



THE NAPLES ROUNDTABLE

Exploring Ways to Strengthen & Improve the Patent System

IN THE QUEST TO STRENGTHEN AND IMPROVE THE PATENT SYSTEM: THE IMPERATIVE FOR ELEVATING PATENT EXAMINATION INTEGRITY

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*PHOENIX ISSUE I: HAS THE VALUE OF U.S. PATENTS DECREASED OVER THE LAST 10 YEARS
ARE THERE WAYS TO STRENGTHEN AND IMPROVE THE PATENT SYSTEM?
WHAT CAN AND SHOULD BE DONE TO IMPROVE THE PROCESS?*

Summary and Overview

The goals of *strengthening* and *improving* the U.S. patent system are not independent and distinct objectives. Strengthening the U.S. patent system ultimately depends on improving the most foundational aspect of the patent system, *patent examination*. The entire premise that established patent rights should be accorded deference and respect hinges on the integrity of the patent examination process. Efforts to increase the value of patents thus mandate an unflinching focus on patent examination integrity.

To support a strong patent system, examination needs to proceed with *promptness, thoroughness, and accuracy* in assessing patentability. The near-exclusive focus of examination should be on a rigorous application of the *key statutory patentability requirements*—the “three D’s” of *disclosure sufficiency of the patent specification with respect to the breadth of the patent’s claims, definiteness in distinguishing what is and is not within each claim’s scope, and differentiation in a novel and non-obviousness manner over the most pertinent “prior art.”*

Aspects of today’s patent examining procedures in the United States Patent and Trademark Office work to undermine examination integrity. The patent examination process today is characterized by several features that *defeat promptness* (by delaying a final determination of the patentability for all the claims initially presented for examination), *detract from the thoroughness* of the examination process in addressing the key statutory patentability requirements (by requiring patent examiners to devote examining resources to non-essential issues), and *defy an accurate examination* on patentability (by failing to identify and focus examination on the most pertinent prior art). Each of these structural delays, detractions, and distractions present in the examination process can be remedied through reforms. The needed reforms are straightforward and relatively few in number. The Patent Examination Integrity Act, discussed below, provides such reforms. It reworks the patent law in ways calculated to radically improve the integrity of the patenting process in the USPTO. As such, it offers an essential predicate for a stronger patent system—a system in which patent rights, once issued, will be more greatly valued.

Pre-Conference Discussion Draft

BUILDING A STRONG PATENT SYSTEM ON PATENT EXAMINATION INTEGRITY

A strong patent system is one able to serve its constitutional purpose of promoting investment in the development and commercialization of new technology. Such a system requires that issued patents provide reliably valid protection for the innovations they claim. A strong patent system cannot exist unless it produces patents that are respected as affording clearly defined and consistently enforceable property rights. That can only happen if such rights are the product of a *high-integrity examination process*. A high-integrity examination process is one that permits a patent to issue only after a *prompt, thorough, and accurate* vetting for patentability. The Patent Examination Integrity Act of 2019 offers a set of coordinated and comprehensive reforms to the patent examination procedures with the objective of assuring that a high-integrity patent examination process can serve as the foundation of a strong patent system. The Act's major components will accomplish the following:

