



AMERICANBARASSOCIATION

Intellectual Property
Law Section

321 N. Clark Street
Chicago, IL 60654-7598
T 312.988.6254
iplaw@americanbar.org
www.americanbar.org/iplaw

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2024-2025**

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Amy Mandel
Communications / Publications

Christopher Katopis
Legislative Consultant
Washington, DC
chris.katopis@americanbar.org

November 13, 2024

Ms. Sharon Israel
Chief Policy Officer and Director for International Affairs
Office of Policy and International Affairs
U.S. Patent and Trademark Office
U.S. Department of Commerce
600 Dulany Street
Alexandria, VA 22314

Dear Director Israel:

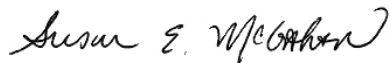
On behalf of the American Bar Association Section of Intellectual Property Law ("Section"), I write to share the enclosed Section White Paper on Patent System Reliability ("White Paper") . The views expressed herein have not been reviewed or approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the policy of the American Bar Association. These comments do not represent the policy or views of any government employee who is a member of the Section, its Council, or its interest groups.

Since 1894, the Section has advanced the development and improvement of intellectual property laws and their fair and just administration. As the forum for rich perspectives and balanced insight on the full spectrum of intellectual property law, the Section serves within the ABA as a highly respected voice within the intellectual property profession, before policy makers, and with the public. Section membership includes attorneys who represent IP owners, inventors, corporations, small businesses, universities, and research institutions across a wide range of industries, technologies, and science.

The Section and its membership commend Director Vidal, the USPTO staff, and you for your unrelenting efforts to foster public discussion and to develop initiatives to "Ensure the Robustness and Reliability of Patent Rights." Likewise, the Section convened a special Task Force on Improving the Durability and Reliability of the Patent Right. These efforts resulted in a series of important initiatives including a webinar series, a Section Chair Town Hall series, and the publication of the White Paper.

If further opportunities arise in connection with such patent policy review or subsequent stakeholder discussions, the Section would be pleased to participate and continue to assist you and others in the Administration in your pursuit of this and similar efforts. Should you have any questions or would like to discuss these issues further, please do not hesitate to contact me at sm1561@att.com or at 908-645-4944. Thank you again.

Sincerely,

A handwritten signature in cursive script, reading "Susan E. McGahan".

Susan E. McGahan, Chair
ABA Section of Intellectual Property Law



IPL Section White Paper On Patent System Reliability

SIMPLIFY PATENT LAW AND PRACTICE; ENHANCE PATENT SYSTEM RELIABILITY

**Eliminate From “Prior Art” Any Subject Matter Not Available To The Public And
Require A Pre-Issuance Disclaimer Of Any Term Exceeding 20 Years From The Inventor’s
First Public Use Or Sale Of A Claimed Invention, If More Than 6 Years Before Filing**

**Eliminate Incorrect Inventorship As A Ground For Patent Invalidity Or Unpatentability
Unless Consequential To Patentability Over Prior Art And
Bar Patent Enforcement Unless and Until Any Incorrect Inventor Naming That Would Result
In A Change In Patent Ownership Has Been Corrected**

**Eliminate “Double Patenting,” As Between Two Patents, Unless—For One Claim From
Each Patent—Neither Claimed Invention Is Prior Art To The Other,
Eliminate “Double Patenting” As A Ground of Patent Invalidity Or Unpatentability, And
Apply Res Judicata Principles To The Patents Involved In “Double Patenting” By Treating
The Claims Of Both Involved Patents As Though They Had Issued In A Single Patent**

**Limit The Unenforceability Consequences Of “Inequitable Conduct” Allegations In Civil
Actions To the Patent Claims Found To Be Invalid In The Action
Thereby Facilitating Reforms To Eliminate “Patent Thickets” Built From Continuations
Application Filings**

**Eliminate Examiner Restriction Requirements, Except For Allowing Examiners To Require
Confining Independent Claims To A Single, General Inventive Concept And
Require Separate Issue/Maintenance Fees For Each Independent Patent Claim In Excess of A
Fixed Number That Is Not Fewer Than 3**

**Eliminate Both The Current Patent Reissue And Continuation Application Statutes And
Enact, As A Substitute, A New Continuation Application Statute:**

- (1) Permitting The Of Filing A Continuation Application Only After The Issuance Of Either
An Original Patent Or A Prior Continuation Patent Referenced in the Continuation,**
- (2) Permitting Amended Or Otherwise New Claims In The Continuation Application, And**
- (3) Upon Issuance Of The Continuation Patent, Canceling The Referenced Patent,**

And

***Restrict The Filing Of A Continuation Application That Recaptures Or Otherwise Broadens
Patented Subject Matter To A Period That Is Fixed At Not Less Than 6 Years After The Filing
Date Of The Original, Non-Continuation Patent***

The views expressed herein have not been reviewed or approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the policy of the American Bar Association. These comments do not represent the policy or views of any government employee who is a member of the Section, its Council, or its Interest Groups. The comments also do not represent the policy or views of any individual voting member of the Section Council or his/her employer.

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Preface

The American Bar Association, Intellectual Property Section (ABA IPL) commissioned a task force to study and address the most vexing issues confronting the patent system. The goal of the task force is a more transparent and more predictable patent system that has at its core a valid patent right that is durable and reliable. The task force advanced the dialog, sought to build consensus, and ultimately developed concrete solutions to improve the patent system.

The dialog and consensus building were not limited to ABA IPL task force members. The ABA IPL hosted a series of webinars, entitled *The Chair's Townhall: Planning a Better Patent System*, to engage thought leaders, including academic professors, former senior United States Patent and Trademark Office (USPTO) staff members, and experienced patent prosecutors and litigators. Following the webinar discussions, the deliberative processes of the ABA IPL – the committees and Council – engaged to further refine these solutions. This work culminated in the following *IPL Section White Paper on Patent System Reliability*.

On October 4, 2022, the USPTO published a notice titled, “Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights.” The notice sought comments on bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge, which will promote innovation and competition.¹ This notice reflected many of the same vexing problems. The costs to engage the patent system, including enforcement, have grown substantially, despite the positive improvements of the American Invents Act. Perhaps now more than ever, the patent system needs reform to meet its critical role to protect inventions and advance prosperity.

This white paper provides the roadmap to a more durable and reliable patent right. It seeks to simplify the law, increase transparency and predictability, reduce the costs to engage the system, and balance the interests of all stakeholders. We hope it advances the discussion and ultimately leads to a better patent system.

Sincerely,

Robert Armitage
(former Section Chair)
Gordon Arnold
(former Section Chair)
Matt Blackburn
William Boudreaux
Jon Bowser
(current Patent Division Chair)
Steve Caltrider
(current Section Chair)

Katharine Helm
Keisha Hylton-Rodic
Lauren Mitchell
(current Patent System Planning Chair)
Scott Partridge
(former Section Chair)
Terry Rea
(former Acting Undersecretary of Commerce for
Intellectual Property and Acting Director of the
U.S. Patent and Trademark Office)
Stephanie Roberts

¹ See 87 FR 60130.

Mark Dickson
(former Section Chair)
Amy Fix
(current Patent System Planning Chair)

Jon Sick
(Task Force co-Chair)
Madhulika Vishwanathan
(Patent Division, Vice Chair)
Charri Vorndran-Jones (Task Force Co-Chair)
Stan Weinstein (Patent Division, Vice Chair)

The Section expresses its gratitude for the work of an outstanding collection of IP law thought-leaders who agreed to review and comment on selected proposals during the webinar series that was an important part of the Section's deliberative process. These efforts by the individuals named below were critical to the development of the work product reflected in this White Paper:

Professor Lisa Ouellette	Professor Arti Rai
Professor Carl Moy	Professor John Whelan
Professor Rochelle Dreyfuss	Professor John Duffy
Phillip Johnson	Joe Matal
Sherry Knowles	Jane Love
Corey Salsberg	Nicolas Kim
Andrew Baluch	Brad Pedersen
Bob Bahr	David Jones

Problem Statement: The Case For Comprehensive Reforms

Inventors using the patent system have longstanding concerns with the limited reliability of the patent examination process conducted in the USPTO. When challenged in the courts, or in in post-issuance administrative proceedings back in the USPTO, a distressingly high percentage of commercially relevant patents are found to contain invalid claims. Given the billions of dollars inventors invest in user fees charged by the Office—in addition to billions more in expenses incurred in securing patent professionals to represent them before the Office—inventors have at least a strong pecuniary interest in exploring significant changes to patent law and practice that could substantially enhance the reliability of issued patent right. Of particular interest would be changes in law and practice that might simultaneously encourage greater respect for and deference to patent rights, while not diminishing opportunities in the USPTO to secure full and fair protection for any claimed inventions to which a patent applicant might be entitled and not issuing patents on subject matter not entitled to a patent under the statute.

Among the ways in which inventors seek to mitigate uncertainty as to whether the claims of a patent might, first, be commercially relevant and, second, sustained as valid, is through the use of continuation applications. From a prosecution practice that was rarely utilized decades ago, “continuation patents” now represent a substantial percentage of all patents issued by the USPTO, and the number continues to grow at an alarming rate. Moreover, the timing of the filing of continuation applications now commonly extends to near the end of the 20-year patent term, with continuation patents serially issuing at 10 years or 15 years or even longer into a continuation patent’s 20-year patent term.

Inventors justify seeking these so-called “thickets” of continuation patents, including the “submarine patents” that issue with the 20-year patent term mostly gone, because the patent law may be changed by the courts, competitors may emerge with unanticipated developments, the understanding of the initially disclosed technology may evolve, or the embodiments selected for commercialization may also evolve over time. Competitors, on the other hand, plead for claiming not to be a 20-year odyssey in uncertainty—a target ever moving, potentially to the very day that the continuation family of patents each finally expires.

This white paper offers a package of integrated reforms that were developed together, in hopes that the reforms could be considered together. Implemented together, inventors, their competitors, and the greater public would have the benefits of a patent system that was more reliable, operated with greater integrity, and afforded all constituencies affected by patents with a far greater degree of certainty.

Forging A Simpler Patentability Law – More Reliably Valid Patents

- To simplify patentability issues requiring possible patent examiner consideration, the scope and content of prior art upon which patentability is determined would be confined to information available to the public, such that an invention placed “in public use or on sale,” even in a manner attributable to the inventor, could represent “prior art” only to the extent of any subject matter thereby made available to the public. As an adjunct to confining prior art to publicly available information, a claimed invention would become unenforceable in the event it had been placed in public use or on sale, through inventor-attributable conduct, more than six years prior to the effective filing date of the claimed invention, unless the patent owner had made a pre-issuance disclaimer of any patent term extending more than 20 years from the first date the claimed invention was placed in public use or on sale.

Simplify Prior Art

Eliminate From “Prior Art” Any Subject Matter Not Available To The Public And

Require A Pre-Issuance Disclaimer Of Any Term Exceeding 20 Years From The Inventor’s First Public Use Or Sale Of a Claimed Invention, If More Than 6 Years Before Filing

- To simplify patentability issues requiring possible patent examiner consideration, the issue of incorrect naming of the inventor would no longer be considered during ex parte patent examination because incorrect inventor naming would no longer bear on patentability or patent validity of a claimed invention. Inventor naming issues would be addressed outside the examination process and the sole consequences of incorrect inventor naming would be confined to unenforceability of the patent in the circumstance where correction of inventorship would result in a change in patent ownership.

Simplify Inventor Naming Law

Eliminate Incorrect Inventorship As A Ground For Patent Invalidity Or Unpatentability Unless Consequential To Patentability Over Prior Art And

Bar Patent Enforcement Unless and Until Any Incorrect Inventor Naming That Would Result In A Change In Patent Ownership Has Been Corrected

- To simplify patentability issues requiring possible patent examiner consideration, the law on obviousness-type double patenting would no longer involve any examination of claimed inventions in the USPTO and no longer bear on the patentability or validity of any claimed invention. Double patenting

Simplify “Double Patenting” Law

Eliminate “Double Patenting,” As Between Two Patents, Unless—For One Claim From Each Patent—Neither Claimed Invention Is Prior Art To The Other, Eliminate “Double Patenting” As A Ground of Patent Invalidity Or Unpatentability, And

Apply Res Judicata Principles To The Patents Involved In “Double Patenting” By Treating The Claims Of Both Involved Patents As Though They Had Issued In A Single Patent

would be limited to patents where at least one claim from each of the involved patents lacked any prior art relationship, i.e., neither claimed invention represented prior art to the other. When obviousness-type double patenting was present, the issue would be limited to patent enforceability. This would be accomplished by treating the claims of the involved patents as though only a single patent had been issued when applying res judicata principles.

- To remove one incentive that patent applicants have to secure a multiplicity of patents from a single, original, nonprovisional patent application, the patent unenforceability defense that can be pled in a civil action based on

Eliminate Incentives To Spread Claims Among Patents

Limit The Unenforceability Consequences Of “Inequitable Conduct” Allegations In Civil Actions To the Patent Claims Found To Be Invalid In The Action
Thereby Facilitating Reforms To Eliminate “Patent Thickets” Built From Continuations Application Filings

prosecution misconduct during ex parte patent examination would be limited to just the patent claims found to be invalid in the action. Under current “inequitable conduct” law, the unenforceability of a later-sought, later-secured continuation patent based upon prosecution misconduct does not affect the ability to secure any of the earlier-sought, earlier secured continuation patents of the same patent family. Limiting the unenforceability consequences to claims found to be invalid would, thus, remove a strong disincentive in the current “inequitable conduct” law from seeking to secure all possible claims in a single patent, rather than spreading the claims among a “thicket” of continuation patents.

- To eliminate the inefficiency in current USPTO “restriction practices” limiting the claims that an inventor may be entitled to have examined upon the filing of a patent application, a set of changes would entirely eliminate all such limitations on the examination of pending claims, as well as the necessity for seeking “divisional patents” on any “restricted” claims by (1) ending all current “restriction” practices” limiting the scope of claims being examined in any single patent application to one independent and distinct invention, (2)

Eliminate “Divisional” Applications

Eliminate Examiner Restriction Requirements, Except For Allowing Examiners To Require Confining Independent Claims To A Single, General Inventive Concept And
Require Separate Issue/Maintenance Fees For Each Independent Patent Claim In Excess of A Fixed Number That Is Not Fewer Than 3

substituting a new restriction practice under which a patent examiner would be permitted (but not mandated) to require restriction of any independent claims to a *single, general inventive concept* (the international unity of invention standard), and (3) requiring that separate patent issuance and maintenance fees be paid for each independent claim in excess of fixed number that would be set at not fewer than 3 independent claims.

- To eliminate the possibility that “continuation patents” can contribute to “patent thickets”—or that “submarine patents” (patents issuing on late-filed continuation applications, with claims that broaden previously issued claims of the continuation application’s parent patents) can belatedly raise freedom-to-operate issues for competitors—replace all currently available options for recapturing previously claimed subject matter or otherwise broadening

claims of a patent once issued with a single vehicle for amending the claims of any issued patent through a new type of “continuing application for patent” that (1) could only be filed after the patent referenced in the continuation application had been issued (which could be an original, non-continuation patent referenced or a subsequently issued continuation patent referenced), (2) could only recapture or otherwise broaden the claims of the referenced patent if filed within a fixed period set at not less than 6 years from the filing date of the original, non-continuation patent (i.e., the filing date used to determine the commencement of the continuation patent’s 20-year term), and (3) would trigger the cancelation of the referenced patent upon issuance of the continuation patent—*thereby precluding any possibility that the filing of a nonprovisional patent application could result in the existence of more than a single patent at any point during the entire 20-year patent terms even if a series of continuation applications were filed and patents were granted on such patent filings.*

Ending All “Continuation Patent” Thicketing
<p>Eliminate Both The Current Patent Reissue And Continuation Application Statutes And Enact, As A Substitute, A New Continuation Application Statute:</p> <p>(1) Permitting The Filing A Continuation Application Only After The Issuance Of Either An Original Patent Or A Prior Continuation Patent Referenced In The Continuation,</p> <p>(2) Permitting Amended Or Otherwise New Claims In The Continuation Application, And</p> <p>(3) Upon Issuance Of The Continuation Patent, Canceling The Referenced Patent, And</p> <p><i>Restrict The Filing Of A Continuation Application That Recaptures Or Otherwise Broadens Patented Subject Matter To A Period That Is Fixed At Not Less Than 6 Years After The Filing Date Of The Original, Non-Continuation Patent</i></p>

Addressing Reforms In A Coherent, Balanced Package

Gridlock amongst stakeholders would be inevitable for any significant change to the patent laws that focused solely on restricting opportunities for securing patents or restricting opportunities for challenging patents. Historically, some interested parties who have supported the former have opposed the latter and—in a perfect *vice versa* manner—communities opposing the former have supported the latter. This makes it virtually impossible to advance reform proposals that would be one-sided—however principled or meritorious the proposals for change. To avoid a “white paper” of political futility, the measures proposed above reflect compromise and seek to coherently address in a balanced manner core concerns with the operation of the patent system that compromise its integrity, engender wanton unpredictability, and inject needless complexity.

Policy Background

Optimizing Accuracy, Integrity, and Efficiency of Patent Examination

At the core of the U.S. patent system lies patent application examination conducted in the United States Patent and Trademark Office. The USPTO is a user-fee-funded, multibillion-dollar enterprise.² The accuracy, integrity, and efficiency under which the patent system operates is tied to quality of USPTO's patent examination work product, most specifically the efforts of a corps of over 8,000 patent examiners.³

Aside from USPTO user fees, patent applicants incur billions of dollars in additional patent procurement expenses paid to patent professionals. While such massive expenditures fuel the patenting process, they are effectively for naught if the work product of patent examination process does not produce patents of *reliable validity*—patents that enjoy deference and respect.

A patent examination process failing to produce *reliable determinations of patentability*—and commanding neither respect nor deference by competitors—*cannot long endure*. It makes neither economic nor policy sense for devoting billions upon billions of dollars to patenting costs that routinely result in the issuance of patents for which patent validity, if challenged, is no more predictable than the result of a coin toss.

The accuracy of the USPTO patent examination process—and the durability implications of the process if its determinations are only coin-toss dependable—has fostered often contentious debates:

- Critics of the patent system point to the seeming ease with which “thickets” of “continuation” patents can be amassed from a single initial patent filing, with the continuation patents alleging continuation patents face an increasingly less rigorous review during the patent examination process—and with new, so-called “submarine” claims first surfacing in continuation patents sought and issued more than a decade after an initial patent filing.
- At the spectrum's other end, patent owners often express outright disgust with how readily presumptively valid patents can be invalidated back in the USPTO, once subject to further review.

Challenges for Optimizing the Quality of Patent Examination

Producing reliably valid patent rights self-evidently demands that the patenting processes within the USPTO operate with an *optimized quality*. Optimizing the patenting process, however, is not as simple as pursuing accuracy in examination at any cost.

² “The USPTO's Fiscal Year (FY) 2024 President's Budget Submission (Budget) requests authority to spend agency user fee collections of \$4,196 million, comprised of \$3,696 million in patent fees... .” Budget and Financial Information at <https://www.uspto.gov/about-us/performance-and-planning/budget-and-financial-information>.

³ <https://www.uspto.gov/about-us/events/attend-2022-patent-examiner-virtual-recruitment-open-house>.

Advancing examination quality, while necessary, is by no means a sufficient objective if the patent system is to achieve its constitutional objective to promote progress in useful arts. Without preserving *affordability*, a single-minded focus on examination quality—at any cost—could deny full access to the patenting process for many inventors. Optimized patent examination quality must be accompanied with *optimized examination efficiency*.

These, however, are not the only examination parameters that are foundational to a durable, reliable patent system. Quality and efficiency objectives must result in timeliness to the final determinations of patentability in the USPTO. Patent rights that take too long to process in the USPTO can render those rights economically meaningless, by coming too late to secure the investments needed to develop and commercialize the patented invention. Of equal importance, the public has a right to understand—as early as possible in the patenting process—what subject matter can be lawfully patented and what subject matter will remain free from a patent’s exclusionary rights. That public right can be frustrated if permitted patent examination practices have the ultimate effect of encouraging patent applicants to engage in claiming games of “hide” and “belatedly seek.”

Role of Substantive Patentability Standards in Driving Quality and Efficiency

Moreover, quality, efficiency, and timeliness in patent examination do not depend solely on optimizing processes and procedures with the USPTO. Quality, efficiency, and timeliness are also driven by substantive standards defining patentability and patent applicant practices.

