the basis of live testimony before an independent Article III judge rather than by administrative patent judges who work off written evidentiary submissions.[20] 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"

[19]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.

[20]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.

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.[21]

A further failing of the current system is its inability to recognize that restraint should be exercised before allowing challenges where innovators have long relied upon their patent rights in connection with the development, introduction and marketing of their inventions. Examples of such factors include situations where the patent holder (or its licensees) 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).[22] An additional appropriate factor to be considered should be 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.

2. Restore patent eligibility to its traditional, Constitutionally-appropriate scope by abrogating the judicially-created exceptions that now deny patent protection for inventions of processes, machines, manufactures and compositions of matter that have practical utilities, including but not limited to high quality inventions in the fields of diagnostics, biotechnology, and software.

A quartet of 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 have 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, and therapeutic biologics.

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[21] Another suggested improvement would be to preclude instituting an *inter partes* review if relevant discovery is not likely to be available to the patentee or where witness and/or expert credibility is likely to be outcome determinative. A further improvement would be to require IPR Petitioners to have Article III standing and be subject to a duty of candor and full disclosure pertaining to evidence relevant to their petitions.

[22] *See* the Testimony of Philip S Johnson before the Subcommittee on Courts, the Internet, and Intellectual Property of the Committee on the Judiciary, House of Representatives, November 7, 2017 at pages 12-15, describing the interplay between Hatch-Waxman cases and IPRs, available at www.republicans-judiciary.house.gov/hearing/sovereign-immunity-intellectual-property-system/

These impacts to our nation's innovation policies have been engineered entirely 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.[23] 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.[24] As former Director Iancu explained:

> [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.[25]

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.[26]

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[23] 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).

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

[25] Iancu, Keynote Address, supra.

[26] Both the IPO and AIPLA have proposed similar, straight-forward language to solve this problem. The joint IPO/AIPLA 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.

An additional judicial exception to patentability that should be abrogated is the outmoded, judicially-created doctrine of obviousness type double patenting ("OTDP"). Originally developed when patents were accorded seventeen years from their grant regardless of how long they had been pending, OTDP has no place in today's patent system. Due to changes related to the GATT treaty, all U.S. patent applications filed since the mid-1990's are already limited to terms of twenty years from their original (priority) filing dates. The sole exceptions now stem from certain statutes passed by Congress explicitly intended to grant longer patent terms in certain instances for time lost due to undue administrative delay or due to regulatory delays which are no fault of the patentee.[27] No judicially created policy should override such explicit statutory provisions.

3. Ensure that our patent system secures inventors exclusive rights to their inventions for limited periods of time by making injunctions available to stop patent infringement unless the grant of an injunction under the particular circumstances would be clearly contrary to the public interest.

The traditional rights and remedies which attach to a valid U.S. patent, including the right to 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 adopting the use of equitable considerations to routinely deny injunctions to patentees.[28] Moreover, while long-standing statutes recognize issued U.S. patents as personal property (35 USC § 261), the Supreme Court has recently endorsed an ill-advised "public franchise" view of patent rights which facilitates duplicative, harassing attacks on patent validity, dramatically diminishing the value and reliability of U.S. patents.[29] For these reasons, legislative solutions, including ensuring that there is a presumption of irreparable harm when there is a finding of infringement of a valid patent, would more appropriately balance the interests.

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* 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.[30] In doing so, *TC*

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[27] Congress has defined the conditions entitling an applicant to receive an extension to the term of a patent whose late issuance was the result of the USPTO's undue administrative delay. The requirements for granting such an extension, known as a" patent term adjustment" are enumerated in 35 USC 154(b). Congress has further provided that a patent term extension may be granted to recover part of the time lost due to premarket regulatory delay caused by the FDA's premarket testing and review requirements pertaining to a regulated drug. The requirements for these extensions, and the limitations thereon, are enumerated in the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585 (codified at 21 U.S.C. 355(b), (j), (l) and in 35 U.S.C. 156,.