- Focus the examination process on the key patentability issues—the three D's of *disclosure sufficiency of the patent specification with respect to the breadth of the patent's claims, definiteness in distinguishing what is and is not within each claim's scope, and differentiation in a novel and non-obviousness manner over the most pertinent "prior art."* Eliminate patentability issues that can be more effectively and efficiently handled through limitations on claim construction or limitations on other aspects of the enforceable rights under a patent. *In particular, abrogate the judge-made "implicit exception" to the subject matter that is eligible for patenting and the "double patenting" doctrine—replacing them with new statutory claim construction and patent enforcement limitations.*
- Impose new disclosure requirements on patent applicants to identify in concise terms the potential relevance of any prior art submitted for consideration during examination, with the option for the USPTO to charge a separate fee for each item of prior art so submitted—thereby creating incentives to end the existing practice by some patent applicants of “over disclosing” prior art of little or no relevance and “under explaining” the potential significance of any prior art submitted for consideration by the patent examiner. Abrogate the “inequitable conduct” unenforceability defense (in part as a further incentive to end the “over disclosure” and “under explanation” of prior art), but maintain the USPTO's existing “duty of candor and good faith” that requires patent applicant submissions of all material prior art.
- Examine *all* claims presented for examination in a patent application at one time, without requirements for restriction to—or election of—selected claims, *i.e.*, such that only a single patent filing is needed to protect all novel and non-obvious subject matter disclosed in the patent's specification. Eliminate from the examination process all manner of “continuing applications” for patent. Provide for the USPTO to charge new “excess fees” for issuing and maintaining patents claiming multiple general inventive concepts to finance these changes.
- Align the post-issuance review procedures with the goal for a high-integrity pre-issuance examination process, by creating greater incentives for the public to challenge patents in the USPTO immediately upon issuance, in preference challenges brought after patent rights are long-established. Reduce the redundancy in such proceedings. In addition, afford patent owners more flexibility in making corrections or other changes to an issued patent.

PATENT EXAMINATION INTEGRITY ACT OF 2019

Overview

If the United States is to continue to enjoy a strong patent system—in which patent rights are broadly respected—the examination procedures in the United States Patent and Trademark Office used to secure those rights need to operate with the utmost in integrity. Patent examination needs to be carried out with a rigorous and relentless focus on the key issues that should define patentability. These are the so-called “three D’s” under 35 U.S.C. § 112(a), § 112(b), and §§ 102/103: *disclosure sufficiency of the patent specification with respect to the breadth of the patent’s claims, definiteness in distinguishing what is and is not within each claim’s scope, and differentiation in a novel and non-obviousness manner over the most pertinent “prior art.”*

When a patent is issued as a result of a high-integrity examination, both the patent owner and the public can have far greater confidence that all the claims of the patent, if ever asserted against an infringer, will be found to satisfy these core patentability requirements. Only when patents issue following such a high-integrity examination process can they serve as a reliable asset, one able to spur and support investments in the development and commercialization of new technology.

The hallmarks of a high-integrity patent examination process are its *promptness, thoroughness, and accuracy*. Patent owners and the public must have confidence that the examination of all claims to each of the inventions disclosed in a patent specification can be completed *in a timely manner* after the patent is initially sought. Such an objective can be frustrated, however, when patent examination takes place a piecemeal fashion, extending over a period of many years, and potentially involving a series of different patent examiners—each of whom must not only begin anew to understand and evaluate the application for the invention being claimed, but also review and consider the possible impact of earlier examination activities that had taken place in related patent filings.

Similarly, the USPTO, patent applicants and the public each have responsibilities to assure that the examination will be *thorough*. No patent examination can be regarded as thorough, however, if the patent examiner does not have access to—and does not center the examining on—the information of the greatest relevance to patentability. This necessary information includes all of the most pertinent prior art needed to assess novelty and—most especially—non-obviousness for any subject matter being claimed.

Finally, and above all else, patent examination must be *accurate*. Patent examiners need to reach a correct determinations on each patentability issue for each claim presented for examination. While inventors should not be wrongly denied claims meeting the requirements for a valid patent, the public should not be burdened with patents granted on non-meritorious claims that, if asserted against an alleged infringer, can be difficult and expensive to erase from a patent.

Many factors in the patent examination process work against achieving consistently accurate results. The greater the number of separate issues of patentability, the greater the

prospect that one or more such issues will be errantly decided. The more subjective and complicated the issue of patentability is for the patent examiner to apply, the greater the potential variability in the decision-making process and the greater the likelihood that a judicial challenge to a patent's validity will reach a different conclusion from that of the patent examiner. Also, the greater the number and complexity of separate issues on which the patent examiner must make patentability-related determination, the less focused the patent examination process can be on the “three D’s”—*disclosure sufficiency, definiteness in claiming, and differentiation over prior art.*

In prior efforts to reform the patent laws, Congress was not asked to undertake a single-minded and concerted effort to focus attention on the impact of proposed patent law changes on the patent examination process itself. The Patent Examination Integrity Act was conceived and is constituted to have just such a legislative focus, with each of its provisions targeted to achieve—or complement the achievement of—more prompt, thorough, and accurate patent examinations.