The substantive standards defining patentability can profoundly impact the ability to optimize examination reliability, efficiency, and timeliness. Patentability standards that are transparent—dependent only on accessing information available to the public—and are objective—avoiding considerations of state of mind or intent—can operate to greatly enhance the prospects that determination of patentability made in the USPTO will be a dependable one—and can be made economically and promptly once a patent filing has taken place. The courts have recently moved the patent system farther from—rather than closer to—this objective of transparent, objective patentability criteria, particularly as it relates to subject matter that was placed in public use or on sale.

Applicant practices also profoundly impact the quality, efficiency, and timeliness in patent examination. So-called defensive prosecution practices seek to focus on avoiding future allegations of prosecution misconduct, rather than helping to focus examination on procuring allowable subject matter. More than 30% of all applications are continuations, and the number continues to grow. This is a significant burden on USPTO, the public and competitors, who legitimately seek avoid infringement or design around an invention.

Advancing quality, efficiency, timeliness, and integrity in patent examination have become vastly more challenging over the past half-century. Patents today are being sought on more complex technologies than ever before. Both the number and size of patent application filings with the USPTO has grown dramatically. The quantity of available “art” that must be accessed for searching during examination now grows exponentially by the decade.

Opportunities Arising from New Technologies and New Examination Paradigms

These challenges to sustaining a reliable and durable patent examination process exist alongside unprecedented opportunities for elevating quality, efficiency, and timeliness in patent examination. The remarkable promise of information technologies offers the possibility of ever-more-effective tools for managing the greater volume and complexity of patent filings. With sufficient funding and development, next-generation IT tools, some taking advantage of the explosive growth in artificial intelligence technology, could help support a more efficient, timely, and accurate USPTO examination process.

One objective of any effort at addressing reliability and durability issues as they relate to examination must be to facilitate, rather than impede, the promise of more effective IT tools. It is essential to rethink both the existing “duty of disclosure” imposed on patent applicants and its desired—but often frustrated—objective of focusing examination on the most relevant prior art.

Imperative to Elevate Examination Integrity Consistent with a Full Opportunity to Claim

Lastly, for issued patents to be accorded respect and deference, the hallmark of the patent examination must be its integrity. The public must have sound grounds for believing that the process of patenting in the USPTO is abuse-proof, that it is devoid of scheming and gamesmanship; and that patenting in the USPTO is entirely focused on promptly rewarding inventors with exclusive rights only to those inventions that assuredly meet rigorous requirements for patentability that have been rigorously applied.

One immediate challenge faced by any effort at optimization of patent examination is how to best bring together and integrate all the factors that must be carefully balanced. This includes taking account of current USPTO capabilities, anticipating the possibilities for streamlining of the substantive patent law to be applied in patentability determinations, and preparing to harness ever-growing opportunities arising from ever-expanding IT capabilities.

A second and possibly more difficult challenge is balancing two potentially competing timing objectives as they relate to patent application examination. One core patent system policy objective is that a patent applicant should be accorded a full and fair opportunity to secure the broadest and most complete set of claims meeting the requirements for patentability. Patent owners have legitimately contended that the needed clarity on the optimal scope for patent claims may take years to achieve, typically depending on the time required to develop the invention for commercialization.

This contention that time is needed to perfect the claiming, however, exists in tension with the more fundamental notion of what constitutes an adequate “written description” in a patent specification. A patent specification must demonstrate, *on the very day the patent was sought*, that the inventor possessed a completed conception of the subject matter to be claimed⁴—“a

⁴ “Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of ‘invention’—that is, conceive of the complete and final invention with all its claimed limitations — and disclose the fruits of that effort to the public.” *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc).

definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”⁵ Since the patent specification as originally filed must contain some demonstration that the inventor possessed a *recognition* or *appreciation* of what the invention is,⁶ affording an inventor an extended time post-filing to further refine or otherwise confine claims can be relatively easy to excuse—while affording an extended period after filing in which to identify how much more extensive (or broad) the claimed subject matter might be would appear to be anathema to compliance with the “written description” law.

In addition, members of the public—and often patent owners themselves—have a vital interest in achieving “claim certainty” as soon as possible after the initial, nonprovisional patent filing has taken place. Of particular concern are the so-called “submarine claims” that first surface in belatedly filed continuation patent applications. These continuation applications can be filed 10 or 15 years (or even longer) after the filing of the initial patent application in which these “submarine claims,” had they been timely presented, could have been patented.⁷

Belatedly filed continuation applications are not the only type of patent filing that can frustrate the public interest in securing prompt “claim certainty.”⁸ As noted above, “divisional” patent applications,⁹ arising from “restriction requirements”¹⁰ made during patent examination can produce the same consequence. Such applications can likewise be filed 10 or 15+ years after the filing of the initial patent application in which the “restricted claims,” had they been “elected,” could have been patented.

⁵ *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994).

⁶ “[C]onception requires that the inventor appreciate that which [the inventor] has invented.” *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005).

⁷ Spreading the examination of the disclosure in a single patent application over substantial period of time via continuation application filings—during which a patent applicant can continue to seek ever broader claims—raises the specter that the successive examinations in the USPTO will not be conducted with the same rigor as that of the original, nonprovisional application, even if the same examiner is assigned to examine the successive continuation applications. In contrast, a file-once-examine-once-issue-once regime, even if it results in a greater use of multiple, concurrent patent filings does not present the same “examiner inconsistency” issue. Modern information management tools can be readily used to assure that all such concurrent patent applications filings by an applicant can be contemporaneously assigned to the same patent examiner for a consistent, concurrent examination of all the claims presented in related applications of this type.

⁸ The belated claiming practices across various technologies have resulted in efforts to use the “prosecution laches” doctrine to invalidate such claims. See [*Sonos Inc. v. Google LLC*, 20-06754 WHA, 2023 WL 6542320 \(N.D. Cal. Oct. 6, 2023\)](#) for a recent effort at the district court level doing so.

⁹ Patent applicants, in many circumstances, are not permitted to secure a patent on all the claims to which they might be entitled upon the filing of the original, nonprovisional patent application. Patent examiners routinely limit the nature and number of originally presented claims that can be examined in any patent filing through *restriction requirements* under 35 U.S.C. §121. A restriction requirement mandates filing so-called *divisional patent applications*. Thus, a single, original patent application filing can be (and often is) restricted, with dozens of resulting separate applications needed to secure claims to all the patentable subject matter in the original patent filing.

¹⁰ Multiple standards exist for determining which claims of a patent application are subject to “restriction.” When the USPTO examines international applications that have entered the national phase under the Patent Cooperation Treaty, a “unity of invention” standard applies, under which claims can be restricted to a single general inventive concept.¹⁰ Under 35 U.S.C. §121, the claims of an application can be restricted to a single “independent and distinct” invention. Both practices can result in various patents issued based on the claims of an initial patent filing.

Simplify Prior Art – Limit to Subject Matter Publicly Available

**Eliminate From “Prior Art” Any Subject Matter Not Available To The Public
And**

***Require A Pre-Issuance Disclaimer Of Any Term Exceeding 20 Years From The Inventor’s
First Public Use Or Sale Of A Claimed Invention, If More Than 6 Years Before Filing***

Problem Statement

The determination of patentability and patent validity for a claimed invention is grounded on the concept that only subject matter novel and nonobvious with respect to the “prior art” merits the award of a patent. As a consequence, the ability of a patent system to produce efficient and reliable determinations of patentability depends upon the nature and extent of the effort needed to ascertain the scope and content of the prior art that has a bearing on patentability.

Patent systems outside the United States have long fostered durability and reliability in making patentability determinations by limiting the subject matter that can represent prior art to information available from public sources. In foreign patent systems, *availability to the public* is the touchstone for determining whether a disclosure of information can represent prior art. In contrast, in the United States, non-public or secret information long played a central role in the ability to determine what subject matter might or might not be prior art—and, thus, might or might not be patentable.

The America Invents Act,¹¹ enacted in 2011, represented an effort to enhance the durability and reliability of patentability determinations by moving the U.S. patent law closer to the international patentability norms.¹² One driver leading to the enactment of the AIA was a set of recommendations from the National Academies of Science arising out of a four-year study of the patent system by the Academies’ National Research Council.¹³ The AIA contained provisions recommended by the National Academies that were aimed at greater international harmonization of patentability determinations.¹⁴

¹¹ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

¹² “Within the AIA are two ‘sense of Congress’ provisions that expressly state the objectives and policies of the legislation. Behind the first-inventor-to-file regime, as embodied in revised 35 U.S.C. §102, were Congress’s expressly stated objectives of achieving both (1) ‘harmonization of the United States patent system’ with those commonly used throughout the world and (2) ‘greater certainty regarding the scope of protection’ provided by U.S. patents. AIA §§3(o), 3(p). Regarding the first objective, because the vast majority of patent applications filed outside the United States are filed in jurisdictions where secret commercialization is not regarded as prior art, the elimination of this category of prior art brings the U.S. patent system in line with the rest of the world.” Amicus Brief of the Naples Roundtable in Support of Petitioner, *Helsinn v. Teva* (No. 17-1229), On Petition for Writ of Certiorari, pp. 3-4. (http://www.supremecourt.gov/DocketPDF/17/17-1229/41959/20180402153611913_17-1229%20Brief%20of%20Amicus%20Curiae.pdf)

¹³ National Research Council. 2004. A Patent System for the 21st Century. Washington, DC: The National Academies Press. <https://doi.org/10.17226/10976>.

¹⁴ See NRC Report, *supra*, at p. 83, “The United States, Europe, and Japan should further harmonize patent examination procedures and standards to reduce redundancy in search and examination and eventually achieve mutual recognition of results.” In both Europe and Japan, novelty and patentability are tied to prior disclosures that have been made “available to the public.” As an example, the European Patent Convention Article 54(2) provides

The AIA attempted to harmonize “prior art” law, by confining prior art to a pair of simple, transparent, and straightforward components universally present in patent systems outside the United States:

- (1) subject matter *available to the public* before the inventor’s patent filing and
- (2) *disclosures made in earlier patent filings*, but only if such earlier patent filings eventually become public (*i.e.*, either when such other applications for patent publish or issue as patents).

The AIA’s congressional sponsors noted that the intent of the AIA was to have prior art assessed under a set of more internationally harmonized rules, including a public availability standard for assessing whether subject matter could constitute prior art.¹⁵ The objective was to achieve for the U.S. patent system the relative transparency and simplicity present in patentability determinations made outside the United States.

In an effort to deliver on this objective, Congress repealed patent statute’s core provision defining the requirements for patentability. 35 U.S.C. § 102 was replaced with a new section rewritten from the ground up. The new AIA §102(a)(1) provided that prior art, except for prior patent filings, should be confined to subject matter that was [1] patented, [2] described in a printed publication, or [3] *in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention*.

Since subject matter that is patented or described in a printed publication is inherently limited to publicly available disclosures, the only possibility that new §102(a)(1) might not achieve the harmonizing objective would be if the new statutory text “*otherwise available to the public*” did not limit “on sale” activities to subject matter that was publicly available.

Unfortunately, in its *Helsinn* decision,¹⁶ this is exactly what the Supreme Court held. According to the Court, the term “on sale” in §102(a)(1) was to be understood to cover the same types of secret commercial activities that it had covered under the repealed statute.¹⁷

The pre-AIA §102 had rendered inventor-attributable “on sale” activities undertaken in the United States patentability-defeating irrespective of whether those activities had resulted in any

that: “The state of the art shall be held to comprise everything made *available to the public* by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.” Similarly, in Japan, defeating novelty is based upon “(i) inventions that were *publicly known* in Japan or a foreign country prior to the filing of the patent application [or] (ii) inventions that were *publicly worked* in Japan or a foreign country prior to the filing of the patent application...” Japanese Patent Act (Act No. 121 of April 13, 1959).

¹⁵ See the amicus brief of Congressman Lamar Smith, who was the “Smith” of the Leahy-Smith America Invents Act at http://www.supremecourt.gov/DocketPDF/17/17-1229/60461/20180823130453156_17-1229%20Amicus%20Brief%20of%20Congressman%20Lamar%20Smith.pdf.

¹⁶ *Helsinn Healthcare v. Teva Pharmaceuticals*, 139 S.Ct. 628 (2019).

¹⁷ See Mark A. Lemley, *Does “Public Use” Mean the Same Thing It Did Last Year?*, 93 Texas Law Review 1119 (2015).

(<https://law.stanford.edu/sites/default/files/publication/924011/doc/slspublic/Lemley%2093%20Texas%20Law%20Review%20Does%20Public%20Use%20Mean.pdf>)

subject matter being made available to the public.¹⁸ The Supreme Court’s *Helsinn* decision, thus, had the effect of leaving the United States the only country in the world in which this type of “secret prior art” can result in a claimed invention being found unpatentable.

In deciding the *Helsinn* appeal, amici¹⁹ offered the Supreme Court two possible policy justifications for having “on sale” activities constitute a bar to patentability of a claimed invention irrespective of public availability. The first is avoiding any *prolonged delay* in seeking a patent. The second is preventing an *unjustifiably long period* after the initial commercialization before patent protection expires.²⁰

Whatever the merits of these supposed policy justifications, the “on sale” patentability bar has historically imposed a most draconian punishment (patent invalidity) even in circumstances where the supposed crime was trivial in nature. First, there is no minimum quantum of “on sale” activity needed to trigger an “on sale” bar to securing a valid patent on a claimed invention. Relatively *de minimis* non-public commercial activity can trigger the bar.²¹ Second, the bar can apply in situations where the *de minimis* non-public activity took place just days before the start of the one-year statutory “grace period” during which inventor-attributable “on sale” activities are disregarded for patentability purposes.²²

¹⁸ See generally Masur, Jonathan S. and Ouellette, Lisa Larrimore, *Real-World Prior Art* (January 27, 2023). Stanford Law Review, Vol. 76 (forthcoming 2024), University of Chicago Coase-Sandor Institute for Law & Economics Research Paper No. 973, U of Chicago, Public Law Working Paper No. 821. (available at SSRN: <https://ssrn.com/abstract=4339879> or <http://dx.doi.org/10.2139/ssrn.4339879>). At pp. 35-36, the authors note that, notwithstanding any uncertainty arising under the statute, “placing an invention in commercial use—such that either the invention itself or a product or service produced by the invention is on sale—is prior art even if it is secret and non-enabling, but we think this on-sale bar is best understood as party specific: it creates prior art against the seller, but not against third parties.”

¹⁹ Brief of Amici curiae of 45 Intellectual Property Professors, http://www.supremecourt.gov/DocketPDF/17/17-1229/66149/20181009122047518_17-1229_Helsinn%20v.%20Teva_bsac.pdf.

²⁰ “Requiring inventors who put their inventions to commercial use to promptly file a patent application serves two goals. First, it discloses the invention to the world. [The “in public use or on sale” bar] forces the inventor who wants to make commercial use of [a claimed] invention to choose early between patent and trade secret protection, and it biases that choice in favor of patenting. ... Second, the ... rule prevents the commercializing inventor from delaying the filing of her patent application in order to extend the life of her patent and her control over the invention. This has long been an important policy that underlies the statutory bars in patent law.” Lemley, Mark A., *Does “Public Use” Mean the Same Thing It Did Last Year?* (February 11, 2014). Stanford Public Law Working Paper No. 2394153, 93 Texas Law Review 1119 (2014), pp. 16-17, <https://ssrn.com/abstract=2394153> or <http://dx.doi.org/10.2139/ssrn.2394153>.

²¹ “*Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94, 24 L.Ed. 68 (1877) (‘[A] single instance of sale or of use by the patentee may, under the circumstances, be fatal to the patent...’); cf. *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 257, 8 S.Ct. 122, 31 L.Ed. 141 (1887) (‘A single sale to another... would certainly have defeated his right to a patent ...’)” *Helsinn*, *supra*, 139 S.Ct. at 633.

²² One example of *de minimis* commercialization—undertaken just days before the patent filing deadline—barring a patent is the Pfaff activities described in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998). As explained by the Supreme Court, Pfaff filed a patent application on April 19, 1982, but had filed a single, small order for the claimed invention (invoiced for less than \$100,000) in July 1981. While the order was filed less than one year before the patent filing, this order was confirmed on April 8, 1982—one year and 11 days before seeking the patent for the claimed invention. Although the claimed invention had not been produced—that is, reduced to practice—more than one-year before seeking a patent, a “sketch” of the claimed invention and an oral purchase order both existed approximately 13 months before the patent filing took place. Eventually, the claimed invention was a commercial success, producing millions of dollars of sales annually. Nonetheless, Pfaff’s relatively *de minimis* “on sale” activities, undertaken only a brief period before the one-year bar date, sufficed to invalidate the Pfaff patent.

The supposed policy considerations that underlie the “on sale” patentability bar require avoiding a prolonged interval between the commencement of inventor-attributable “on sale” activities and seeking a patent on the “on sale” subject matter, but these policy concerns by themselves do not dictate that only a one-year “grace period” following an inventor-attributable commercialization must be imposed. While the current patent law provides an inventor such a one-year “grace period” during which inventor-attributable “on sale” activities are disregarded in determining patentability, the patent statute historically offered inventors a much longer “grace period,” specifically a two-year period that was in effect from 1839 through 1939.²³ Indeed, a period of time much longer than one or two years could be justified on other policy grounds. For example, setting a longer time period would be consistent with not imposing a patentability bar at all before the claimed invention was established in the marketplace and was producing more than *de minimis* revenues.

A second factor supporting a longer deadline for seeking a patent is that any “grace period” should not be set so short that it forces, rather than discourages, continued trade secret protection in lieu of seeking patent protection. The current one-year “on sale” patentability bar, for example, has the self-evident effect of encouraging continued trade secret protection once the one-year period has expired. Removing the bar altogether—or at a minimum deferring it to a longer time period following initial commercialization—would be consistent with a policy of affording inventors a continuing incentive to seek patent protection (in lieu of forcing continued trade secret protection) notwithstanding any prior commercial activities.

Finally, as a consequence of the *Helsinn* decision, the “on sale” patentability bar arising from secret commercialization activities is now fraught with new durability and reliability concerns. First, the *Helsinn* decision did more than merely maintain the *status quo* in “on sale” law. Sitting inside the AIA’s new 35 U.S.C. §102, the “on sale” patentability bar has been expanded to cover activities undertaken globally and is now subject to other uncertainties as to its reach. In addition, various provisions of the AIA were enacted into law on the assumption that the “on sale” issue in *Helsinn* would be decided differently. In effect, the *Helsinn* decision has milled “on sale” activities into a square peg that simply does not fit the AIA’s round holes. Each of these concerns is addressed in the discussion that follows.

Summary Of Proposed Solutions

The reform proposal would amend the patent statute, *inter alia*, to remove the words “on sale” as it appears in the new section of the patent statute defining prior art and, in place of a patentability bar arising from secret, pre-filing, inventor-attributable commercial activities, impose a new bar on enforceability that would arise only in the circumstance where the period of pre-filing

²³ The permitted period during which a commercialization attributable to the inventor before seeking a patent was set at two years in Sec. 7 of the Patent Act of 1839, Ch. 88, 5 Stat. 353-355 (March 3, 1839) Ch. LXXXVIII.-(“An Act In Addition To ‘An Act To Promote The Progress Of The Useful Arts.’”), which two-year period Congress reenacted into law in 1870 under Sec. 24 of the Patent Act of 1870, Ch. 230, 16 Stat. 198 (1870) (“An Act to Revise, Consolidate, and Amend the Statutes Relating to Patents and Copyrights”). This two-year period remained in the law for a century—until the enactment of Sec. 1 of the Patent Act of 1939, Ch. 450, 53 Stat. 1212 (August 5, 1939), reducing the two-year period to the one-year period continued under the Patent Act of 1952.

commercialization had been extended. Under the reform proposal, more than a six-year, pre-filing commercialization attributable to the inventor would require that the patent owner disclaim any patent term that would extend more than 20 years from the date of commercialization—and do so before the patent issued—to avoid having the patent held permanently unenforceable.

Overruling Helsinn Would Restore The Reform Expectations In Enacting The AIA

The *Helsinn* Construction Of “On Sale” Does Not Fit New 35 U.S.C. § 102(a)(1)

The *Helsinn* holding of the Supreme Court is remarkably simple: “Because *we determine that Congress did not alter the meaning of ‘on sale’ when it enacted the AIA*, we hold that an inventor’s sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under §102(a).”²⁴ Even if the *meaning* of the words “on sale” not change, the *statute* in which these words appear did change—and is quite different from pre-AIA 35 U.S.C. §102(b) where the words “on sale” appeared.²⁵

Unlike pre-AIA §102(b), AIA §102(a)(1) contains *no geographic limitation* on the qualifying “on sale” activities that can render a claimed invention unpatentable. The pre-AIA §102(b) was specific that these activities must take place “in this country” to be able to bar a patent. AIA §102(a)(1) is devoid of any similar geographic restriction. This produces the indefensible consequence that all U.S. patent rights can be forfeited based upon even a single, *de minimis* non-public offer for sale in a foreign country (e.g., Uzbekistan) even a day prior to the start of the one-year “grace period.”