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

[29] *Oil States Energy Services v Greene's Energy Group*, __U.S. ___, 138 S. Ct. 1365 (2018).

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

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) threatens the ability of 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 most patent owners who sometimes must bring suit to protect their investments and protect 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 in the districts 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.[31]

[31] This proposal has broad cross-industry support, having been adopted as a resolution by the IPO in 2019, worded as follows:

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

5. Overturn (a) the Supreme Court's Lexmark decision to restore the right of U.S. manufacturers to use their U.S. patents to sue unlicensed foreign imports and (b) the Supreme Court's Helsinn decision to require that prior art be limited to publicly accessible information, as the AIA intended.

In its decision in *Impression Products v. Lexmark*,[32] 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.

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process related to the patent or patents in dispute; (b) research and development of a 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) Foreign Defendants – Motion to Transfer. In civil actions where venue is established against a foreign defendant, a district court shall transfer the civil action against the foreign defendant, and any related entities, upon motion by such foreign defendant showing that:

1. it is the parent of, subsidiary of, or shares at least 50% common ownership with a United States resident entity, and

2. such United States entity (a) has a substantial presence in the United States, and (b) has imported, made, used, sold, or offered for sale the same accused product or process that forms the basis of the claim asserted against the foreign defendant, as long as the United States entity did not perform such acts primarily for the purpose of creating venue.

Upon such a showing by the foreign defendant, the court shall transfer the civil action to any district or division where venue would be proper as to any United States resident entity satisfying (B)(1) and B(2) and the foreign defendant, including a district or division where related litigation is currently pending.

The foreign defendant must file its motion to transfer before answering or otherwise moving against the complaint, and the district court shall rule on a motion for a temporary restraining order if the plaintiff files such a motion before the motion to transfer.

C) Effect of Retail Sales. For the purposes of determining venue, a facility intended primarily for retail sales of consumer products by a retailer will only constitute a regular and established facility with respect to the offer for sale or sale of such consumer products when the plaintiff brings suit in the district where the facility is located and has also brought suit in the same district in the same action against a separate entity responsible for manufacturing or distributing the accused product.

A retailer is an entity (or its affiliate) that generates revenues predominately through the sale to the public of consumer products, but specifically does not include an entity (or its affiliate) that is also (or is separately) responsible for manufacturing, causing the manufacture of, or distributing the accused products, or relevant parts thereof.

Available at: https://ipo.org/index.php/venue-in-patent-suits/ See also IPO's resolution relating to appropriate venue in Hatch Waxman and BPCIA cases: https://ipo.org/index.php/venue-in-hatch-waxman-and-bpcia-patent-infringement-suits/

[32] 581 U.S. 1523 (2017).

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 contend 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 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 *Lexmark* fix 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."

Also troubling is the Supreme Court's *Helsinn* decision, which unintentionally created a vast new class of worldwide secret "on sale" and "commercial use" prior art never intended by the AIA.[33] In *Helsinn*, the Supreme Court incorrectly construed 35 USC §102(b) as amended by the AIA, which limits prior art to "an invention [that] was patented, described in a printed

[33] Helsinn Healthcare S. A. v. Teva Pharms. United States, Inc., 139 S. Ct. 628 (2019)

publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention," to include activities that were not available to the public. A principal purpose of enacting the AIA, which moved our first-to-invent system to a first-inventor-to-file patent system, was to eliminate the possibility that prior secret activities could later be used to invalidate a granted patent. This restriction of prior art to that which was "available to the public" meant that the USPTO could then have all the relevant prior art available to it when deciding whether to grant a patent, and that that patent would not be vulnerable to later attack based upon unknown and unknowable information, such as the prior invention or prior secret use of the invention by another. Accordingly, this fix is needed to restore the AIA's definition to its originally intended scope. *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.[34] As a result, the intended incentives to be provided by our patent system have been severely undermined, and inventors may no longer expect that they will ever enjoy quiet title to their U.S. patents.

[34] *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.