The Patent Examination Integrity Act is grounded on the premise that elevating patent examination integrity represents a common interest among all stakeholders affected by the patent system. For this reason, examination integrity reforms, when done in a balanced and comprehensive manner, should offer a unique capability to generate the type of broad constituency in support of such changes that is required to enact major patent reform legislation. Unlike legislative efforts in past years, for which no consensus on the spirit or content of needed reforms ever emerged, supporters of greater patent examination integrity should cut across the diverse perspectives of the full range of stakeholders who will be affected by significant changes to the patent statute.

Indeed, the thrust of the Act is of particular importance to advocates for a strong patent system. Legislation targeting greater *promptness, thoroughness, and accuracy* in the USPTO examination processes offers the prospect of muting much of the criticism of current patent examining practices—including criticism of the “quality” of U.S. patents that issue from those examinations. Allegations of patent examination quality shortcomings feed into “patent troll” and “patent abuse” counter-narratives that undermine support for strong and effective patent rights. In particular, contentions that “poor quality” patents serve as tools for “trolls,” fostering patent infringement lawsuits on patents of little or no merit, can be directly countered by integrity-fostering measures that hold the promise of a sea change in promptness, thoroughness, and accuracy in patent examination.

To these ends, the Patent Examination Integrity Act provides an array of statutory interventions. Several interventions target abrogation of certain judge-made patentability and patent enforceability requirements, including two such requirements currently applied by patent examiners during patent examination that needlessly distract the focus of patent examination from the “three D’s.” The requirements removed from patent examination process are alternatively addressed in the Act through new statutory limitations on patent rights that do not consume examination resources. Other interventions abolish longstanding patent examination practices that serve as unneeded obstacles to advancing examination integrity—needlessly slowing and complicating the ability of patent applicants to secure full and complete protection for patentable subject matter.

In addition, the Act introduces into the patent statute new integrity-fostering requirements and obligations directly on patent applicants. These new requirements specifically target “prior art” information disclosures from patent applicants.

The Act also works to facilitate the ability of members of the public to make challenges to the validity of an issued patent earlier rather than later during the life of the patent. Ultimately, therefore, the Patent Examination Integrity Act is premised on changing—in a comprehensive and coordinated manner—the job of the patent examiner, the behavior of patent applicants, and the role of the public through its integrity-optimizing reforms.

The Six Areas of Integrity-Driven Reforms to the Patent Examination Process

The Patent Examination Integrity Act includes major reforms that can be broken down into six general areas. In the first two areas of reform, the Act abrogates two judge-made unpatentability doctrines in favor of limitations on patent claim scope and patent enforcement.

Under the Act, the Supreme Court’s “implicit exception” to the statutory provision on subject matter eligibility for patenting and the judge-made law on “double patenting” both disappear as grounds on which a claimed invention might be held unpatentable. As a replacement for these abrogated judge-made laws, new statutory limitations on claim scope and patent enforcement are created under the Act that will operate without the need to consume USPTO examination resources to reject claims.

The third area imposes new affirmative information disclosure requirements on patent applicants, as well as enacts disincentives to making disclosures of prior art of little or no relevance. To make these reforms workable, the Act abrogates the much-criticized judge-made “inequitable conduct” unenforceability defense to patent infringement, *i.e.*, the so-called “plague on the patent system,”¹ while leaving the existing “duty of candor and good faith” placed upon patent applicants in full force and effect. These provisions of the Act are central to the integrity-enhancing objectives of greater thoroughness and accuracy in the patent examination process.