Second, AIA §102(a)(1) contains no explicit provision limiting the “on sale” patentability bar to inventor-attributable “on-sale” activities. While this limitation may have been implicit in pre-AIA §102(b) as applied to “in public use or on sale” activities,²⁶ nothing in the new statute indicates any differentiation is to be made between secret “on sale” activities attribute to the inventor and such activities attributable to others.

In addition, there is no one-year “grace period” in AIA §102 that would apply to any activities that are not inventor-attributable. Unless AIA §102(a)(1) “on sale” prior art is deemed to be implicitly limited to inventor-attributable activities, then any “on sale” activities anywhere in the world even a day before a patent application is filed could represent “prior art” to a claimed invention in such a patent filing.

The *Helsinn* Construction Of “On Sale” Does Not Fit With Other AIA Provisions

Other provisions of the AIA were enacted with the assumption that no non-public activities could constitute prior art or otherwise bear on patentability:

²⁴ 139 S.Ct. 634.

²⁵ Pre-AIA 35 U.S.C. §102(b) provided that a valid patent could not be granted for an invention “in public use or on sale *in this country*, more than one year prior to the *date of the application for patent in the United States...*”

²⁶ See *WL Gore & Associates, Inc. v. Garlock, Inc.*, 721 F. 2d 1540, 1550 (Fed. Cir. 2019). A patent claiming a process that was the secretly commercialized in a manner not attributable to the inventor did not render the claimed invention “in public use or on sale” under pre-AIA 35 U.S.C. §102(b).

- The post-grant review provisions of the AIA were limited to patents subject to the first-inventor-to-file provisions of the AIA. This limitation on PGR availability was enacted to avoid injecting into these proceedings the discovery-intensive issues relating to patentability determinations under the pre-AIA law, such as establishing dates of invention and the *content of secret commercialization activities*. The ability to limit the need for extensive discovery is of critical importance to the fairness and efficiency of the PGR process given the one-year deadline for the PGR to reach a final decision on patentability. A secret commercialization “on sale” bar simply does not fit the AIA’s overall statutory framework.
- The AIA simultaneously eliminated the ability of an inventor to rely on a pre-filing “date of invention” and expanded the availability of so-called “prior user rights” in which the prior domestic commercial use of a patented invention could constitute a defense to patent infringement.²⁷ In expanding this defense based on prior commercial use, together with the AIA’s adoption of the first-inventor-to-file principle (which eliminates the ability to avoid “prior art” by relying on an earlier date of invention), the AIA assured that there would be no incentive for an inventor to delay filing for a patent until after a secret commercialization had commenced—since such a delay in filing can result in the patent on the invention being invalid based upon a public disclosure made even a day before the patent was sought, *as well as being unenforceable against anyone who has independently commenced commercialization more than one year prior to the patent filing*.²⁸

Overruling *Helsinn* Aligns With Congressional Intent In Enacting The AIA

²⁷ Such a defense is a nearly universal feature of patent systems outside the United States that define prior art as limited to subject matter made available to the public. “Currently, nearly every foreign country that has adopted a first-inventor to file system recognizes prior user rights.” See *Prior User Rights – Strengthening U.S.*

Manufacturing and Innovation: Hearing Before the Subcommittee on Intellectual Property, Competition, and the Internet of the Committee on the Judiciary, House of Representatives, One Hundred Twelfth Congress, Second Session (February 1, 2012) at p. 2. (https://www.google.com/books/edition/Prior_User_Rights/kLL7IKtwObEC)

²⁸ See *Report on the Prior User Rights Defense: Report to Congress January 2012*, by the United States Patent and Trademark Office (https://www.uspto.gov/sites/default/files/aia_implementation/20120113-pur_report.pdf), discussing two limitations on the defense under the AIA: the one-year “holdoff” period before a commercial use can qualify for the defense and the inability of the completion of substantial preparations for commercial use to qualify for the defense. The defense currently is codified in 35 U.S.C. §273 could be amended in two respects that would be consistent with international norms for the defense, i.e., to allow for substantial preparations for commercial use to suffice to invoke the defense and to remove the one-year “holdoff” period before the defense takes effect. The earliest legislative efforts that resulted in the AIA, i.e., H.R. 2795 (109th Congress) (available at <https://www.congress.gov/bills/109/congress-house-bill/2795/text>), would have made both these changes to §273. See §9(b)(2)(ii), “striking ‘at least 1 year before the effective filing date of such patent, and’ and all that follows through the period and inserting ‘and commercially used, or made substantial preparations for commercial use of, the subject matter before the effective filing date of the claimed invention.’” *Enacting these additional reforms expanding the reach of the prior user rights statute would not be inconsistent with—and, instead, could further advance the policy objectives that motivate—removing the text “in public use or on sale” from 35 U.S.C. §102(a)(1), accompanied by the enactment of the proposed patent application filing laches defense, as set out in the above reform proposal.*

Overruling *Helsinn* legislatively would be consistent with the full implementation of the international harmonization recommendations of the National Academies.²⁹ It would restore the intent of the congressional sponsors of the AIA to implement the National Academies' recommendations.

It would eliminate the untoward consequences of maintaining a non-transparent aspect of pre-AIA patent law, i.e., a form of "secret prior art." that is at best a poor fit within the confines of the new AIA statute built upon transparency in prior art.

Moreover, doing so would have the salutary policy effect of affording inventors with a continuing incentive to seek patents on subject matter that had been secretly commercialized, in lieu of forcing resort to continued trade secret protection. This is consistent with the underlying disclosure-for-exclusivity bargain that lies at the heart of the patent system.

Addressing Prolonged, Pre-Filing Commercialization Though an Unenforceability Defense

If *Helsinn* is legislatively overruled, an entirely separate question arises as to whether any compelling policy considerations would support additional statutory changes to limit the ability of inventors to enforce patents in situations where the patent was sought only after an unacceptably prolonged delay following the inventor's initial commercialization. If so, a pair of considerations would need to be addressed.

The first issue is the time period before the initial patent filing during which secret commercialization activities should be disregarded altogether in the determination of whether a patent can be successfully enforced. The second issue is the time period, after the date of initial commercialization, on which patent rights should end.

As to the first issue, a policy tension exists as between imposing a very short period during which the patent filing must take place and allowing a longer period during which the inventor would have a continuing incentive to seek patent protection in lieu of forcing resort to continued trade secret protection. Historically, as noted above, the patent law provided a one- or two-year period for disregarding inventor-attributable "on sale activities. Other time periods, however, merit consideration. The policy involved in encouraging prompt action, and penalizing a prolonged delay in taking action is, in effect, an effort to define the *laches* period—establishing the time after which the delay in filing for a patent was unreasonable.

²⁹ The National Academies cited several "unharmonized" aspects of U.S. patent law, including "the U.S. exception to the rule of publication of patent applications after 18 months." See NRC Report, p. 83. *Enacting this harmonizing change to the 18-month publication statute would not be inconsistent with—and, instead, could further advance the policy objectives that motivate—removing the text "in public use or on sale" from 35 U.S.C. §102(a)(1), accompanied by the enactment of the proposed patent application filing laches defense, as set out in the above reform proposal.* Such a change could facilitate moving ahead with a patent filing on a claimed invention that is about to be—or had already been—commercialized, by eliminating any possibility that novelty or nonobviousness might be belatedly defeated upon issuance of a competitor's *long-pending, long secret, domestic-only* patent filing. This is a risk not faced in Europe, China, Japan, and other countries that mandate universal publication of pending applications.

In assessing the period for a “patent application filing laches defense,” a six-year period would be appropriate, particularly given other precedents in the patent law. For example, until the Supreme Court overruled the laches as a defense to infringement,³⁰ patent owners were accorded a six-year period during which an action for infringement must be commenced. Similarly, in the application of a laches defense during *ex parte* patent prosecution, the Federal Circuit has established a six-year period during which prejudice is presumed.³¹ Given the desirability on policy grounds of not prematurely forcing inventors to forego patenting in favor of continued trade secret protection, a six-year laches period would represent a precedented, appropriate interval, prior to the initial patent filing, during which secret, inventor-attributable “on sale” activities should be disregarded.

As to the second issue, the Uruguay Round Agreements Act provided that the patent expiration date would be set at 20 years from the date of the initial, nonprovisional patent filing. If the patent filing is delayed until after commercialization of a claimed invention, there can be no concern over the possibility of an unjustified delay the expiration of the patent so long as the patent term truncated to expire not later than 20 years from the date of the initial commercialization of a claimed invention. For example, the expiration date in such a situation would be earlier in time than had a provisional patent filing taken place immediately *before* commercialization commenced.

If a patent application filing laches defense to the enforceability of a patent³² were to be implemented—to address the situation where a prolonged delay had taken place in seeking a patent after commercialization of a claimed invention—the policy considerations involved could be addressed by providing a six-year laches period for making the initial patent filing and by mandating the patent term be truncated to a 20-year period from the date of initial commercialization.³³ A patent application filing laches defense build on these parameters could

³⁰ *SCA Hygiene v. First Quality Baby Products*, 137 S. Ct. 954, 967 (2017). “Laches cannot be interposed as a defense against damages where the infringement occurred within the period prescribed by [35 U.S.C.] §286.”

³¹ *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1370 (Fed. Cir. 2021). “[I]n the context of a §145 action, the PTO must generally prove intervening rights to establish prejudice, but an unreasonable and unexplained prosecution delay of *six years or more* raises a presumption of prejudice...”

³² The proposed patent application filing laches defense would represent a policy-driven unenforceability defense to infringement that would arise, if at all, based on applicant-attributable conduct. Other such defenses, based on inventor- or applicant-attributable conduct, are recognized by the courts. This includes the unenforceability defense based upon prosecution misconduct, i.e., the so-called “inequitable conduct” defense. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc). “Inequitable conduct” can have the effect of rendering a patent permanently unenforceable—just as the proposed patent application filing laches defense would do. Similarly, the “prosecution laches” defense renders otherwise valid patent claims unenforceable based upon applicant conduct during prosecution. *Personalized Media Communications v. Apple Inc.*, 952 F.3d 1336 (Fed. Cir. 2020). Because such defenses arise in special circumstances, based upon applicant-attributable conduct, they have not been regarded as running afoul of obligations under the TRIPs Agreement, Article 21(1), requiring that “patents shall be available and patent rights enjoyable...” See Agreement on Trade-Related Aspects of Intellectual Property Rights (Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC), 1869 U.N.T.S. 299.

³³ The proposed patent application filing laches defense could raise a potential issue of U.S. compliance with the WTO TRIPs Agreement, but only to the extent that the *current* U.S. patent law similarly raises such an issue of TRIPs compliance—on account of the *Helsinn* decision. Under the AIA, as interpreted in *Helsinn*, 35 U.S.C. §102(a)(1) now extinguishes an inventor’s patent rights if it is determined that inventor-attributable, on-sale activities (irrespective of availability to the public) had taken place more than one year prior to the inventor’s

supersede any policy justification for treating “on sale” activities as prior art, or otherwise considering such activities either in ex parte examination or during a post-grant review proceeding.

Possible Implementing Legislative Text

The reform proposal could be implemented through a pair of amendments to §102(a)(1) and §283 of title 35, as described below:

(1) Amendment to 35 U.S.C. §102(a)(1) Removing “In Public Use or On Sale”

Congress could categorically confine “prior art” under 35 U.S.C. §102(a)(1) to subject matter *made available to the public*, thereby overruling *Helsinn*, by simplifying paragraph (1) to read:

“A ~~[person shall be entitled to a patent unless]~~ patent for a claimed invention may not be obtained if ... (1) the claimed invention was patented, described in a printed publication, ~~[or in public use, on sale,]~~ or otherwise available to the public before the effective filing date of the claimed invention... .”

(2) Amendment to 35 U.S.C. §282 Creating a Patent Application Filing Laches Defense

Congress could address any inventor-attributable, secret commercialization of a claimed invention (i.e., placing the claimed invention “in public use or on sale”) before the patent for the invention was sought through a *patent application filing laches defense* that would bar patent enforceability, by amending 35 U.S.C. §282 to add the following paragraph:

“If the inventor or a joint inventor, directly or indirectly, had placed a claimed invention in public use or on sale in the United States more than six years prior to the effective filing date of the claimed invention, the patent claiming the invention shall be unenforceable unless, prior to the date on which the patent was initially issued, the patentee had disclaimed under section 253(b) at least the term of the

initial patent filing. The proposed amendments to title 35, United States Code, have the sole effect of further limiting the consequences of *Helsinn* on an inventor’s ability to secure and enforce a valid patent—and to no extent expands its consequences. The proposed amendments allow valid and enforceable patent rights to exist so long as an initial patent filing takes place within six years, rather than only a single year, from the initiation of inventor-attributable on-sale activities. Hence, to the extent that the *Helsinn* bar limiting an inventor’s ability to secure enforceable patent rights is TRIPs compliant, a more limited bar taking effect only after a six-year period must be a *fortiori* TRIPs compliant. Indeed, the proposed patent application filing laches defense then goes a step farther in limiting the effect of *Helsinn*—even if the six-year laches period is exceeded. In such circumstances, the proposed amendments allow valid, enforceable patent rights to exist *so long as the inventor agreed to limiting the combined commercialization/patent protection period to not more than 20 years, which is the time period set out in TRIPs Article 31 for a TRIPs-compliant patent term*. Assuming that *Helsinn* is TRIPs-consistent—for example, because under Article 30 of TRIPs the United States is permitted to “provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”—the proposed defense must be regarded as both assuredly TRIPs compliant and generally consistent with the 20-year minimum protection period that Article 31 of TRIPs contemplated.

patent extending beyond 20 years from the date on which the claimed invention was first placed in public use or on sale in the United States directly or indirectly by the inventor or a joint inventor.”

Conclusions

In *Helsinn*, the Supreme Court’s holding reflected the concern that prolonged, inventor-attributable commercialization of a claimed invention before seeking a patent can result in an unjustified exclusivity windfall. This concern can be most efficiently addressed—in those rare situations in which an inventor has secretly commercialized a claimed invention for a prolonged period before seeking a patent—by holding the patent unenforceable. The unenforceability based on delayed patent filing would be imposed whenever the inventor’s patent filing had been delayed for more than six years following the first inventor-attributable commercialization. The inventor would have a one-time opportunity to avoid unenforceability based on delayed patent filing by taking action, prior to the issuance of the patent, to disclaim patent term extending beyond 20 years from the date of first inventor-attributable commercialization. This patent application filing laches unenforceability defense fully addresses any policy possible concerns over a prolonged, inventor-attributable commercialization before seeking a patent. In addition, it would eliminate any need for maintaining the current “on sale” invalidity defense based on information not made available to the public.

Simplify The Law On Incorrect Inventor Naming

**Eliminate Incorrect Inventorship As A Ground For Patent Invalidity Or Unpatentability
Unless Consequential To Patentability Over Prior Art**

And

***Bar Patent Enforcement Unless and Until Any Incorrect Inventor Naming That Would Result
In A Change In Patent Ownership Has Been Corrected***

Problem Statement

Naming correct inventors is required under the U.S. Constitution, and a failure to do so can have untoward consequences to the enforceability and validity of the patent right. As most prosecuting attorneys can attest, however, inventorship determinations are difficult to make and easy to second guess. Courts have characterized the law governing inventorship as “one of the muddiest concepts in the muddy metaphysics of patent law.”³⁴ Compounding the complexity in the law is the fact-dependency and subjectivity inherent in an inventorship determination. Furthermore, as a matter of sound patent policy, committing the resources at the time of filing to be confident that inventorship is unassailable is neither practical nor prudent in an effective patent system. It dramatically increases the costs to engage the system with a patent application without any corresponding benefit to support or advance innovation.

Congress has recognized this as well. While it is necessary to name the correct inventors, the law following the American Invents Act is most forgiving and accommodating to corrections. Errors are now correctable, including errors resulting from deceptive intent or other malfeasance that led to a patent application being filed with unnamed inventors. Unfortunately, the procedures to correct inventorship post-issuance under current law are also complicated and expensive. For example, an unnamed inventor can be named as an inventor by the Director by application of all the parties under 35 U.S.C. §256, without regard to deceptive intent. And, if there was deceptive intent, the parties can separately correct any misrepresentations to the office, effectively eliminating any allegation of inequitable conduct, through 35 U.S.C. §257. If the parties are not cooperative and agreed on the change in inventorship, the unnamed inventor can bring a derivation proceeding under §135(b) before the USPTO or bring proceedings in Federal district court to correct inventorship. And, if corrected, at the end of these procedures an unnamed inventor is without a remedy, e.g., if the named inventors licensed the patent before correction, unless a claim can be made in law outside of IP.³⁵ Collectively, these corrective measures are unnecessarily complicated, expensive, and can be highly prejudicial to an unnamed inventor.

³⁴ *Mueller Brass Co. v. Reading Indus., Inc.*, 352 F.Supp. 1357, 1372 (E.D. Pa. 1972).

³⁵ See, for example, *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298 (Fed. Cir. 2003)

Summary of the Proposed Solutions

To advance a more durable and reliable patent system, it is highly desirable that inconsequential inventor-naming errors do not have outsized consequences—while at the same time assuring that any and all material inventor-naming errors can be swiftly and efficiently corrected. Once corrected, the rightful inventor should have assurance that its patent rights can be reliably enforced. This is effectuated by implementing by law or regulation the following three principles:

- (1) The United States Patent and Trademark Office should have additional authority—beyond that currently present in 35 U.S.C. § 116, 35 U.S.C. § 256, and 35 U.S.C. § 135—to address any issue of incorrect inventorship, including by conducting such contested proceedings in the Office as would be necessary to do so, upon a petition timely made to the Office by a person whose ownership interest in the application or patent would be affected such correction;³⁶ and
- (2) The incorrect naming of the inventor in a patent or in a patent application should not be a ground on which any claimed invention in a patent could be held invalid, or any claimed invention in a patent application could be found unpatentable,³⁷ provided that—
 - a. If the correction of the naming of the inventor in a patent would result in a change in the ownership of the patent, such patent should be unenforceable unless and until such correction has been made.³⁸
 - b. If the correction of the naming of the inventor in a patent would result in a change in the scope and content of the prior art, the change in inventorship would not preclude a finding of unpatentability or invalidity under 35 U.S.C. § 102 or § 103;
- (3) If correction of the inventorship of a patent results in a person acquiring a joint ownership interest in the patent, the resulting joint owners shall be subject to an accounting, with respect to one another, for acts taking place prior to the date such correction was made that, absent rights under the patent, would have constituted an infringement thereof.³⁹

³⁶ The intent is to leverage USPTO expertise from interference and derivation proceedings to offer the parties involved, relative to the opportunities available in the federal district courts, with a faster and less expensive forum before legal and technical experts, to resolve inventorship disputes.

³⁷ Consistent with current law.

³⁸ Under current law, a jointly owned patent cannot be enforced without the agreement of the joint owners. This change clarifies that correct ownership is a pre-requisite to enforcement.

³⁹ The proposal for an accounting addresses potential inequities or unfairness with an unnamed joint inventor. Any proceeding for an accounting, if not resolved between the parties, would be before a Federal district court.

Introduction and Background

Under the patent statute,⁴⁰ as authorized under the U.S. Constitution,⁴¹ Congress provided that only inventors, or their assignees,⁴² are entitled to secure patents on an inventor's discoveries. For this reason, the patent statute requires the naming of the inventor in every nonprovisional patent application that is filed.⁴³ Assuring the correct ownership of a patent is entirely dependent upon accurately naming the correct inventor in the application on which the patent is issued.

In some circumstances a single individual is the inventor of the subject matter being claimed in a patent, while in other circumstances two or more joint inventors may form the "inventive entity" of the subject matter being claimed in a patent.⁴⁴ Whether the inventorship is sole (by a single individual) or joint (by a collection of two or more individuals), inventor-naming errors can result in patents (1) that have been issued to individuals or entities not legally entitled to patent ownership rights or, (2) even if entitled to such rights, that exclude others with legitimate ownership interests in the patents involved.

Determining correct inventorship is a "question of law" and depends upon an assessment of when the "conception" of the subject matter being claimed was completed.⁴⁵ The term "conception," in connection with inventorship determinations, references activities taking place

⁴⁰ "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. §101.

⁴¹ See also U.S. Constitution, Article I, Section 8, Clause 8: "[The Congress shall have Power] To 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."

⁴² "A person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent. A person who otherwise shows sufficient proprietary interest in the matter may make an application for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties. If the Director grants a patent on an application filed under this section by a person other than the inventor, the patent shall be granted to the real party in interest and upon such notice to the inventor as the Director considers to be sufficient." 35 U.S.C. §118.

⁴³ "An application for patent that is filed under section 111(a) or commences the national stage under section 371 shall include, or be amended to include, the name of the inventor for any invention claimed in the application. Except as otherwise provided in this section, each individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application." 35 U.S.C. §115(a).

⁴⁴ See the definitions in 35 U.S.C. §100:

"(a) The term 'invention' means invention or discovery.

"(f) The term 'inventor' means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.

"(g) The terms 'joint inventor' and 'coinventor' mean any 1 of the individuals who invented or discovered the subject matter of a joint invention."

Under U.S. law, the term "inventor" now specifically references the collection of individuals who invented the subject matter being claimed—with a "sole inventor" being a single individual and a "joint inventor" being a multiplicity of individuals."

⁴⁵ "Determining 'inventorship' is nothing more than determining who conceived the subject matter at issue, whether that subject matter is recited in a claim in an application or in a count in an interference. Conception, and consequently inventorship, are questions of law that this court reviews *de novo*." [Sewall v. Walters](#), 21 F.3d 411, 415 (Fed. Cir. 1994).

in the human mind.⁴⁶ As a result, an inventorship determination must involve addressing questions such as *who thought of what, and when did that thinking take place?*

The “conception” of an invention cannot be regarded as being complete until there is nothing left to be accomplished to put the invention into practice that is not routine work by individuals of ordinary skill in the particular technology to which the invention relates.⁴⁷ Moreover, “conception” is never complete before there is the mental recognition or appreciation of the existence of something new.⁴⁸

The determination of whether the inventorship is “sole” or “joint” must be assessed under rather complex and somewhat opaque jurisprudence. A “joint inventor” can be any individual that has made some *not qualitatively insignificant* contribution to the conception of a claimed invention.⁴⁹ In addition, such a contribution can arise based upon only a limited “collaboration”⁵⁰

The patent statute itself was amended in 1984 to emphasize the flexibility that can apply to the determination of the joint efforts that can serve as a predicate for joint inventorship.⁵¹ One 1984 change to inventorship law is that joint inventorship of a patent now requires no more than that a contributing individual provide a not-qualitatively-insignificant contribution to a single claim of

⁴⁶ “A complete conception ... of the invention consists in the complete performance of the mental part of the inventive act. All that remains to be accomplished in order to perfect the act or instrument belongs to the department of construction, not invention. It is therefore the *formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice* that constitutes an available conception within the meaning of the patent law.” *Townsend v. Smith*, 36 F. 2d 292, 295 (C.C.P.A. 1929).

⁴⁷ “Conception is the touchstone of inventorship, the completion of the mental part of invention. ... Conception is complete only when the idea is so clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. ... Because it is a mental act, courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention. ... “The idea must be definite and permanent in the sense that it involves a specific approach to the particular problem at hand. It must also be sufficiently precise that a skilled artisan could carry out the invention without undue experimentation. And, of course, the alleged conception must be supported by corroborating evidence.” *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1227-1230 (Fed. Cir. 1994).

⁴⁸ “It is now well settled that ... there is no conception or reduction to practice where there has been *no recognition or appreciation of the existence of the new [subject matter]*.” *Heard v. Burton*, 333 F.2d 239 (C.C.P.A. 1964); and *Langer v. Kaufmann*, 465 F.2d 915 (C.C.P.A. 1972).” *Silvestri v. Grant*, 496 F. 2d 593, 597 (C.C.P.A. 1974).”

⁴⁹ “All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is *not insignificant in quality*, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real [joint] inventors well-known concepts and/or the current state of the art.” *Pannu v. Iolab Corp.*, 155 F. 3d 1344 (Fed. Cir. 1998).

⁵⁰ “What is clear is that the statutory word ‘jointly’ is not mere surplusage. For persons to be joint inventors..., there must be some element of joint behavior, such as collaboration or working under common direction, *one inventor seeing a relevant report and building upon it or hearing another’s suggestion at a meeting*. Here there was nothing of that nature. Individuals cannot be joint inventors if they are *completely ignorant of what each other has done until years after their individual independent efforts*. They cannot be totally independent of each other and be joint inventors.” *Kimberly-Clark v. Procter & Gamble*, 973 F. 2d 911, 917 (Fed. Cir. 1992).

⁵¹ 35 U.S.C. §116 was amended to liberalize joint inventorship qualifications: “When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not *physically work together or at the same time*, (2) each did not *make the same type or amount of contribution*, or (3) each did not make *a contribution to the subject matter of every claim of the patent*.”

a patent.⁵² This change alone has vastly increased the opportunities for an individual to be named as a joint inventor—and for such joint-inventor status to potentially ebb and flow as claims are amended during the examination of a patent application as the claims of the application are amended.

Inventorship determinations have become further complicated in recent decades with the advent of information technologies that can assist in the formation of the complete “conception” needed for the act of invention to be completed. Some forms of artificial intelligence have begun to make not qualitatively insignificant contributions to what is being disclosed and claimed in patent filings. Nonetheless, the patent law is clear that only individuals qualify as the inventor or a joint inventor of a patent filing.⁵³

No matter how potentially difficult, or how potentially subjective, the determination of inventorship for a patent application might be, correct inventorship is a requirement for securing a valid patent.⁵⁴ When inventorship of a pending patent application is incorrect, the patent statute permits the USPTO to correct inventorship.⁵⁵ The USPTO has similar, but more limited authority in the case of incorrect inventorship of a patent once issued.⁵⁶ In addition, rarely used procedures in the USPTO can result in a correction of inventorship in cases of so-called “derivation.”⁵⁷ The courts appear to have the same authority in cases of derivation.⁵⁸

⁵² As a consequence, “[the] interplay between inventorship and ownership creates the anomalous situation that a co-inventor of even a single claim can then assert a right of joint ownership over an entire patent with multiple claims.” *Israel Bioengineering v. Amgen*, 475 F. 3d 1256, 1264 (Fed. Cir. 2007).

⁵³ “To perform this mental act, inventors must be *natural persons* and cannot be corporations or sovereigns.” *University of Utah v. Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften EV*, 734 F. 3d 1315, 1323 (Fed. Cir. 2013). “[O]nly natural persons can be ‘inventors.’” *Beech Aircraft Corp. v. Edo Corp.*, 990 F. 2d 1237, 1248 (Fed. Cir. 1993). “Statutes are often open to multiple reasonable readings. Not so here. This is a case in which the question of statutory interpretation begins and ends with the plain meaning of the text. ... In the Patent Act, ‘individuals’—and, thus, ‘inventors’—are unambiguously natural persons.” *Thaler v. Vidal*, 43 F. 4th 1207, 1213 (Fed. Cir. 2022).

⁵⁴ “One court has said that the ‘exact parameters of what constitutes joint inventorship are quite difficult to define. It is one of the muddiest concepts in the muddy metaphysics of patent law.’ *Mueller Brass Co. v. Reading Indus., Inc.*, 352 F.Supp. 1357, 1372 (E.D. Pa. 1972). But this court has stated that ‘[d]etermining “inventorship” is nothing more than determining who conceived the subject matter at issue...’ *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994). Whether such a determination is ‘nothing more than’ or ‘quite difficult,’ a valid patent requires correct inventorship.” *In re VerHoeft*, 888 F. 3d 1362 1365 (Fed. Cir. 2018).

⁵⁵ “Whenever through error a person is named in an application for patent as the inventor, or through an error an inventor is not named in an application, the Director may permit the application to be amended accordingly, under such terms as he prescribes. 35 U.S.C. §116(c).

⁵⁶ “Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.” 35 U.S.C. §256(a)

⁵⁷ “In a derivation proceeding instituted under subsection (a), the Patent Trial and Appeal Board shall determine whether an inventor named in the earlier application derived the claimed invention from an inventor named in the petitioner’s application and, without authorization, the earlier application claiming such invention was filed. *In appropriate circumstances, the Patent Trial and Appeal Board may correct the naming of the inventor in any application or patent at issue.* The Director shall prescribe regulations setting forth standards for the conduct of derivation proceedings, including requiring parties to provide sufficient evidence to prove and rebut a claim of derivation.” 35 U.S.C. §135(b).

⁵⁸ “The owner of a patent may have relief by civil action against the owner of another patent that claims the same invention and has an earlier effective filing date, if the invention claimed in such other patent was derived from the

While the current patent statute treats all incorrect inventorship invalidity issues identically, some inventor-naming errors are entirely inconsequential to patent ownership, while others can force a change in patent ownership (i.e., upon inventorship correction, the patent owner or no pre-correction joint patent owner, as the case may be, would remain as the patent owner or a joint patent owner). For example, changing the names of the joint inventors on a patent does not impact ownership where the originally named individuals and the correctly named joint inventors have each assigned all their rights in the patent to the same assignee. On the other hand, naming just a single additional individual as a joint inventor can produce joint ownership of the patent, with the joint owners each having rights to practice the patented technology without accounting to any other joint owner.

Allegations of invalidity based upon inventor misnaming not only inject uncertainty in the enforcement of patent rights, but impose significant financial burdens on patent litigants. In addition, allegations of fraudulent inventor misnaming historically created additional risks that the patent in question could be found to be permanently unenforceable.⁵⁹ The AIA attempted—through a multiplicity of provisions—to create a pathway for fraudulent misnaming of the inventor of a patent to be fully corrected, such that the correct inventor would be vested with title to a patent that could be found valid and fully enforceable. However, the AIA provisions—amendment of 35 U.S.C. § 116 and § 256 to remove the limitation “without deceptive intention on inventorship corrections; the rewriting of 35 U.S.C. § 135 to create a derivation procedure that authorized the Patent Trial and Appeal Board to correct any inventor-naming errors, whether or not fraudulent; and the addition of 35 U.S.C. § 257 providing a “supplemental examination” pathway for purging any unenforceability based on fraudulent conduct in the original, errant inventor naming—have limitations and costs borne of the procedural complexity of the array of statutory provisions involved. Perhaps, most notably, these limitations and costs burden the patent system and detract from its objective to advance innovation. There is a better way.

The better way is to simplify the mechanisms to correct inventorship and minimize the “land mines” for the unwary. Once corrected, the rightful inventor should have assurance that its patent rights can be reliably enforced. These objectives are particularly important given the somewhat opaque and subjective nature of all determinations of inventorship, the ease with which inventor misnaming can be pleaded, and the procedural complexity addressing issues of potential unenforceability arising from any original misnaming misconduct.

Finally, the patent statute currently dictates that no accounting is required among the joint owners of a patent with respect to any acts undertaken separately to exploit rights under the

inventor of the invention claimed in the patent owned by the person seeking relief under this section.”
35 U.S.C. §291.

⁵⁹ Permanent unenforceability as a remedy based upon other types of prosecution misconduct (e.g., concealing prior art known to be anticipatory) are typically justified on the ground that such a fraud on the public, in securing an invalid patent, should deprive the fraudfeasor of any enforceable rights. Fraudulent misnaming of the inventor where the claims of the patent are otherwise valid and could be enforceable does not burden the public with exclusionary rights that should not exist, but constitutes a fraud on the omitted inventor or joint inventors. The appropriate remedy, rather than holding an otherwise entirely valid patent permanently unenforceable ought to be to unwind the fraud—and secure the correct inventor with ownership rights in the valid patent.

patent. The absence of any accounting applies even in situations where corrected inventorship results in a belated correction of patent ownership. In these circumstances, fairness among the corrected joint owners of the patent may require that this default “no accounting” rule be limited. The prospect of such an accounting could provide an incentive for collaborators to make careful assessments of joint inventorship in the course of preparing the original patent filings.

Possible Implementing Legislative Text

As a starting point in the discussion on how to implement the principles set out herein, possible legislative text was drafted. Such text is expected to be perfected as the principles evolve from concepts to concrete solutions.

Eliminate Inconsequential Inventor Naming Errors as a Ground for Invalidity

A key element of the reform proposals would eliminate incorrect inventorship (misjoinder or nonjoinder of individuals named as the inventor or a joint inventor on a patent) as an issue of patent validity, unless consequential to patentability over prior art. It would address all inconsequential inventorship issues, other than patentability over prior art, solely as matters of patent enforceability. The proposal would specifically bar the enforcement of a patent in situations where (1) correction of incorrect inventorship would result in a change in patent ownership and (2) such a correction has not been made. In addition, as discussed in the section below, the Director would be given new authority to correct inventor naming in patents. These aspects of the first reform proposal could be implemented by amending 35 U.S.C. §256 to read as follows:

“§256. Incorrect inventorship and correction.

“(a) INCORRECT INVENTORSHIP.—Except as provided in subsection (b), a patent shall not be held to be invalid or unenforceable under sections 101, 115, or 116(a) for naming an individual as the inventor or a joint inventor who is not the inventor or a joint inventor of any claimed invention therein or for the failure to name as the inventor or a joint inventor an individual who is the inventor or a joint inventor of at least one claimed invention therein.

“(b) ENFORCEABILITY.—If a patent incorrectly names the inventor and the correction of inventorship would result in a change in the ownership of the patent, such patent shall not be enforceable unless and until the naming of the inventor of the patent is corrected as provided under subsection (c).

“(c) INVENTORSHIP CORRECTION.—No correction of the naming of the inventor of a patent may be made except by—

“(1) a court before which such matter is called in question, whereupon the court may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly; or

“(2) the Director as provided under section 135 or section 136.”

These changes to the patent statute would simplify the law given that, for the vast majority of patent filings, any possible inventor-naming error would be inconsequential to patent ownership *because any individuals who would be candidates for consideration as joint inventors would all*

have assigned the patent rights to their common employer. In such cases where incorrect inventorship is inconsequential to patent ownership, the “little harm, more of a technical foul” rule should apply, such that a patent claim should neither be invalid nor unenforceable based upon incorrect inventorship.

Addressing inconsequential inventorship issues as irrelevant to patentability or patent validity under 35 U.S.C. § 101, § 115, or § 116—or patent enforceability based thereupon—would simplify a raft of patent disputes, from post grant reviews to ITC §337 actions to patent infringement actions. It would do likewise for ex parte patent examination. In addition, providing that no patent is enforceable until such an ownership-consequential inventorship correction is made would assure that neither the rightful patent owner nor owners nor the public would be prejudiced by an *inconsequential* inventor-naming error.⁶⁰ Finally, this proposed text would not impact raising patentability or invalidity issues under 35 U.S.C. § 102/§ 103 arising based upon misjoinder.

Under current law, the only manner in which a patent is enforceable is through an action for infringement brought by a patent owner. If a patent is jointly owned, this requires that the action be brought by the joint patent owners. The proposed reform serves to reinforce this principle of law through the explicit limitation on enforceability of a patent where an inventor-naming error is consequential to patent ownership.

New Avenue for Correction of Inventor-Naming Errors in Patents.

As noted above, the first complementary element of the reform proposal would provide additional and broader authority for the USPTO to address and correct inventor-naming errors. In addition to the amendment in 35 U.S.C. § 256(c)(2), referenced above, this could be accomplished by repealing 35 U.S.C. §116(c) and by adding a new 35 U.S.C. §136 to read as follows:

“§136. Inventorship correction by Director.

“(a) IN GENERAL.—If all parties concerned have joined in a request for correction of the naming of the inventor in a patent or an application for patent, the Director shall order such correction.

“(b) CONTESTED CASES.—Any person alleging an ownership interest in a patent or an application for patent may petition the Director for a correction of the naming of the inventor in such application or patent as may be required to correct the ownership of the application or patent. A petition under this subsection must be accompanied by payment of such fee as may be established by the Director, identify all real parties in interest, identify with particularity the facts on which a correction is alleged to be required,

⁶⁰ Inventor-naming errors can be consequential to patentability on prior art grounds, i.e., based upon 35 U.S.C. § 102/§ 103, and the consequences of fraudulent naming of an individual as a joint inventor to wrongfully attempt to eliminate patentability-defeating prior art under 35 U.S.C. § 102(b)(2)(1)(A) would be unaffected by the above changes to 35 U.S.C. § 256. Such a misrepresentation during ex parte examination under 35 U.S.C. § 115 would remain *material to patentability* under *Therasense*, would constitute consequential prosecution misconduct, if intentionally deceptive, in addition to invalidity consequences under 35 U.S.C. § 102/§ 103. As such, the prosecution misconduct could further result in liability under competition laws for attorney fees and trebled damages, all of which would be unaffected by the proposed change to 35 U.S.C. § 256.

establish that the petition was filed in a timely manner after the petitioner discovered the error in the naming of the inventor, and provide evidence sufficient to establish a reasonable likelihood that such correction is required. If the Director deems that a petition filed under this subsection was filed in a timely manner and has established a reasonable likelihood a correction is required, the Director shall conduct such proceedings as may be necessary to determine whether clear and convincing evidence requires a correction to the naming of the inventor.

Because *correct inventorship can be important to the individuals seeking recognition as the inventor or as a joint inventor, and can be necessary to assuring correct patent ownership*, the USPTO should be given expanded statutory authority to undertake inventorship determinations—beyond just the USPTO’s current ability to address any consensual inventorship changes—under which the Office could address *contested requests for material inventorship corrections*. This authority should extend to correction requests, upon petition to the Director, if *timely presented, well substantiated, and consequential to patent ownership*. Once a final USPTO determination had been made, an interested party would have the right to appeal to the courts, as with any such determination,⁶¹ or through whatever special mechanism that Congress might establish with respect to a determination under §136.⁶² Such a procedure could take advantage of the expertise of the Office and offer the possibility of more rapid and economical resolution of inventorship disputes.

“Accounting” Consequences of Joint Ownership Changes

The second complementary element of the proposal provides an incentive for collaborators to affirmatively assess correct inventorship through an “accounting” requirement for pre-correction acts in circumstances where correction of joint inventorship produced a change in ownership. This change in the law could be accomplished by amending 35 U.S.C. §262 as follows:

§262. Joint owners.

In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners, except that each joint owner shall be subject to an accounting to the others for such acts, if any, that would constitute infringement of the patent, absent rights thereunder, taking place prior to the date, if any, on which an inventorship correction results in a change in ownership of the patent adding one or more persons as joint owners of the patent.

⁶¹ The Director’s determination under 35 U.S.C. §136, constituting a final agency action, would be subject to judicial review, i.e., final decisions on petitions can be subject to judicial review under the Administrative Procedure Act (APA). See 5 U.S.C. §§ 702-704, 706. Under 5 U.S.C. §702, “A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.” This would include district court review pursuant to 28 U.S.C. §1331, followed by appeal to the Federal Circuit. See, generally, the discussion in *Thaler v. Vidal*, 43 F. 4th 1207, 1210 (Fed. Cir. 2022), addressing the issue of inventorship.

⁶² Compare, for example, the special statutory provisions for USPTO inventorship determinations made pursuant to 35 U.S.C. §135 (derivation proceedings), providing a dual appeal pathway through 35 U.S.C. §141(d) (Federal Circuit) and §146 (civil action).

The “accounting” consequences from a change in joint ownership of a patent that would arise under amended 35 U.S.C. §262 as a consequence of the correction of joint inventorship of a patent should offer an incentive to collaborators to undertake a careful, deliberate exercise to assure that the inventorship of the patent is correct and the inventor of the patent is correct at the time the nonprovisional application for patent is initially filed.

Conclusions

The proposed reform proposals focus on making any required inventorship corrections efficiently in the USPTO. They provide for sanctioning inventor misnaming when sequential to ownership, unless and until corrected, or when consequential to *Therasense*-material “prior art.” Where a joint ownership change does result from corrected inventorship, the reform proposals provide that pre-correction acts exploiting the patent be subject to an accounting.

Simplify Double Patenting – Add New Enforceability Limits

**Eliminate “Double Patenting,” As Between Two Patents, Unless—For One Claim From Each Patent—Neither Claimed Invention Is Prior Art To The Other,
Eliminate “Double Patenting” As A Ground of Patent Invalidity Or Unpatentability,
And**

Apply Res Judicata Principles To The Patents Involved In “Double Patenting” By Treating The Claims Of Both Involved Patents As Though They Had Issued In A Single Patent

Problem Statement

As the non-statutory doctrine of obviousness-type double patenting was originally conceived by the courts, its application was limited to the situation where an applicant prosecuted a simultaneously or subsequently issued patent (a “double patent”) that contained at least one claim that was “patentably indistinct” from a claim present in a simultaneously or previously issued patent (the “reference patent”). Obviousness-type double patenting, and the concept of “patentable indistinctness” as between such a pair of claims, originally applied only to the situation where neither of the claims represented prior art subject matter with respect to the other, *such that the statutory nonobviousness requirement did not apply to assure that one of the two claims was nonobvious, and confined to patentably distinct subject matter, relative to the other.* If such a claim in a second patent was found to be patentably indistinct (i.e., obvious) over the corresponding claim in a reference patent, the claim of the second patent was rendered invalid under obviousness-type double patenting principles unless the second patent was subject to a two-fold disclaimer of rights with respect to the reference patent, i.e., an “alienation disclaimer” (the second patent would be unenforceable if the second patent did not remain commonly owned with the reference patent) and a “disclaimer of term” (the second patent could not be enforced after the expiration date of the reference patent).