The fourth area for reform relates to the provisions in the patent statute authorizing the filing of “continuing applications” for patent—continuation applications, continuation-in-part applications, and divisional patent applications. The Act abolishes all forms of such applications.

The elimination of continuing application filings has two salutary effects. First, it allows the patent examination process to proceed by considering on the merits all claims presented in an application at one time. Second, it eliminates from the examination process the efforts by patent examiners to first impose and then defend requirements for restriction before any examination on the patentability merits of the claims commences.

¹ “[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.” *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

The fifth area of examination-related reforms relates to post-issuance USPTO patentability determinations. These procedures are tuned to encourage prompt public challenges to patent claims that were errantly granted and provide disincentives to making such challenges later in the life of an issued patent.

The last reform area focuses on complementary statutory changes relating to the scope of enforceable patent rights. It codifies rules for infringement based upon equivalents of a claimed invention and the experimental use exception to infringement. In both of these enforcement-related areas, no current statutory provisions exist to clearly define the scope of available patent protection. For this reason, the Act supersedes the judge-made law with more precisely defined and delineated statutory standards. Finally, the Act expands the prior domestic commercial use defense to infringement to better align the defense with international norms.

The reforms in these six areas are explained in greater detail below.

1. Replacing the “implicit exception” with limitations on claim construction

The Act’s most significant change among its integrity-driven reforms to the patent examination process lies in the Act’s abrogation of the judicially imposed “implicit exception” to subject matter that is eligible for patenting. In decisions over the past decade,² the Supreme Court has imposed a standard for assessing whether a claimed invention is ineligible for patenting that is highly unpredictable in practice. The expressed intent of the judicially imposed exception is to render unpatentable claims directed to—or that otherwise preempt access to—a law/product of nature, natural/physical phenomenon, or other abstract idea or concept. The Court has indicated that permitting such protection through a patent is antithetical to the constitutional purpose to promote progress in useful arts, *i.e.*, valid patent rights must not prevent access to the basic tools of science and technology.³

In actual practice in the examination of patent applications, the Court’s jurisprudence has placed an overemphasis on subject matter eligibility during the patent examination process—at the expense of according a proper and more balanced consideration of the key statutory patentability issues of disclosure sufficiency, definiteness in claiming, and differentiating in non-obviousness ways over the most pertinent prior art. This overemphasis, coupled with the subjectivity, vagueness and near arbitrariness in applying the Court’s judicially mandated exception, demands that Congress identify a more workable alternative to it. The Patent Examination Integrity Act takes on this task.

To this end, the Act provides an alternative statutory limitation on the protection accorded under a patent fully addresses all the policy considerations that underlie the Supreme

² *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), *Mayo Collaborative v. Prometheus Labs.*, 132 S. Ct. 1289 (2012), *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347 (2014).

³ “[T]he Court’s precedents . . . warn us against upholding patents that claim processes that too broadly preempt the use of a natural law.” *Mayo*, 132 S. Ct. at 1294. “[M]onopolization of [the basic tools of scientific and technological work] through the grant of a patent might tend to impede innovation more than it would tend to promote it.” *Id.* at 1293.

Court’s rationale for denying patent eligibility to excessively conceptual claims (*i.e.*, claims directed to a law/product of nature, natural/physical phenomenon, or abstract idea). The Act does so through *claim construction limitations*. Such limitations on what subject matter may be covered by a claim entirely obviate the need for rejecting claims during examination that otherwise would have protected (or preempted access to) a law/product of nature, natural/physical phenomenon, or other abstract idea or concept.

The Act formulates the new statutory limitations on claim construction by relying on the foundational work of Congress in enacting the 1952 Patent Act. In this regard, the new statutory limitation on claim construction for a law/product of nature, natural/physical phenomenon, or abstract idea builds on the existing template in 35 U.S.C. § 112(f) that similarly limits claim construction to maintain the patentability of what otherwise would constitute invalid claims.