The “alienation disclaimer” coupled with the “disclaimer of term”—and codified in USPTO regulations as a “terminal disclaimer”—was required in order to obviate the policy concerns under which the courts justified imposing obviousness-type double patenting principles as a ground of unpatentability or patent invalidity. These were:

(1) the “potential for harassment” if the patent with the patentably indistinct claims were ever to become separately owned such that accused patent infringers might be subject to threats of separate enforcement of the otherwise valid claims of both patents and

(2) the potential for an applicant to prosecute the second or double patent to receive an unjustified timewise extension of exclusionary rights under the second patent if its term extended beyond the 17-year period of exclusionary rights granted to the reference patent.

Prior to the Patent Law Amendments Act of 1984,⁶³ the application of obviousness-type double patenting law was entirely confined to the situation where the same inventive entity had sought two patents containing patentably indistinct claims.⁶⁴ In all other situations, the nonobviousness requirement under 35 U.S.C. §103 operated to assure that a pair of issued patents could only obtain patentably distinct claims, i.e., no claim of either patent would be obvious with respect to any claim of the other patent.⁶⁵

Prior to the Uruguay Round Agreement Act of 1994,⁶⁶ obviousness-type double patenting served a second, constitutional purpose by providing a “limited Time”⁶⁷ for exclusionary rights in the case where patentably indistinct claims were present in separate patents. Since the pre-URAA period of exclusionary rights for a patent was limited to 17 years starting for the issue date of a patent, obviousness-type double patenting law required a “disclaimer of term” to be filed with the USPTO in any situation where the second patent was not issued simultaneously with the reference patent. Not only did such a disclaimer remove the possibility that the combined period of exclusionary rights of the reference patent and the double patent could exceed 17 years, but—absent such a disclaimer of term—nothing in the patent statute itself would have precluded perpetual protection for patentably indistinct claims through the issuance of separate patents, e.g., patents issued on an unlimited series of continuation applications, each with a separate 17-year term from the date of issuance.⁶⁸

Over the past quarter century, the judicially imposed doctrine of “obviousness-type double patenting” has remarkably expanded, with the law becoming vastly more complicated and, in some respects, confused. The doctrine can now apply in situations where the claims in two separate patents have a prior art relationship to one another.⁶⁹ This violates one of the most fundamental, historical constraints on the obviousness-type double patenting doctrine—that it applies only in situations where separate, potentially valid patents might have issued with patentably indistinct claims.

⁶³ Patent Law Amendments Act of 1984, Pub. L. No. 98–622, § 103, 98 Stat. 3383.

⁶⁴ “The term “double patenting” is properly applicable only to cases involving two or more applications and/or patents of the same inventive entity and should not be applied to situations involving commonly owned cases of different inventive entities. . . .” “Double Patenting” (834 Official Gazette 1615, January 9, 1967).

⁶⁵ In effect, obviousness-type double patenting could exist only where the inventor’s own prior patent filings—absent being a statutory bar—did not constitute prior art and, thus, did not preclude securing a valid patent with patentably indistinct claims in a subsequently sought patent.

⁶⁶ Uruguay Round Agreements Act, Pub. L. No. 103–465, § 101, 108 Stat. 4809.

⁶⁷ “[The Congress shall have Power . . .] To promote the Progress of . . . useful Arts, by securing for *limited Times* to . . . Inventors the *exclusive Right* to their respective . . . Discoveries.” U.S. Constitution, Art. I, Sec. 8, Cl. 8. [Emphasis added.]

⁶⁸ In contrast, under the URAA, the maximum theoretically possible period of aggregate exclusionary rights for a reference patent and a double patent is fixed at a “limited Time” of 22 years. This theoretical possibility arises if, after the issuance of the reference patent, a double patent is filed at the end of the one-year pendency of a provisional patent application that was filed at the end of a possible one-year “grace period” from the reference patent’s issue date.

⁶⁹ Recent decisions of the Federal Circuit that have found obviousness-type double patenting in situations where one of the two patents was prior art to the other, including *In re Hubbell*, 709 F. 3d 1140 (Fed. Cir. 2013), *Sun Pharmaceutical Industries v. Eli Lilly and Co.*, 611 F. 3d 1381 (Fed. Cir. 2010), *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F. 3d 955 (Fed. Cir. 2001). These decisions permit the application of “obviousness-type” double patenting principles to patentably distinct inventions of separate patents.

Similarly, the doctrine can now be applied to invalidate a previously issued patent as a “double patent” based on a subsequently issued patent as the “reference patent” in the double patenting.⁷⁰ This has the consequence of belatedly rendering a patent invalid notwithstanding that, as of the date the patent was issued, it had met all the requirements for securing a valid patent. This consequence can now arise because courts have recently ruled that a patent meeting all the statutory requirements for patentability as of its issue date can be rendered retroactively invalid under obviousness-type double patenting principles by treating a subsequently issued patent as a “reference patent” rather than the “double patent” for obviousness-type double patenting purposes.

Recently, the courts have justified the application of obviousness-type double patenting law on the basis that the patent term adjustment (PTA) provisions of 35 U.S.C. §154(b) had produced a patent with a later-in-time expiration date relative to other members of the same family of patents that constituted a “double patent” with respect to other family members.⁷¹ Under the URAA, absent the PTA, each member of the patent family had a common expiration date. According to the Court, a disclaimer of the §154(b)-adjusted patent term would have been needed for the “double patent” to be held valid, i.e., a disclaimer to restore a common expiration for the patents. In this appeal, for the first time, the court explicitly held that additional patent term that Congress had legislatively justified in the enactment of 35 U.S.C. §154(b) as part of the American Inventors Protection Act⁷² must be negated to preserve patent validity under obviousness-type double patenting principles.

Finally, obviousness-type double patenting principles are now applied to prevent the issuance of patents, or invalidate patents once issued, irrespective of whether aggregate period of exclusionary rights under a reference patent and a double patent approach, much less exceed, the 17-year term that every inventor was guaranteed when the doctrine was created. Indeed, in some situations, obviousness-type double patenting invalidity applies where the aggregate period of exclusionary rights is far less than 17 years.⁷³

Disclaimers of term are required by the USPTO for all “double patents” subject to the URAA, even though Congress acted through the URAA to justify far longer periods of exclusionary rights for any single patent, e.g., up to 20 years. This 20-year period in the case of an original, nonprovisional patent filing is only shortened by the processing time required in the USPTO to issue the patent.⁷⁴

⁷⁰ See *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F. 3d 1208 (Fed. Cir. 2014).

⁷¹ *In re Collect, L.L.C.*, 81 F. 4th 1216 (Fed. Cir. 2023).

⁷² Public Law 106-113 (November 29, 1999).

⁷³ Under the URAA, for a double patent that issues on a continuation application filed with respect to the reference patent, in which the reference patent required more than three years of processing time in the USPTO prior to issuance (and for which no patent term adjustment is available), the combined period of exclusionary rights for the two patents will be less than 17 years.

⁷⁴ Congress has also acted to expressly justify “patent term extensions” under 35 U.S.C. §156 and “patent term adjustments” under 35 U.S.C. §154 for “limited Times.” As noted above, the URAA itself specifies that the “limited Time” for exclusionary rights for patentably indistinct claims cannot exceed a theoretical maximum of 22-years. Unlike that pre-URAA patent statute that afforded no “limited Time” for exclusionary rights under patentably indistinct claims, Congress has now explicitly and comprehensively limited through statute the Time any “invention” or obvious variations thereof can be protected. As such, the policy-based congressional determination

As a consequence of these and other emerging facets of the judge-made law, its administration in the USPTO has become commensurately more burdensome, both for patent examiners and patent practitioners. Even though decades have passed since the enactment of the URAA, obviousness-type double patenting law can still confound even learned commentators in attempting to clearly understand the post-URAA parameters of the doctrine.⁷⁵

In light of these judicial developments, particularly given the enactment of the URAA and its justification of a period of exclusionary rights under a single patent of up to 20 years, the reform proposals would rebuild of the law on obviousness-type double patenting in a manner that would both clarify and simplify the law the reach of the law, thereby confine its application to situations where its policy justifications apply and extend its reach only to the extent required for those policy justifications to be vindicated. As a consequence, the reform proposal would operate to overrule elements and aspects of the law that currently have no discernable policy justification.

Summary Of The Proposed Solution

Obviousness-type double patenting would be defined as the existence of two patents in which at least one pair of claims from the respective patents had no a prior art relationship with respect to the other and, for at least one such pair of claims, one of the pair of claims would have been obvious under 35 U.S.C. § 103 had the other claim constituted prior art to it. When obviousness-type double patenting was present, the reform proposal would address the consequences with respect to the involved patents as follows:

- (1) Obviousness-type double patenting would not raise an issue of patentability or patent validity, such that applications for patent would no longer require an examination for obviousness-type double patenting. The sole consequences of obviousness-type double patenting would arise should either of the involved patents be enforced. Claim of patent application would no longer be examined for obviousness-type double patenting.
- (2) For the purposes of applying res judicata principles in any civil action involving the involved patents, the claims of the respective patents would be treated as though only a single patent had been issued containing all the claims. This would address the potential for harassment that is currently addressed through USPTO terminal disclaimer practice in which a disclaimer of alienation (non-CREATE Act patents) or a disclaimer of separate enforcement (CREATE Act patents) is currently required.
- (3) The current practice of requiring disclaimers of term would end on the ground that the 20-year patent term under the Uruguay Round Agreements Act has fully addressed the policy considerations relating to the unjustified timewise extension of the right to

under its Article I, Section 8, Clause 8 authority must be given deference by the courts. *Eldred v. Ashcroft*, 537 US 186 (2003).

⁷⁵ “The billion-dollar question is how ODP applies to post-URAA patents that are related. Unfortunately, the Federal Circuit’s statements provide inconsistent guidance.” Daniel Kazhdan, *Obviousness-Type Double Patenting: Why it Exists and When it Applies*, Akron Law Review (2019): Vol. 53, Iss. 4, Article 6, p. 1046. (<https://ideaexchange.uakron.edu/akronlawreview/vol53/iss4/6>)

exclude. In the regard, Congress not only justified that two patents could have a combined period of exclusive rights (i.e., from the date of the first-issuing patent to the later-expiring patent of up to 20 years, but has specifically justified patent protection for additional “limited Times,” under the PTA, PTE, provisional filing, and “grace period” statutes.

Confine “Double Patenting” To The Possible Existence of Indistinct Claims

The proposed reform seeks to limit any consequences of obviousness-type double patenting law to the situation where a possibility exists that claimed inventions in separate patents might be directed to patentably indistinct subject matter. A pair of claims from different patents can always be regarded as patentably distinct if (1) one of the claimed inventions is prior art to the other and (2) the “prior art” claimed invention does not render obvious the other claimed invention (either alone or in combination with other items of prior art). For this reason, there is no policy basis for applying obviousness-type double patenting law to patents where the claims from the respective patents have such a prior art relationship. Two valid patents in such a circumstance can only exist in this circumstance only if their respective claims are patentably distinct under 35 U.S.C. §103.

Historically, the USPTO recognized this inherent limitation on the applicability of obviousness-type double patenting to a claimed invention by confining obviousness-type double patenting to different patent filings of the same inventor.⁷⁶ Only when Congress changed the patent statute in 1984 to exempt claimed inventions from different inventive entities from the reach of 35 U.S.C. §103 in cases of common ownership,⁷⁷ did the USPTO respond and apply obviousness-type double patenting principles to commonly owned application.⁷⁸ Unfortunately, the courts have nonetheless found obviousness-type double patenting to apply in situations where there is inevitably such a prior art relationship between the claims in the involved patents (i.e., neither the same inventor nor the same owner nor a joint research agreement under the CREATE Act⁷⁹)—and have gone so far as to deny even the possibility of filing a terminal disclaimer to obviate invalidity on obviousness-type double patenting grounds.⁸⁰

⁷⁶ See the USPTO’s 1967 interpretative guidance, declaring “‘double patenting’ is properly applicable only to cases involving two or more applications and/or patents of the same inventive entity.” See 849 O.G. 1615 (January 31, 1967).

⁷⁷ See the Section-By-Section Analysis of H.R. 6286, Patent Law Amendments Act of 1984, Cong. Rec. H10525-10529 (October 1, 1984), “The Committee expects that the Patent and Trademark Office will reinstitute in appropriate circumstances the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting. This will be necessary in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter. In accordance with established patent law doctrines, double patenting rejections can be overcome in certain circumstances by disclaiming the terminal portion of the term of the later patent, thereby eliminating the problem of extending patent life.” *In re Hubbell*, 709 F.3d 1140, 1151 (Fed. Cir. 2013), J. Newman in dissent.

⁷⁸ “The Patent and Trademark Office has withdrawn the Commissioners Notice of January 9, 1967, Double Patenting, 834 O.G. 1615 (Jan. 31, 1967).” M.P.E.P. 804.03, Rev. 6.2 (July 1996) at p. 800-25.

⁷⁹ Pub. L. No. 108-453, 118 Stat. 3596-3597 (2004).

⁸⁰ “The court today not only finds ‘double patenting’ when there is neither common inventorship nor common ownership, but having so found withholds the standard remedy of the terminal disclaimer, and simply denies the application. This novel ruling is contrary to statute and precedent, with no policy justification for changing the law.”

The proposed reform would return the law on obviousness-type double patenting to its policy roots by applying limiting the existence of obviousness-type double patenting to the situation where at least one pair of claims selected from each of the involved patents did not have a prior relationship. As noted above, this is the sole circumstance that could give rise to the existence of patentably indistinct claims being present in the involved patents that could have been addressed under 35 U.S.C. §103 had it applied.

Possible Implementing Legislative Text

The proposed reforms address the issue of potential harassment of accused infringers arising from the presence of patentably indistinct claims in two patents that constitute obviousness-type double patenting solely by applying the principles of res judicata as though only a single patent had issued containing all the claims of both patents. This policy consideration underlying obviousness-type double patenting law has continued viability given the dramatic increase in situations where the potential for such harassment can exist, particularly through an array of commonly owned patents.

As noted above, when Congress amended the patent statute in 1984 to remove as “prior art” claims presented in certain commonly assigned patent applications, it instructed the USPTO to broaden the application of obviousness-type double patenting principles to accommodate the expanded number of commonly owned patent filings that could now contain patentably indistinct claims. In addition, changes in patent prosecution practices since 1984 have further expanded the number of commonly owned patents containing patentably indistinct claims. For example, double patents now routinely arise from the more widespread use of continuation application filings. The consequence can be the creation of a “thicket” of commonly owned patents, all of which may contain claims that are patentably indistinct from one another.

Moreover, the “potential for harassment” concern as a policy grounding for obviousness-type double patenting law became entrenched in statutory patent law through the AIA, codifying the legislative history of the CREATE Act in §3(b)(2),⁸¹ which directed the USPTO to impose the disclaimer of “separate enforceability” in cases of obviousness-type double patenting under the CREATE Act.⁸²

⁸¹ AIA §3(b)(2) reads as follows: “CONTINUITY OF INTENT UNDER THE CREATE ACT.—The enactment of section 102(c) of title 35, United States Code, under paragraph (1) of this subsection is done with the same intent to promote joint research activities that was expressed, including in the legislative history, through the enactment of the Cooperative Research and Technology Enhancement Act of 2004 (Public Law 108–453; the “CREATE Act”), the amendments of which are stricken by subsection (c) of this section. *The United States Patent and Trademark Office shall administer section 102(c) of title 35, United States Code, in a manner consistent with the legislative history of the CREATE Act that was relevant to its administration by the United States Patent and Trademark Office.* [Emphasis added.]

⁸² The relevant history is the floor statement of Senator Orring B. Hatch made on June 25, 2004, Cong. Rec. at S7520-S7522, which provided in part: “To protect the public interest, these separately owned patents must be subjected to a new form of disclaimer that will protect the public against *separate actions for enforcement* of both the first-issued patent and any patents with claims that are not patentably distinct over the claims of the first-issued patent.” AIA §3(b)(2) now mandates that the USPTO impose a specific form of disclaimer described in the floor statement: “To give effect to this requirement, *the disclaimer in the patentably indistinct patent must be executed by all involved patent owners, as the right to separately enforce the first-issued patent apart from the patentably*

Obviousness-type double patenting principles have historically only addressed the “potential for harassment” that arises from separate patents with patentably indistinct claims in situations where the reference patent and a double patent become separately owned. This concern over separate ownership has, however, proven to be almost entirely theoretical in nature. Patent owners who build “patent thickets” composed of continuation patents or other patents having patentably indistinct claims typically do so with the intention of amassing a fortress of patents with which to protect a product or technology from competitors and therefore tend to maintain common ownership of the entire thicket.

In such situations, the existing obviousness-type double patenting principles may impose no real-world consequences. The filing of an alienation disclaimer is of no relevance if the intent is to maintain common ownership. The filing of a disclaimer of terms is without effect where the parent patent and all continuation patents share a common expiration date. What is of relevance, as is now clear from AIA §3(b)(2), is that whether the ownership—whether common or separate—of the involved patents ought not to result in the ability for such patents to be *separately enforced*.

The potential for harassment of an accused infringer that can arise from the issue of a single patent, including a single patent containing a very large number of claims, has historically been addressed through res judicata principles. This is because a single patent gives rise to only a single cause of action with respect to an accused infringer’s accused acts of infringement. Under res judicata principles, asserting some claims of a patent unsuccessfully does not permit a second action to be brought to enforce the non-asserted claims of the same patent against the same alleged infringer for the same acts of alleged infringement.

While a disclaimer of alienation may address the largely theoretical possibility for harassment of accused infringers based upon alienation of a double patent, application of res judicata principles in situations of obviousness-type double patenting could not only fully address this theoretical concern, but also address the harassment potential, irrespective of whether the involved patents were separately or commonly owned. Since the underlying principle of obviousness-type double patenting is that the inventor is entitled to only a patent on any single invention, *res judicata* principles could be applied as though all the patents containing patentably indistinct claims had been issued in a single patent.

If neither the courts nor the USPTO acts to address the potential for harassment through a bar on separate enforceability applying res judicata principles, the proposed reforms could be accomplished through codification in Title 35, United States Code, by adding to 35 U.S.C. §282 to a subsection (b) to address enforceability:

“(b) DOUBLE PATENTING UNENFORCEABILITY DEFENSE.—A claimed invention in a patent alleged to be infringed in a civil action shall be unenforceable in such action if—
“(1) the infringement allegation would have been barred on

indistinct patent cannot be avoided unless the owner of the first-issued patent has disclaimed its right to do so.”
[Emphasis added.]

res judicata grounds had each of the claims of a second patent been included as claims of the asserted patent;

“(2) such second patent had been the subject of a prior infringement adjudication with respect to the same accused infringer with respect to the same acts of infringement; and

“(3) such second patent contains at least one claimed invention that is patentably indistinct from at least one claimed invention in the asserted patent for which—

“(A) neither of such claimed inventions represents prior art to the other and

“(B) at least one of the two claimed inventions would not be confined to novel and nonobvious subject matter had the other constituted prior art to it.”

Eliminate “Disclaimer of Term”

The proposed reforms, now that all patents issuing are subject to the Uruguay Round Agreements Act of 1994, would not impose a requirement for any disclaimer of patent term (including any extensions or adjustments of term as provided under 35 U.S.C. §154 and §156) in order for patentably indistinct claims of patents involved in double patenting to be found valid and enforceable.

Prior to the URAA, obviousness-type double patenting law was grounded on the foundational assumption that Congress had only authorized a fixed period of 17 years of exclusionary rights for a single patent, such that multiple patents containing claims to patentably indistinct inventions should not be entitled to an aggregate exclusivity period of greater than 17 years. The courts have never suggested that a 17-year period of exclusivity under the pre-URAA patent law was not “justified.”

As noted above, however under the URAA, Congress justified a period of exclusionary rights under a URAA patent for terms far longer than 17 years. Indeed, in passing the URAA, Congress expressly extended the terms of previously issued patents beyond their pre-URAA 17-year terms in situations where the USPTO processing time had been less than 3 years.⁸³ In assessing obviousness-type double patenting issues after enactment of the URAA, the courts have continued to assess the “justified” period for exclusionary rights by focusing a “later expiration date” of a double patent relative to the reference patent even though the expiration date by itself no longer sets the duration of the exclusionary rights—as was the case for any pre-URAA patent. The paradoxical consequence is that, as Congress justified *longer* periods of exclusionary rights under a single patent through the URAA, the courts have demanded disclaimers in order to obviate double patenting that now commonly result in *shorter* aggregate periods of exclusionary rights than any individual patent was granted under pre-URAA law. Moreover, while the pre-URAA patent statute did not limit the time period during which patents with patentably indistinct claims could issue with separate 17-year exclusivity periods from

⁸³ 35 U.S.C. §154(c)(1): “The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.”

issuance—*such that the statute itself failed to provide any constitutionally mandated “limited Time” for exclusionary rights in patentably indistinct claims*—the URAA has now capped the aggregate exclusivity period for patentably indistinct claims at 22 years. This 22-year period is both a “limited Time” and a congressionally justified time limit—given that Congress in enacting the URAA justified the one-year provisional application filing period (35 U.S.C. §119) as delaying the start of the 20-year patent term, and, as recently as the enactment of the America Invents Act in 2011, confirmed that inventors should have full enjoyment of a one-year “grace period” before the filing of even a provisional application for patent might be necessary (AIA 35 U.S.C. §102(b)(1)).

For these reasons, URAA’s patent term can be viewed as having mooted altogether the possibility the aggregate exclusivity period of two patents in cases of double patenting could ever extend beyond a period now explicitly justified by Congress in the patent statute itself. With the enactment of the URAA, there is no longer any possible constitutional impediment to abrogating the need for any disclaimer of term in cases of obviousness-type double patenting—because the URAA eliminated the possibility of successive 17-year patent terms from the date of patent issuance could protect patentably indistinct claims for unlimited times.

If the USPTO or the courts do not act to overrule the pre-URAA practices, as they relate to the current need for “terminal disclaimers” to obviate invalidity for obviousness-type double patenting, Congress could limit the consequences of obviousness-type double patenting consistent with the proposed reforms by decreeing that the issue of enforceability of the patents involved should be limited by res judicata principles and the law should provide otherwise the following: “Except as provided under section 101 that precludes patenting of multiple claimed inventions defining the identical subject matter, section 102 that requires novelty with respect to a claimed invention representing prior art, section 103 that requires non-obviousness over a claimed invention representing prior art, and section 112(d) that precludes dependent claims lacking a further limitation, no claimed invention of a patent shall be invalid on account of patentable indistinctiveness with respect to a claimed invention of the same or another patent. Claimed inventions in applications for patent must not be examined by the Office for similarity with respect to one another, except to assure compliance with sections 101, 102, 103, and 112(d). The judicial doctrine of obviousness-type double patenting is overruled as moot in light of the unenforceability defense mandating the application of res judicata principles in any action to enforce a patent involved in obviousness-type double patenting.”

Remove Obviousness-Type Double Patenting as a Patentability or Patent Validity Issue

Under the Constitution, Congress is given the authority to enact statutes to provide exclusive rights to inventors for their respective discoveries for “limited Times.” For the courts to act entirely outside such statutes and judicially impose non-statutory grounds to gainsay the statutory requirements for patentability demands some constitutional justification for doing so. Prior to the URAA, the patent statute itself specified no “limited Time” for the aggregate period of exclusionary rights that could be secured by a patent owner for patentably indistinct claims. This more than sufficed as a basis for judicial action to impose at least a disclaimer of term in cases of obviousness-type double patenting.

For patents subject to the URAA, no necessary basis remains for imposing obviousness-type double patenting principles as a means for addressing the enforceability of patents containing patentably indistinct claims unless either (1) res judicata principles would not suffice to more fully and comprehensively address any potential for harassment based upon separate enforcement of patents containing patentably indistinct claims or (2) the “limited Times” now specified in the patent statute itself for the aggregate period of exclusionary rights for a reference and double patent is unjustified.

Given the changes to the patent statute through the URAA, if the USPTO or the courts do not change or overrule their double patenting practices or precedents, Congress itself could act to refocus obviousness-type double patenting principles to apply solely to the issue of enforceability of the reference and double patents, such that obviousness-type double patenting law would no longer represent an issue of patentability or patent validity—and no longer require examination or obviousness-type double patenting during patent examination. This would leave the sole issue of obviousness-type double patenting to adjudications of the res judicata issues in the exceedingly rare situation in which a second action for infringement might be brought on a patentably indistinct claim against the same alleged infringer with respect to the same alleged acts of infringement.

Conclusions

The USPTO presently devotes substantial resources to address double patenting issues in a post-URAA environment where the 20-year patent term has eliminated the historical policy justification for obviousness-type double patenting—the ability to secure a longer period of exclusive rights through two patents with similar claims, than could have been possible had all the claims issued in a single patent. These resources could be better deployed, leaving it to the courts to eliminate the possibility that such patents could be separately enforced against that same infringer with respect to the same alleged acts of infringement where res judicata principles would have done so had only a single patent issued containing all the indistinct claims.

Prevent The IC Defense From Encouraging Patent Thickets

Limit The Unenforceability Consequences Of “Inequitable Conduct” Allegations In Civil Actions To the Patent Claims Found To Be Invalid In The Action

Thereby Facilitating Reforms To Eliminate “Patent Thickets” Built From Continuations Application Filings

Problem Statement

Arguably no single aspect of the patent law has had a more turbulent history—and more perverse impact on ex parte patent filing and prosecution practices before the USPTO—than the judge-made doctrine that has allowed patents with valid claims, even entirely valid patents, from being found permanently unenforceable on account of prosecution misconduct. While the doctrine has its origins in 1930’s Supreme Court jurisprudence that addressed the very rare circumstance of a fraudulently procured patent, lacking in any conceivable merit,⁸⁴ by the 1980’s the defense had become nearly ubiquitous, prompting the Federal Circuit to note “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”⁸⁵

From time to time the Federal Circuit has attempted to cut back on the doctrine, notably with a 1988 *en banc* holding in *Kingsdown v. Hollister*⁸⁶ reversing earlier precedent that “gross negligence” alone sufficed to establish the defense and a 2011 *en banc* decision in *Therasense*⁸⁷ that again reversed course and offered a more stringent “but for” standard for determining if the concealment or misrepresentation of information was material.

At best, these *en banc* efforts have produced periods of relative calm between “inequitable conduct” storms, as the “inequitable conduct” defense continues to be pursued to this day by accused patent infringers. As discussed in greater detail below, whether during a period of relative calm, or during a stormier era, for the IC defense in the courts, patent prosecutors are obliged to continue to develop and deploy tactics to preempt allegations that material information had been concealed during examination—or material misrepresentations had been made. These strategies demand over-disclosing information to the USPTO—often items of prior art of no identifiable relevance to patentability—and characterizing nothing about the content of items of prior art being disclosed. The current IC defense raises fundamental issues of patent policy: What actual benefit could possibly justify the burdens and cost to the patent system? What opportunities for improving the quality and efficiency of patent examination might be possible were the defense to fully and permanently recede—and again apply to the types of egregious misconduct that are the hallmarks of true fraud?

The objective of the patent system is to advance innovation. At its core – indeed, the sole purpose of the system – is to grant valid and enforceable patent rights that inventors, patent owners, investors, and the public can confidently rely on to drive an innovation-based economy,

⁸⁴ *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933).

⁸⁵ *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

⁸⁶ *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988).

⁸⁷ *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011).

which creates jobs and betters mankind. Issues that run counter to reliable durable patent right and/or introduce unnecessary cost and burdens, which act as a barrier to engaging the system, need to be critically examined. For the reasons outlined above, the unenforceability defense based on prosecution misconduct allegations is such an issue.

The defense of inequitable conduct has been long justified as a means of motivating compliance with the “duty of candor and good faith.” The defense applies when concealment of material information—or its misrepresentation—was undertaken with a specific intent to deceive or mislead the USPTO during the course of the examination of a patent application.

Notwithstanding the unassailable policy justification for sanctioning any lack of patent applicant candor or good faith in dealings with the USPTO, the real-world consequences of imposing of this type of “prosecution misconduct” defense have been catastrophic to the primary objective of the patent system – to issue a reliable and durable patent right.

Because very few patents are ever litigated—and the defense is pleaded far more often than any “inequitable conduct” is found—the real-world impact of the “inequitable conduct” defense plays out most routinely during patent examination before the USPTO. Given the professional consequences of being accused of prosecution misconduct and the draconian nature of a finding of “inequitable conduct,” patent applicants today routinely undertake patent defensive prosecution strategies—strategies designed to *defend against* the possibility of later allegations that material information was concealed or misrepresented. Such practices include “over-disclosure” if items of publicly available information, avoiding any explanation of how any of the disclosed information could be of possible relevance to patentability.⁸⁸ The consequences of defensive prosecution tactics are demonstrably counter to procuring a reliable and durable patent right.⁸⁹

⁸⁸ Most notoriously, patent applicants play “prosecution defense” by *disclosing excessive* amounts of “prior art” information to avoid any possibility of “concealment” of information that might be alleged in patent litigation to have been “material.” As a consequence, the bulk of the “prior art” information disclosed by patent applicants during patent examination will typically have no bearing whatsoever on any issue of patentability. Defensive prosecution tactics undertaken by patent applicants also involve *deliberate ignorance and calculated silence*—as applicants refrain from searching or making any characterization of the possible relevance of any of the items of prior art being disclosed. Silence of this type is designed to avoid the possibility that any characterization of the import of any particular item of prior art might be later attacked during patent litigation as a misrepresentation of its contents. A reference never found or identified in a search is a reference that cannot serve as a basis for inequitable conduct allegation.

⁸⁹ Critics of the “inequitable conduct defense” support their contention that the defense constitutes a barrier to elevating the completeness and accuracy of patent examination by citing to recent data published by the USPTO. Data suggesting that defensive prosecution tactics represent the antipathy of thoughtful and productive engagement by patent applicants with patent examiners can be found in the [2023 Patent Public Advisory Committee Report](#) (p. 30), which indicates the profound ineffectiveness of applicant submissions of large numbers of prior art references in cases where the Patent Trial and Appeal Board ultimately adjudicates that one or more patent claims were invalid: “Successful challenges having at least one independent claim in [final written decisions in an IPR/PGR] issued in calendar year 2021 were sampled. *Ninety-three percent (93%) of these challenges finding unpatentability of at least one independent claim were based on prior art not cited in prosecution...* Seven (7%) of the challenges finding at least one independent claim unpatentable are based on prior art cited during examination of the patent. *The vast majority of these cases (82%) had more than 100 references cited by the applicant in an information disclosure statement (IDS).*” Such submissions also appear to have only a limited impact on the actual quality of patent examination, at least in terms of assuring that the most relevant prior art is present within the heap of references cited. Notably, the same report indicated that the prior art not previously cited was found to be art that is findable, namely domestic and foreign patent documents and non-patent literature that

In addition, the consequence of an “inequitable conduct” determination in a civil action is that all claims of the patent are rendered permanently unenforceable. The consequences, thus, prevents the enforcement of any claims of the patent that were determined not to have been invalidated under any of the substantive defense to claim validity that were raised and adjudicated in the action. In effect, the consequence of the IC finding is that claims are held invalid notwithstanding that the existence of such claims did not represent a fraud—or patent protection otherwise that was not merited under the rigorous requirements for patentability that are set out in the patent statute.

By operating in this manner, the existence of the IC defense forms a disincentive for patent applicants to seek and secure just a single patent containing all the claims to which the patent applicant might be entitled based on a single, original nonprovisional patent application filing. Instead, the IC defense encourages spreading such claims among a variety of continuation patents, which might be serially filed and secured throughout the 20-year patent term. By doing so, for example, if an IC defense is successful against one of the later-filed, later-issued patents in such a family of continuation patents, the unenforceability of the claims is limited to that patent, rather than any of the earlier-filed, earlier-issued patents with the family.

Thus, the IC defense today operates as a strong disincentive to securing all the patent claim “eggs” in a single patent “basket.” As such, as the defense currently operates, it represents what is likely to be an insuperable obstacle to reforms that aimed at ending any possibility for eliminating “patent thicket” practices based on the filing of continuation applications.

Summary Of The Proposed Solution

To advance a more durable and reliable patent system, it is essential to examine the aspects of the inequitable conduct doctrine that force patent applicants to pursue defensive prosecution tactics that are counterproductive achieving the dialogue with the USPTO that lies at the foundation of the duty of candor and good faith—and *vital to remove any incentive to seek a thicket of separate patents where claims could all instead be issued in a single patent*—while preserving the core policy principle that no true fraud should go unpunished. These objectives can be achieved restoring the basic concept from the Supreme Court fraud cases such as *Keystone Driller* that unenforceability based on prosecution misconduct should be grounded on particularly egregious, fraudulent misconduct that resulted in the issuance of an invalid patent, by limiting the unenforceability only to those claims of a patent found to be invalid in a civil action and could not have been issued by the USPTO but for a material misrepresentation, or the concealment of material information..⁹⁰

was not obscure. The PPAC observes “understanding why this prior art was neither cited by applicants or identified during prosecution may be informative to the public and applicants.” USPTO Patent Public Advisory Committee 2023 Annual Report, see page 30.

⁹⁰ In all situations involving prosecution misconduct, treble damages and attorney fee awards would be available, as under current law, in situations where the misconduct violated competition laws. *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

Introduction and Background

Notwithstanding recent judicial developments, the United States retains a unique aspect of its patent law that can result in entirely valid and otherwise fully enforceable patent claims being held permanently unenforceable based upon actions of a patent applicant in failing to disclose—or misrepresenting—“material” information during the patent examination process. This element of U.S. patent law is commonly referenced as the “inequitable conduct” defense to the enforceability of a patent. This non-statutory, globally unique aspect of U.S. patent law has been most recently affirmed in the Federal Circuit decision in *Therasense*.⁹¹

“Candor And Good Faith” Genesis; Defensive Prosecution Practices Reality

The defense has been long justified in the courts as a means of motivating compliance with the “duty of candor and good faith” that is imposed on patent applicants. This duty of candor is defined in regulations of the United States Patent and Trademark Office but was initially imposed by the courts through jurisprudence that long preceded any USPTO regulations.⁹² The defense applies when concealment of material information—or its misrepresentation—was undertaken with a specific intent to deceive or mislead the USPTO during the course of the examination of a patent application.

Notwithstanding the unassailable policy justification for sanctioning any lack of patent applicant candor or good faith in dealings with the USPTO, the real-world consequences of imposing of this type of “prosecution misconduct” defense have in recent years become almost entirely unintended ones. Since very few patents are ever litigated—and the defense is pleaded far more often than any “inequitable conduct” is found—the real-world impact of the “inequitable conduct” defense plays out most routinely during patent examination before the USPTO. Given the potential professional repercussions of being accused of prosecution misconduct and the draconian nature of a finding of “inequitable conduct,” patent applicants today routinely undertake patent defensive prosecution strategies—strategies designed to *defend against* the possibility of later allegations that material information was concealed or misrepresented.

Most notoriously, patent applicants play “prosecution defense” by disclosing excessive amounts of “prior art” information to avoid any possibility of “concealment” of information that might be alleged in patent litigation to have been “material.” As a consequence, the bulk of the “prior art” information disclosed by patent applicants during patent examination will typically have no bearing whatsoever on any issue of patentability.⁹³

⁹¹ See *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F. 3d 1276, 1317 (Fed. Cir. 2011), in which the Federal Circuit concluded that, even if a claim is valid, prosecution misconduct can be found so long as the USPTO *would not have allowed* the patent to issue, i.e., “an applicant who conceals information with the intent to deceive the PTO will be free to enforce his patent unless it can be proved by clear and convincing evidence that the patent would not have issued but for the fraud.” A prosecution misconduct, thus, can be raised—and can succeed—even if the PTO *should have allowed* the patent claims to issue but, on account of a concealment or misrepresentation of information *would not* have done so. Once the defense is established, all the claims of the patent become permanently unenforceable, irrespective of whether any or all the claims of the patent were found to be invalid.

⁹² *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933).

⁹³ . Critics of the “inequitable conduct defense” support their contention that the defense constitutes a barrier to elevating the completeness and accuracy of patent examination by citing to recent data published by the USPTO.

Defensive prosecution tactics undertaken by patent applicants also involve *calculated silence*—as applicants refrain from making any characterization of the possible relevance of any of the items of prior art being disclosed. Silence of this type is designed to avoid the possibility that any characterization of the import of any particular item of prior art might be later attacked during patent litigation as a misrepresentation of its contents.

Defensive prosecution tactics undertaken by patent applicants also involve *calculated ignorance*—as applicants refrain from searching the prior art. The considerations of whether to search the prior art or not prior to filing a patent application are complex, including considerations of cost and timing, but prior art never found or considered cannot be fodder for an inequitable conduct allegation. Not searching therefore is part of defensive prosecution tactics.

As a consequence, a compelling case can be made that the “inequitable conduct” defense not only produces these demonstrably unintended consequences, *but is virtually devoid of its intended ones*. Dumping large numbers of prior art publications into the patent prosecution record hardly amounts to “candor” in patent applicant dealings with patent examiners. The calculated ignorance or silence as to which of any might be possibly relevant to patentability, much less why, may not reflect “bad faith,” but it cannot be characterized as a constructive engagement by applicant and the examiner to issue valid claims, which is the ultimate objective of any requirement of “good faith.”⁹⁴

The types of defensive patent prosecution practices that the “inequitable conduct” defense stimulates are particularly ill suited to patent examination in an “information age”—when patent examiners have powerful searching tools at their disposal for identifying possibly relevant prior art, and the patenting process is open to the public and public input.⁹⁵ Unlike the situation when

Data suggesting that defensive prosecution tactics represent the antipathy of thoughtful and productive engagement by patent applicants with patent examiners can be found in the [2023 Patent Public Advisory Committee Report](#) (p. 30), which indicates the profound ineffectiveness of applicant submissions of large numbers of prior art references in cases where the Patent Trial and Appeal Board ultimately adjudicates that one or more patent claims were invalid: “Successful challenges having at least one independent claim in [final written decisions in an IPR/PGR] issued in calendar year 2021 were sampled. *Ninety-three percent (93%) of these challenges finding unpatentability of at least one independent claim were based on prior art not cited in prosecution...* Seven (7%) of the challenges finding at least one independent claim unpatentable are based on prior art cited during examination of the patent. *The vast majority of these cases (82%) had more than 100 references cited by the applicant in an information disclosure statement (IDS).*”

⁹⁴ Such submissions also appear to have only a limited impact on the actual quality of patent examination, at least in terms of assuring that the most relevant prior art is present within the heap of references cited. According to the 2023 Annual Report from the USPTO Patent Public Advisory Committee (“PPAC”), ninety-three percent (93%) of successful PTAB challenges finding unpatentability of at least one independent claim in a final written decision were based on prior art not cited during prosecution. The prior art not previously cited was found to be art that is findable, namely domestic and foreign patent documents and non-patent literature that was not obscure. The PPAC observes “understanding why this prior art was neither cited by applicants or identified during prosecution may be informative to the public and applicants.” USPTO Patent Public Advisory Committee 2023 Annual Report, see page 30.

⁹⁵ While producing accurate and complete patent examination should be one of the highest priorities for both the patent applicant and the patent examiner, limiting the issuance of patents to those containing only claims that can be sustained as valid, if contested in the courts, is essential to the integrity of the patent system. Patents, once issued, are presumed valid, and establishing facts to overcome this validity presumption requires clear and convincing

the USPTO first promulgated rules setting out its “duty of candor and good faith,” USPTO searching tools today can provide massive quantities of potentially relevant prior art to patent examiners *electronically*.⁹⁶ As electronic, and increasingly AI-assisted, prior art search tools continue to improve, the ability of patent examiners to secure possibly relevant “prior art” information has further diminished any conceivable value in patent applicants providing long listings of items of prior art.⁹⁷

Perverse Incentive To Spread Claim “Eggs” Among Separate Patent “Baskets”

As noted above, patent owners can *de facto* limit any possibility that patent claims will be unenforceable based upon prosecution misconduct by pursuing a serial strategy of claim-seeking through continuation applications—and then separately issuing continuation patents. In amassing a “patent thicket” of such continuation patents, it is possible to entirely avoid IC unenforceability consequences for the claims of any patent in which there is no clear and convincing of prosecution misconduct. This is most commonly the situation where the misconduct is alleged in a later-sought, later-issued patent—leaving the enforceability of the claims of the earlier-sought, earlier-issued patents entirely unaffected. However, the same non-unenforceability outcome can apply to leave a later-sought, later-issued continuation patent when the earlier-sought, earlier-issued parent patent is held unenforceable.⁹⁸

As efforts are made to address the proliferation of continuation application filings—and potentially limit the ability to secure all claims based upon an original, nonprovisional patent filing in a single patent—and not a “thicket” of continuation patents, a chief obstacle in the path of such efforts is the potential that no matter how slight the misconduct relative to the diversity and breadth of the claims secured—and no matter that only a single claim might have been

evidence. Given that the patent system is to remain a unitary one, in which USPTO examination decisions are to be accorded such legal deference in the courts, it is then vitally important to the integrity of the system that the duty of candor and good faith operate in a manner that provides applicants incentives to offer concise, meaningful, and focused disclosures of the prior art of possible relevance—and to do so in a manner in which all the claims that the patent owner seeks to have issued can be sought, examined, and ultimately granted in one patent application.

⁹⁶ A half-century ago—unlike today under the America Invents Act—making patentability determinations required access to information potentially relevant to patentability that was almost always known only to the patent applicant (e.g., the “invention date”). Moreover, before 1999, the entire examination process was conducted in secrecy (i.e., such that members of the public had no opportunity for input into the examination process). Finally, in the pre-electronic, pre-AI era of patent searching, access to items of prior art was secured largely from physical rather than virtual sources—by a patent examiner rifling through the USPTO collections of earlier-issued U.S. patents that were physically located in a physical search-room where an examiner would finger through the prior art patents in the relevant “shoes,” one by one. See *A Tour of the Public Search Room at the United States Patent and Trademark Office* (2023) at p. 13

(https://www.uspto.gov/sites/default/files/documents/Public_Search_Facility_Guide_2023.pdf). “For over a century, searchers went to ‘the shoes’ in search of prior art.”

⁹⁷ As an example, on December 26, 2023, the USPTO announced its development of AI capabilities to add to the Patents End-to-End (PE2E) Search tool available to Examiners. See USPTO Consolidated Listing of Official Gazette Notices re Patent and Trademark Office Practices and Procedures, 1517 CNOG 1046.

⁹⁸ See *Cordis Corp. v. Boston Sci. Corp.*, 188 Fed. Appx. 984, 988-89 (Fed. Cir. 2006), “Even if the ’312 [parent] patent was obtained by inequitable conduct, that conduct does not necessarily render the ’370 [continuation] patent unenforceable. Because there was no separate inequitable conduct found during the prosecution of the [continuation] patent, the [continuation] patent can be held unenforceable only if the inequitable conduct during the prosecution of the [parent] patent tainted the prosecution of the [continuation] patent.”

tainted by the misconduct, the same penalty is extracted as though the entire patent had been a complete fraud, with no possibility that even a single patent claims could have been properly issued absent the misconduct. The change in the law in “inequitable conduct” consequences is, thus, essential to both successfully addressing the issue of continuation “patent thickets” and securing a proportionality between the misconduct and its consequences.

Claims Not Found To Be Invalid Would Remain Both Valid And Enforceable

To mitigate these defensive patent prosecution practices—and their largely unintended consequences on the patent examination process—and remove any incentive to seek continuation “patent thickets,” the proposed reforms would introduce *a new limitation on the application of the “inequitable conduct” defense*. More specifically, the proposed reforms would further implement the 2004 recommendation of the National Academies of Science⁹⁹ that the “inequitable conduct” defense itself be modified or removed.¹⁰⁰ Under the proposed reforms, *the defense could not render unenforceable any patent claim that was not found to be invalid in the civil action in which prosecution misconduct before the USPTO was found*. This modification of the “inequitable conduct” defense would then not only serve as the predicate for patent applicants engaging in constructive prosecution tactics – citing the most pertinent prior art – and little more – and otherwise facilitating full consideration of the art by the examiner,¹⁰¹ but open a path forward to ending “patent thicket” practices based upon continuation application filings.

While the “inequitable conduct” defense would be limited, the proposed reforms do not go so far as to support overruling the Supreme Court precedents involving cases in which the misconduct extends beyond prosecution misconduct in *ex parte* examination or cases in which egregious misconduct, *leading to the issuance of a patent in which no claim could be found valid*, results in the patent being permanently unenforceable. More specifically, the holdings in *Keystone Driller*

⁹⁹ See National Research Council. 2004. *A Patent System for the 21st Century*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/10976>, at pp. 82-83. “Three provisions of patent law that are frequently raised by plaintiffs or defendants (rarely by the courts) in infringement litigation depend on determining a party’s state of mind, and therefore generate high discovery costs. ... To reduce the cost and increase the predictability of patent infringement litigation outcomes, and to avoid other unintended consequences, these provisions should be modified or removed.” Besides “inequitable conduct,” the National Academies recommended elimination of “best mode” and “willfulness” from patent litigation.

¹⁰⁰ The co-chair of the of the National Academy explained the genesis of the recommendation that the “inequitable conduct” defense might be “modified” rather than “removed” came only from the patent profession, and not from any other community impacted by the patent system: “The interesting thing is on the two [issues, inequitable conduct and willfulness,] where our committee waffled, we have introduced a problem. That is to say, on our committee every single economist and businessperson was convinced that we should eliminate both the willful infringement and inequitable conduct doctrines, period. Get rid of them. They don’t really serve an important purpose. I still believe that personally. But the lawyers on the committee and you can see why, thought, well, maybe just modify them substantially. We could see why they enjoyed that. Look at the debate we just had on those two issues. I mean you do almost anything. You could get almost any opinion about how to modify them. What are we gaining by having these two? Very little. ...” Summation and Closing by Richard C. Levin, President, Yale University, *The National Academies, Board On Science, Technology And Economic Policy, American Intellectual Property Law Association, and Federal Trade Commission, Conference On Patent Reform*, National Academy of Sciences Auditorium, 2101 Constitution Avenue NW, Washington, DC, (Thursday, June 9, 2005).

¹⁰¹ For example, if applicants provide a concise explanation of relevance for a reference, the reference should be found to be fully considered under *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GMBH*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential).

Co. v. General Excavator Co., 290 U.S. 240 (1933) and ¹⁰² *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944)¹⁰³ relating to litigation misconduct, and *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), relating to collusive settlements of fraud-tainted contested proceedings in the Office,¹⁰⁴ would be unaffected.

Similarly, the proposed reforms would not affect the *Therasense* limitation on the prosecution misconduct defense. Claims found to be invalid would be rendered permanently unenforceable if prosecution misconduct were established on an “but for” standard, i.e., the USPTO could not have issued the claims found invalid but for the misconduct. A finding of prosecution misconduct would also support a finding of attorney fees under 35 U.S.C. §285 in cases involving inequitable conduct under *Therasense*. Furthermore, competition law sanctions against such misconduct remain available under *Walker Process*,¹⁰⁵ *in the situation where either some or all of the claims of the patent tainted by misconduct were found to be invalid.*¹⁰⁶

¹⁰² *Keystone Driller* represented a classic “fraud on the court” case, in which the litigation misconduct involved consideration paid to a third party (Clutter) by the patent applicant (Downie) that resulted in the attempted suppression of a prior public use. “Downie then went to ... Clutter and for valuable considerations ... obtained from Clutter an affidavit prepared by Downie to the effect that Clutter’s [prior] use ... was an abandoned experiment, and also obtained Clutter’s agreement to assign [Keystone Driller] any rights he might have as inventor, to keep secret the details of the prior use and, so far as he was able, to suppress the evidence. No proof of such use was produced at the trial of [earlier infringement lawsuits]. The defendants in these suits took Clutter’s deposition early in 1930. He did not then disclose his arrangement with plaintiff for concealment of evidence...” The proposed changes to the law on “inequitable conduct” do not address judicial misconduct in contested proceedings that take place independent from any prosecution misconduct before the USPTO.

¹⁰³ *Hazel-Atlas Glass Co.*—in a manner similar to *Keystone Driller*—involved the “fraud on the court” in which the attorneys involved in the publication of a fraudulent article, cited in the patentee’s brief, which was then relied upon by the court, “[q]uoting copiously” from it. Again, the proposed changes to do not extend to litigation misconduct, such as reliance on a contrived evidence in briefing or other argument before the court.

¹⁰⁴ *Precision Instrument* involved the filing of a fraudulent preliminary statement before the Board of Patent Interferences, alleging false dates of “prior invention” by the Junior Party (Larsen, U.S. Appl. No. 232,732, filed October 1, 1938)—followed by false corroborating testimony (“Larson and eight witnesses testified in the interference proceedings in support of his [false] claims”)—that prevented the Patent Office from awarding priority on the pleadings to the Senior Party (Zimmerman, U.S. Appl. No. 210,869, filed May 31, 1938). The fraudulent conduct, although it became known to the Senior Party, eventually led to a settlement in which the Junior Party’s application was assigned to the Senior Party. The Senior Party, notwithstanding knowledge of the fraudulent representations and testimony before the Board of Patent Interferences, then secured patents on both applications involved in the fraud-tainted interference and asserted them. The proposed changes to the law on “inequitable conduct” do not extend to situations where the fraudulent conduct before the USPTO is then made the basis for collusive conduct, such as the fraud-tainted settlement of a contested matter before the USPTO that results in efforts to enforce rights in resulting patents that could not been sustained absent such a settlement. See 35 U.S.C. § 135(c), § 317(b), and § 327(b) requiring settlements of such contested matters in the Office be in writing and timely submitted to the USPTO.

¹⁰⁵ *Walker Process Eqpt., Inc. v. Food Machinery Corp.*, 382 U.S. 172 (1965).

¹⁰⁶ Procedurally, the limitation on prosecution-misconduct unenforceability would follow an invalidity determination, with the court having the opportunity to assess whether the conduct involved was egregious or otherwise met the “but for” nexus required to establish unenforceability of the claims found to be invalid.

Possible Legislative Implementation

Inequitable conduct reform could be accomplished through a straightforward amendment to the patent statute, e.g., by inserting at the end of subsection (a) of 35 U.S.C. §282:¹⁰⁷

No claim of a patent may be held unenforceable in a civil action based upon a finding of prosecution misconduct during ex parte examination before the Office, including based on any concealment or misrepresentation in connection with the disclosure of information to the Office during such examination, unless the court finds that the claim was invalid and could not have been issued by the Office had the misconduct not taken place.

Conclusions:

The tuning of the “inequitable conduct” defense, such that it would not affect the enforceability of any claim not found to be invalid, leaves in place the current consequences arising from the fraudulent procurement of a patent, while facilitating reforms that would both mandate more meaningful information disclosures by patent applicants that are more consistent with a duty intended to advance both candor and good faith and operate to eliminate any possibility for creating a “thicket” of patents arising from the filing of an original, nonprovisional patent application filing.

¹⁰⁷ 35 U.S.C. §282(a) would read as follows:

“(a) IN GENERAL. —A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. No valid claim of a patent may be held unenforceable based upon prosecution misconduct, including based on any concealment or misrepresentation in connection with the disclosure of information to the Office.”

Create A New “Restriction” Practice; End All “Divisional Patents”

**Eliminate Examiner Restriction Requirements, Except For Allowing Examiners To Require
Confining Independent Claims To A Single, General Inventive Concept**

And

***Require Separate Issue/Maintenance Fees For Each Independent Patent Claim In Excess of A
Fixed Number That Is Not Fewer Than 3***

Problem Statement

Current examining practices can dictate that an inventor must file and prosecution multiple, separate patent applications in order to secure all patentable claims to which an inventor might be entitled based on the discoveries that are originally disclosed in a single, nonprovisional patent filing. The “dividing” of examination into separately filed applications for patent can create profound inefficiencies in the examination process and contributes to the formation of “patent thickets.”

Under the existing USPTO “restriction practice,” patent examiners are entitled to limit the examination of claims to those representing a single “independent and distinct” invention. The resulting piecemeal examination of claims, in addition, to fostering “patent thickets,” typically lengthens the time period before the inventor and the public will know the full extent of the disclosed subject matter that will be covered by patent claims.

Under current restriction practice, the vast majority of “divisional applications” that are filed claiming “independent and distinct inventions” are in fact examined by the same examiner who made the initial requirement for restriction. Thus, in large measure, the effect on the USPTO examining corps of eliminating current restriction practice would be to change the timing of the examination of “independent and distinct inventions” that are postponed—sometimes by years or a decade or longer—until divisional application filings are finally completed. The change to the timing is significant in two respects. First, the examiner is better positioned to examine the application and all the independent claims most effectively in one thorough examination. Examining one or several divisional applications over a period of years requires the examiner to “re-learn” the invention and art, essentially redoing the work. Second, it leaves the public with uncertainty as to what the claimed subject matter is. Today, it is not uncommon for applicants to not pursue restricted claims for lack of commercial or licensee interest. However, until there are no pending family members, the public is uncertain whether the restricted claims will be pursued or dedicated to the public for years or decades. Examining all such claims will provide greater public certainty to the subject matter claimed.

Lastly, patent examination efficiency and quality can be compromised since, over time, serially filed “divisional” patent applications can sometimes be assigned to new patent examiners—who will then need to repeat the efforts of their predecessors to understand the patent application disclosure and the most relevant prior art before commencing examination of the application. The result is a diminution in the quality and integrity of the U.S. patent examination process that

could be obviated by requiring all claims presented for examination in a patent application must be examined at once—in the examination of the original, nonprovisional patent filing.

Summary Of The Proposed Solution

The proposed solution would accomplish the following:

- (1) The USPTO would no longer require the filing of divisional applications arising from “requirements for restriction,” which restrict the claims of any single patent application be restricted to what is termed an “independent and distinct invention.”
- (2) In place of such “restriction requirements,” a patent examiner would be permitted to require the restriction the scope of each independent claim in a patent application. Using established, international norms for restriction, each independent claim in the patent could by a patent examiner be restricted to a single, general inventive concept, so-called unity of invention.¹⁰⁸
- (3) The fee structure as it relates to issue fees and maintenance fees would be adjusted to account for claims to separate general inventive concepts being present in a single patent.

Changes In Patent Prosecution Practices

As a consequence of the elimination of “divisional applications,” instead of the substantive examination for patentability be limited to only an “elected invention,” patent examination would commence with a presentation of the patent examiner’s views on the patentability of all claims presented for examination. This would include any “restriction requirement” that, if maintained, would limit each independent claim of the application to a single, general inventive concept.

By restricting independent claims in this manner, the USPTO would be positioned to assess fees that reflected the level of effort that would be required to fully examine all claims presented for examination. This would include separate issue fees and maintenance fees for patents that contained more than at least 3 independent claims. This would account for the current fee structure in the Office that does not impose additional claim fees for any patent application in which not more than 3 independent claims are presented for examination.

¹⁰⁸ Such an “examine all at once” approach can properly credit patent examiners for the quantity of work involved in examination of applications with claims directed to *multiple general inventive concepts*, i.e., the international standard for determining if multiple inventions are being claimed in a single patent application. In the relatively rare circumstances where the optimal examination would require a second examiner to be involved based upon a greater familiarity with one or more of the general inventive concepts to which pending claims were directed, the USPTO could adapt procedures for affording the involved examiners appropriate “count credit” and coordinating office actions so that the resulting examination could be as complete and accurate as possible—and no less so than under current divisional application practice. The reform proposal anticipates a fee structure under which this type of coordinated examination would be no less possible—and equally sufficiently financed—through the user fees set based upon the total number of independent claims application being examined. Affording patent examiners authority to *restrict the independent claims* of a patent application to a *single general inventive concept* both allows all claims to issue in a single patent and facilitates proper patent examiner credit for examining applications that require additional time to assure complete and accurate examination.

In the past, the USPTO has calibrated the patent issue fee based on the content of the patent application.¹⁰⁹ Using this type of precedent, the Office could impose fees to reflect separate general inventive concepts based separately on the total number of independent claims and the total number of dependent claims.

Possible Legislative Implementation

Prototype statutory language that would implement the proposed reform could take the following form:

(a) RESTRICTION OF CLAIMS.—

(1) IN GENERAL.—Strike section 121 and insert:

“§121. Restriction of independent claims.

“The examiner may object to an independent claim as being directed to multiple general inventive concepts and may require that each independent claim be restricted to a single general inventive concept. The applicant may request a review of any objection under this section by petition to the Director, identifying what the applicant regards as the single general inventive concept present in each independent claim. The validity of a patent shall not be questioned for failure of any claim to be restricted to a single general inventive concept.

(2) CONFORMING AMENDMENT.—In the table of sections for chapter 11, strike the existing entry for section 121 and insert:

“121. Restriction of independent claims.”

(b) FEES FOR EXCESS CLAIMS.—

(1) IN GENERAL.— In chapter 4, insert at the end:

“§ 43. Additional fees for excess claims.

“(a) EXCESS INDEPENDENT CLAIMS.—Upon filing, or upon pendency in an application for patent otherwise, of claims in independent form in excess of 3, in addition to the fee specified in section 41(a)(2), the applicant shall incur an excess claims fee under this section in the amount of the total fee as specified in section 41(a) for the original filing, the search, and the examination of the application for each claim in independent form in excess of 3. Upon issuing a patent containing one or more claims in independent form in excess of 3, in addition to the issue fee specified in section 41(a)(4), the applicant shall incur an additional issue fee under this section in the amount of the fee as specified in section 41(a)(4) for each claim in independent form in excess of 3. At the time of payment of a maintenance fee under section 41(b) with respect to a patent, the patentee shall incur an additional maintenance fee under this section, in the amount of the fee as specified in section 41(b) for maintaining the patent in force, for each claim then in the patent in independent form in excess of 3.

¹⁰⁹ The USPTO, for example, has imposed patent issue fees that varied by the size of the patent specification, e.g., depending on the number of pages in the issued patent. (See Official Gazette of the United States Patent Office 926:1 (September 3, 1974), “Effective October 1, 1974, the Patent Office in calculating the *balance of issue fee due*, after payment of the *Base Issue Fee* specified by the Notice of Allowance, shall charge at the *rate of \$10 a page*, as provided in 35 USC 41, for each printed page of specification (including claims) for which payment has not theretofore been received.”)

“(b) EXCESS DEPENDENT CLAIMS.—Upon issuing a patent containing one or more dependent claims in excess of 30, in addition to the issue fee specified in section 41(a)(4), the applicant shall incur an additional issue fee under this section in the amount of the fee as specified in section 41(a)(4) for each 10 dependent claim in excess of 30. At the time of payment of a maintenance fee under section 41(b) with respect to a patent, the patentee shall incur an additional maintenance fee under this section, in the amount of the fee as specified in section 41(b) for maintaining the patent in force, for each 10 dependent claims then in the patent in excess of 30.”

The aspects of the new “restriction practice” that involve simultaneous examination of all pending claims could serve patent applicants by providing greater flexibility in securing claims directed to differing general inventive concepts. In this regard, applicants might still elect during the initial examination to confine the examination to just a few independent claims, such that only a single set of fees would be due for issuance and maintenance of the patent. For the non-elected claims directed to other general inventive concepts, applicants could still have access to “continuation applications” to broaden claims of an earlier-issued patents, using the new continuation practice proposed below.

In situations where the subject matter of the patent had become commercially obsolete or otherwise of not commercial significance, the ability to avoid proceeding immediately to file a copending divisional application could result in costs savings not available with the existing continuation/divisional application practices.

Conclusions

Through a collection of changes to the current patent examination process, beginning with the elimination of “restriction practice,” patent applicants can enjoy an undiminished opportunity to secure full and fair protection for any patentable discoveries disclosed in an initial nonprovisional patent filing without the need to resort to filing separate divisional applications, which create inefficiency in examination and uncertainty with the public.

Create a New “Continuation” Practice; End Continuation Thickets

Eliminate Both The Current Patent Reissue And Continuation Application Statutes And Enact, As A Substitute, A New Continuation Application Statute:

- (1) Permitting The Filing A Continuation Application Only After The Issuance Of Either An Original Patent Or A Prior Continuation Patent Referenced In The Continuation,**
 - (2) Permitting Amended Or Otherwise New Claims In The Continuation Application, And**
 - (3) Upon Issuance Of The Continuation Patent, Canceling The Referenced Patent,**
- And**

Restrict The Filing Of A Continuation Application That Recaptures Or Otherwise Broadens Patented Subject Matter To A Period That Is Fixed At Not Less Than 6 Years After The Filing Date Of The Original, Non-Continuation Patent

Problem Statement

The relentless criticism of the use of continuation applications to generate “patent thickets” should be decisively addressed, but the challenge in doing so is that the ability of inventors to secure the fullest and most complete protection for their disclosed inventions could be compromised. In a similar manner, so-called “submarine patents” that result from the filing of serial, continuation applications for patent have similarly been the subject of efforts to reign in what is seen as an abuse of this practice. Once again, possible solutions face the challenge to ending practices that appear to be outright abuses of the patent, yet maintaining the ability of an inventor to secure full and fair protection for all the claims to which the applicant might be entitled as a matter of substantive patent law.

Continuation practice also presents a practical issue. Today, “continuation patents” now represent a substantial percentage of all patents issued by the USPTO – more than 30%, and the number continues to grow at an alarming rate. These applications consume a tremendous number of resources. As a matter of patent policy, such resources would be better directed to original applications so that, for example, pendency time could be reduced.

Summary Of The Proposed Solution

The proposed solution would end the existing continuation application and reissue application practices. It would, instead substitute a new procedure for securing new claims the 20-year term of any issued patent through a new type of “continuation application” that would have the following characteristics:

- (1) The “copendency” requirement of current continuation application would be repealed.
- (2) Upon grant of a continuation patent, the original patent or the prior-issued continuation parent patent would be canceled.

- (3) A continuation application seeking to broaden the claims of the patent being continued could only be filed within a fixed period set by statute at least six years from the filing date of the original patent, i.e., within the fixed period from the nonprovisional effective filing date.

The new continuation application practice would eliminate all the special requirements and limitations of patent reissue practice, eliminate any need to maintain application copendency, and afford the public certainty on the ability of the patent owner to secure broader claims.

Introduction and Background

The opportunity to file one or more “continuation applications”—that each can be treated for patentability purposes as though it was filed on the date of the earlier-filed “parent application” from which it originated—has been an opportunity provided to inventors since the inception of the modern system of patent examination.¹¹⁰ All that is required for a patent applicant to secure additional continuation patents based on an original, nonprovisional patent filing is to reference the earlier-filed application or applications and maintain a chain of copendency.¹¹¹

In today’s patent systems, continuation practice can assist in addressing a variety of challenges that inventors and their assignees face. These challenges arise from the need to proceed with patent filings promptly after innovative technology has been identified. This urgency for promptness can arise from suspected competitor R&D efforts, the rapid and relentless advance of technology in certain fields, inventor/assignee obligations to make early public disclosures for regulatory and other reasons, and the risks from an unintended pre-filing disclosure—any one of which can create patentability-destroying prior art.

In these situations, the initial claims in an original, nonprovisional patent filing may be drafted without knowledge of the commercial embodiments—since patent filings today typically are not delayed until commercial development is complete. Continuation applications can, thus, allow a patent applicant to identify patentable claims that may only become clear as development of the invention for commercialization proceeds.

“Reissue applications”—and the “reissue patents” that issue on these applications—can serve a similar purpose to continuation patents, most especially in a circumstance where a patent applicant has not elected to maintain the pendency with a “parent application” required for the filing of a continuation application. Like continuation application, reissue patent applications

¹¹⁰ Patent Act of 1836, Ch. 357, 5 Stat. 117, § 7 (July 4, 1836); *Godfrey v. Eames*, 68 U.S. 317 (1863).

¹¹¹ 35 U.S.C. §120: “An application for patent for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed in the United States, or as provided by section 363 or 385 which names an inventor or joint inventor in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director.”

have existed since 1836.¹¹² Reissue applications, however, operate under a separate set of *procedural constraints* compared to continuation applications:

- A reissue application can only be filed after the issue date of the patent being reissued.
- The grant of the reissue patent requires cancellation of the patent being reissued. Thus, unlike a continuation patent, a reissue patent does not add to a “patent thicket.”

Reissue applications are additionally subject to *substantive restraints* on claiming not faced by continuation applications. These consist of the following:

- A reissue application must identify an “error” in the grant of the patent being reissued.¹¹³
- The claims of the reissue application are subject to a “recapture rule,” i.e., “[a] reissue will not be granted to ‘recapture’ claimed subject matter which was surrendered in an application to obtain the original patent;”¹¹⁴
- The claims of a reissue application are subject to a two-year time limit for “broadening” (i.e., claims that are broader than the originally granted claims).¹¹⁵

The existence of three different types of applications for securing additional claims once an original patent has issued—the continuation application, the divisional application, and the reissue application—offer self-evident opportunities for reengineering all these continuing/reissue application practices in a manner that might better serve the needs of inventors and their assignees for claiming flexibility, as well address the public interest in deterring both “patent thicketing” and “submarine patenting” practices. Specifically, the reform proposal above supports that a *single form of continuing application* be engineered, entirely

¹¹² See Patent Act of 1836, § 13, 5 Stat. 117, 122, providing, in what is an analog to the reissue provision in 35 U.S.C. §251, that “whenever any patent which has heretofore been granted, shall be inoperative, or invalid, by reason of a defective or insufficient description or specification, or by reason of the patentee claiming in his specification as his own invention, more than he had or shall have a right to claim as new; if the error has, or shall have arisen by inadvertency, accident, or mistake, and without any fraudulent or deceptive intention, it shall be lawful for the Commissioner, upon the surrender to him of such patent, and the payment of the further duty of fifteen dollars, to cause a new patent to be issued to the said inventor, for the same invention, for the residue of the period then unexpired for which the original patent was granted, in accordance with the patentee’s corrected description and specification.”

¹¹³ 35 U.S.C. §251(a): “Whenever any patent is, *through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent*, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.”

¹¹⁴ M.P.E.P. 1412.02 Recapture of Canceled Subject Matter [R-07.2022].

¹¹⁵ 35 U.S.C. §251(d), “No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.”

superseding existing patent reissue practice and the need for such a practice, to address the potentially competing policy objectives for an optimized examination procedure.

Defining Key Elements of an Optimized Patent Examination at the USPTO

A major contributor to the so-called “patent thickets” is the patent examination structure imposed by the current patent statute. Patent applicants, in many circumstances, are not permitted to secure a patent on all the claims to which they might be entitled upon the filing of the original, nonprovisional patent application. As noted above in connection with the proposed reform to “restriction practice,” patent examiners routinely limit the nature and number of originally presented claims that can be examined in any patent filing.

Other patent examination practices similarly operate to increase the number of patent application filings that take place based on a single, initial filing. As noted above, the “error” requirement limits the ability of inventors to file reissue applications. If a requirement for restriction is made and a divisional or other form of continuing application is not timely filed, then patent reissue is unavailable to secure claims to any non-elected, restricted subject matter.¹¹⁶

In addition, the “error” requirement forces continuation practice, given the *now-or-never* nature of the ability to file a continuation or divisional application for patent once a “parent” application is about to issue as a patent. This *now-or-never* issue arises because of the copendency requirement that limits the securing benefit off the filing date of the parent application in a continuing application except in the circumstances where “copendency”¹¹⁷ exists from the beginning to the end of a chain of applications.

A second limitation on claims permitted in reissue applications similarly spawns the need to proceed with continuation applications once claims of a “parent” application have been allowed. This limitation is the so-called “recapture rule” described above. Under the current patent statute, the only mechanism available to avoid invocation of the recapture prohibition on claiming is again resort to a continuation application filing—which, again, must meet the copendency requirement.

A similar incentive to pursue continuing applications for patent once the initial patent examination has produced some allowed claims is the prohibition on the use of the patent reissue process to broaden the claims originally granted. Currently the two-year period following patent

¹¹⁶ “Where a restriction (or an election of species) requirement was made in an application and applicant permitted the elected invention to issue as a patent without filing a continuing application on the non-elected invention(s) or on non-claimed subject matter distinct from the elected invention, the non-elected invention(s) and non-claimed, distinct subject matter cannot be recovered by filing a reissue application. A reissue applicant’s failure to timely file a continuing application is not considered to be error causing a patent granted on the elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim.” M.P.E.P. 1412.01 Reissue Claims Must Be for Same General Invention [R-07.2022] (<https://www.uspto.gov/web/offices/pac/mpep/s1412.html>).

¹¹⁷ 35 U.S.C. §120. “An application for patent for an invention disclosed in the manner provided by section 112(a) ... which names an inventor or joint inventor in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, *if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application.*” [Emphasis added.]

grant during which a reissue application must be filed in order to broaden claims renders continuing application of greatest importance where the initial patent examination resulted in the prompt issuance of a patent.

Quality and efficiency in patent examination could be enhanced if the examination procedures did not require that patent claims be pursued in bits and pieces—and if patent applicants were not necessarily forced to immediately resort to filing continuation and divisional applications for patent once claims of the initial, nonprovisional application were allowed. Piecemeal examination practices leading to the proliferation of patents could be eliminated by simultaneously ending “restriction” practice that can limit the claims being examined in an application,¹¹⁸ and simultaneously ending the existing “reissue” practice—and replacing both with a more flexible procedure for securing continuation patents, specifically one that did not require “copendency” between the parent patent and the continuation patent that references the parent patent. For at least some period of time following the original, nonprovisional filing date of a patent, the new continuation application practice, like the existing reissue application procedure could be open to broadening and recapturing of subject matter that had not been claimed in the referenced patent.

Assuming that each of the foregoing factors could be removed as an impediment to an efficient examination process, patent examiners would begin the patent examination process by simply *examining on the merits all claims presented in a patent application*. This would allow a patent examiner to *review the entire patent specification at once*, undertake a *single search of all prior art relevant to all the presented claims*, and provide the patent applicant with a *comprehensive initial patentability report*, as first substantive communication to the patent applicant.

Such an *all-claims-examined-at-once* paradigm offers inventors the opportunity to secure prompt protection of any claimed inventions. For many patent applicants, the initial examination effort could represent a *one-and-done effort* at secure a patent.¹¹⁹ In many circumstances, no commercial need would emerge that would justify pursuit of additional patent claims. In these situations, the “no restriction” on claims being examined translates into greater certainty to the public and lesser prosecution costs to the inventor.

¹¹⁸ The “examine once” aspect of any new examination paradigm would need to account in some manner for the disclosure and claiming of multiple inventions in a single patent filing. This could be done by imposing fees on excess claims and by giving patent examiners authority to limit any independent claim to a single, general inventive concept. A fee structure mandating filing, issue, and maintenance fees for the “excess” independent claims corresponding to the additional general inventive concepts could then account for differential examiner workloads.

¹¹⁹ The current reform proposal specifically addresses the issue of “patent thickets” through the use of “continuation” applications that serially issue based on an original, nonprovisional patent filing. Except through the reform proposal’s “res judicata” enforcement limitation for patents that represent obviousness-type double patenting, it does not seek to address all of the current prosecution practices that can result in the issuance of multiple, related applications. For example, applicants may concurrently file a PCT application and an identical U.S. national application, with the option for the PCT application to later enter the national stage, such that separate patents might issue on both applications. This and other such concurrent application filings would not be barred by the reform proposal, thereby affording inventors “multiple patenting” flexibility in claiming, so long as such concurrent filings are undertaken upfront at the commencement of the patenting process. However, for *enforcement purposes*, these related patents could be treated in substance as though only a single patent had issued containing all the claims of the involved patents.

As discussed below, however, the *one-and-done* size does not fit all circumstances. For this reason, the additional flexibility outlined below addresses the instances where development and commercial needs do necessitate further prosecution opportunities that can result in securing additional claims to subject matter disclosed in the patent application.¹²⁰

Freed from recapture strictures on later claiming, patent applicants would be free to allow a patent to be promptly issued where the initial examination for patentability resulted in only a narrowed set of allowed claims.¹²¹ The opportunity for securing a broader array of claims would not depend on immediately filing a continuation application. Seeking any additional claims through non-copending, continuation application filing could be deferred until such time as the patent statute might impose a limitation on seeking broader claims than those originally issued.

Setting at least a six-year limitation on such a “broadening” continuation application filing could eliminate altogether the need any such filings.¹²² With the elimination of both divisional and traditional continuation applications, the opportunity for patent thickening arising from a single, original, nonprovisional patent application would disappear. A time limitation on broadening continuation applications would also end “submarine patent” possibilities. In addition, the patent statute itself, by sanctioning a specified limitation on the timing of the filing of applications with broadened claims, would supersede the *prosecution laches* doctrine, i.e., through a congressional finding of when such broadening was or was not to be deemed justified.

In certain technologies, the ability to secure successive continuation patents with new or otherwise amended claims can have significant advantages not possible with the current statute.¹²³ That said, the limitation on “broadening” claims beyond a period set at no fewer than

¹²⁰ For example, patent applicants with limited resources (which is often the case for basic research institutes, start-up companies, and independent inventors), particularly such applicants with early-stage inventions dependent upon long-term development efforts before ever achieving commercialization (which is often the case in fields such as biotechnology or other advanced technologies that may require collaborative efforts involving multiple contributing entities) can benefit from flexibility in claiming, even where the underlying inventive concept remains the same. Such flexibility is also important given the potential for unpredictability in legal interpretation that the technical language in patent claims might be given.

¹²¹ This flexibility to initially issue—without prejudice—a subset of all the claims that represent patentable subject matter would particularly assist patent owners with limited financial resources for whom incurring significant USPTO fees for a large number of claims at an early stage in the development and commercialization of an invention might be a significant hardship.

¹²² Time periods of greater than six years could be justified for broadening continuation application filings. Patent applicants are likely to urge that a substantially longer period could be justified, e.g., a 10- or 12-year period. Since some technologies historically experience longer development times before commercialization of a claimed invention is possible, technology-specific time periods could be considered. Some claimed inventions are dependent for commercialization based on regulatory approvals that have patent related implications, which could justify time periods that align with regulatory approvals. Whatever the time period that might be justified, a period of at least six years after an original, nonprovisional patent filing would be vital for recrafting claims in many technologies, none more than in the life sciences.

¹²³ Typical patent filings in these technologies result in numerous inventions being disclosed a single original patent filing. Preclinical and clinical development of the disclosed inventions can result in changing priorities in terms of identifying the best lead candidates for further development. For this reason, as well as changing business needs, inventors expect a sufficient period for presenting additional claims or pursuing alternative claiming strategies. For instance, a parent application might disclose multiple drug candidates. As efforts at commercialization can prioritize some disclosed candidates and deprioritize others, claiming strategies may need to change. The patenting focus can shift to an alternative candidate disclosed in the patent specification when it emerges as potentially safer or more

6 years from the original, nonprovisional filing date referenced in a continuation patent may mean that certain types of desired claim broadening—identified from new developments in proceeding with commercialization of the patented technology or arising from changes in the understanding of the patent law—may not be possible.

While a real concern, this concern appears to be a largely hypothetical one that virtually never arises in practice. Thus far, there have been no cited examples of where the belated issuance of a continuation patent claim that was broader in scope in some respect critical to the commercial value of the patent and ultimately found to be valid when enforced.¹²⁴

Possible Implementing Legislative Text

The above reform proposal would replace traditional continuation and divisional patent applications, as well as reissue application practices,¹²⁵ with new opportunities for securing continuation patents:

(1) A new opportunity to secure additional, including broadened, patent claims through a non-copending continuation application would permit the filing of such applications for patent several years after the original patent had issued. If timely filed, these continuation applications would be exempt from the “claim recapture” doctrine and any limitation of broadening, so long the continuation application were filed within a fixed period set at no fewer than six years from the original, nonprovisional application date of the ultimate patent being reissued.

effective—and may be the only candidate to advance, years after the original, nonprovisional patent filing, into clinical development. *The file-once-examine-once-and issue once approach, coupled with a non-copending continuation application opportunity*” has potentially significant advantages in situation where—as under current practice—the focus of patenting to an alternative clinical candidate comes belatedly in a continuing application. First, the patent term extension (PTE) provisions under 35 U.S.C. §156 eliminate from the “regulatory review period,” used to determine the permitted length of the extension, the entire period of pre-clinical and clinical development before the date of patent issuance. For PTE purposes, however, it is the issue date of the patent issuing on the original, nonprovisional patent application not the continuing application issue date) that starts the clock running on PTE (e.g., see U.S. Reissue Patent 36,755 for Enbrel). Second, the relevant claims protecting the drug candidate can today be spread among a collection of patents in the continuation application family, only one of which will qualify for extension under §156. Under the file-once-examine-once-issue-once regime coupled with “non-copending continuation applications,” all relevant claims will qualify for and can receive the PTE. Hence, viewed as a whole, the file-once-examine-once-issue-once/”open reissue” regime—with an appropriate “claim recrafting” period—can be uniquely valuable for inventors in the life sciences.

¹²⁴ In general, a patent application as filed must contain a description identifying the subject matter regarded as the invention, which normally identifies the broadest scope of claim to which the inventor could possibly be entitled. In almost any imaginable circumstance, a period of at least six years should suffice for the patent applicant to make such a claim in a pending patent filing.

¹²⁵ The current reissue practice before the USPTO is sufficiently complicated that special oversight of reissue applications is provided. See [M.P.E.P. 1456 – Reissue Review \[R-07.2022\]](#). The proposed use of a more straightforward non-copendency, “continuation application” model, in lieu of the current reissue statute, should lessen the need for the same type of specialized oversight, but allow the USPTO to continue to provide such oversight in selected situations, e.g., continuation applications where the parent patent is currently involved in patent infringement litigation. This additional oversight could include a separate “quality review” for a targeted subset of such applications.

(2) In addition, a continuing opportunity would exist for filing continuation application filed after the end of the set period that would be free from the requirement to demonstrate “error.” Currently present in the reissue statute.¹²⁶

Existing “continuation application” practice is a second aspect of the current patent examination process that results in the piecemeal issuance of multiple patents able to generate “patent thickets” that can contain numerous “continuation patents,” all based upon a single, nonprovisional patent filing. This unrestricted ability to seek “continuation patents” from a single patent filing adversely impacts patent examination quality and integrity, particularly when these “continuation patents” continue to issue throughout the 20-year patent term.

The new continuation application opportunity can replace all continuation-divisional-reissue applications. The new continuation patent statute would allow broadened claims during at least the fixed period of at least six years following the nonprovisional filing date. Continuation applications filed during this period would not be subject to either a claim “recapture” or claim

¹²⁶ The reform proposal could be implemented through the following effect to title 35, United States Code:

(a) NEW CONTINUATION APPLICATIONS FOR PATENT.—

(1) IN GENERAL.—Strike section 120 and insert:

§120. Benefit of the original, nonprovisional filing date.

If an application is filed referencing a patent and requesting to amend the claims of the referenced patent, including by presenting new claims, such an application shall be examined as a continuation application, and may be issued as a continuation patent, under section 251. In such a continuation application, a claim shall be given the same effect as though the claim were part of the original, nonprovisional application as original filed, except to the extent that such claim would constitute new matter had it been presented as an amendment to the original, nonprovisional application as originally filed.

(2) CONFORMING AMENDMENT.—In the table of sections for chapter 11, strike the existing entry for section 120 and insert:

“120. Benefit of the original, nonprovisional filing date.”

(b) PROCEDURE FOR SECURING CONTINUATION PATENTS.—

(1) IN GENERAL.—Strike section 251 and insert:

“§251. Continuation applications.

“Whenever the patentee seeks to amend the claims of an original patent or a continuation patent, through the filing of a continuation application, the Director shall, on the payment of the fee required by law, examine the claims of such application and issue a patent on such continuation application, containing such claims as are determined to be allowable. Such a continuation patent shall be issued for the unexpired part of the term of the original patent, and issuance of the continuation patent shall constitute the cancelation of the patent with respect to which the continuation was sought. No new matter shall be introduced into a continuation application and no continuation patent shall be granted enlarging the scope of the claims of the patent being canceled, or recapturing subject matter not claimed on account of amendments made in the original patent or an earlier filed continuation patent, unless the continuation application is filed within six years from nonprovisional filing date of original patent. The provisions of this title relating to applications for patent shall be applicable to continuation applications, except that a continuation application may be made by the assignee of the entire interest if the application does not seek to enlarge the scope of the claims of the original patent or the application for the original patent was filed by the assignee of the entire interest.”

(2) CONFORMING AMENDMENTS.—

(A) In Section 252, strike each occurrence of “reissued patent” and “reissue” and insert “continuation patent” and strike each occurrence of

(B) In the table of sections for chapter 25, strike the existing entries for sections 251 and 252 and insert:

“251. Continuation applications.”

“252. Effect of continuation patent.

broadening limitation or the requirement to demonstrate error. In effect, the new continuation application “open claiming” period would have the opportunities for adding and amending claims that are present in current continuation applications, but without the requirement for “copendency.”

After the expiration of the fixed period set of at least six years, continuation application opportunities would remain, but would bar broadening claims. Because these new continuation patent opportunities would continue to operate throughout the 20-year patent term—and allow maintaining originally issued claims together with any new or amended claims in a single patent—the patent owner would be afforded a full and fair ability to secure additional patentable claims following the initial patent grant, but without the undesirable consequences fostering a thicket of separate patents in the process. Through these changes, a single nonprovisional patent filing can never produce more than one patent, either the original patent or a reissue based on that original patent.

Conclusions

The criticism of the operation of the patent examination process in the USPTO—and the openness of that process to produce so-called “patent thickets” with continuously evolving claims—has grown to a near-existential level. The above reform proposal would address continuation-based “patent thicketing,” as well as “submarine patenting,” in a manner that would nonetheless secure inventors with a full and fair opportunity to protect their discoveries.