Subsection (f) was originally enacted in 1952 to moot Supreme Court precedent rendering unpatentable certain claims with functional elements. Instead of invalidating such claims, § 112(f) was initially drafted to limit such functional elements appearing in claims to the disclosed structures and materials in the patent application for carrying out the stated function. The expanded claim construction limitation provided in the Act moots unpatentability under the “implicit exception,” through exactly the same mechanism. As the new statute does so, it fully supersedes any possibility, much less need, for applying the “implicit exception” as a consideration in examining patent claims—since such claim can never extend to cover the subject matter that the Supreme Court precedents indicates should be beyond protection through a valid patent claim.

2. Replacing non-statutory “double patenting” with enforcement limitations

A second judicial doctrine—non-statutory (obviousness-type) double patenting—is similarly ripe for legislative abrogation. Based on a series of Federal Circuit decisions over the past two decades expanding the reach of this doctrine, it has so grown in significance that is now requires patent examiners to consider an ever increasing number of unpatentability rejections based upon this ground.

The manner in which the Federal Circuit has dictated that “obviousness-type” double patenting applies to invalidate patent claims has resulted in patent examiners rejecting claims as unpatentable in situations where no policy justification for judicial imposing the doctrine exists. Most notably, this includes claimed inventions in two patents that have a prior art relationship to one another, such that the statutory non-obviousness requirement precludes two valid patents from issuing with patentably indistinct claims.

Historically, an “obviousness-type” double patenting rejection could be remedied through the filing of a “terminal disclaimer”—disclaiming both an unjustified patent life attributable to the double patent and separate enforcement of the double patent. Recently, the Federal Circuit has held that no such remedy may apply in certain circumstances, which is again antithetical to any of the underlying policy considerations articulated by the court for enforcing the doctrine.

In a most peculiar expansion of the “double patenting” doctrine, the Federal Circuit held that the first of two patents issuing sequentially can be invalidated for “double patenting.” The court’s holdings in this respect not only complicate the application of the doctrine, but they effectively turn the entire doctrine on its head.

Finally, the Federal Circuit has continued to apply “obviousness-type” double patenting principles to patents subject to the 20-year patent term under the Uruguay Round Agreements Act. While patents issued under the old 17-year patent term merited judicial intervention because the patent statute itself did not limit the aggregate patent term of a series of patents claiming essentially the same invention to a limited period of protection, Congress did affirmatively timewise-limit patent protection to a *finite period* under the URAA, albeit the URAA’s 20-year term from the original nonprovisional patent filing can be extended for additional (but also limited) periods under inventor’s one-year “grace period” after a patent has issued in which a subsequent patent for an indistinct invention might be sought, the patent term adjustment statute in 35 U.S.C. § 154(b), and patent term restoration statute under 35 U.S.C. § 156.⁴

Given the multitude of infirmities with the law as it has developed in the courts, the Act abrogates the non-statutory “double patenting” doctrine as a ground for rejecting patent claims. However, in the case of non-statutory “double patenting,” the abrogation extends only to first-inventor-to-file patent filings. For these patent filings, it replaces the doctrine with a new statutory enforcement limitation that does not require any action on the part of patent examiners during patent examination.

Specifically, for all first-inventor-to-file patent filings, the Act provides a new statutory limitation on patent infringement actions. It bars enforcement of “double patents” through separate lawsuits brought by a separate patent owners whenever—had all the claims of both the patents instead been issued in a single patent jointly owned by the two patent owners—separate enforcement actions would not have been permitted under *res judicata* principles.

The Act further bars patent examiners from requiring disclaimers of patent term for all patent applications for which the 20-year patent term from initial patent filing applies—on the ground that the statutory term and the statutory adjustments and extensions of such term cannot constitute unjustified periods of protection. As a result, for all new original nonprovisional patent filings going forward, no vestige of the judicial “double patenting” doctrine will remain as

⁴ Congress justified the 20-year patent term based on the minimum requirements under the Uruguay Round Agreement under the World Trade Organization. Congress justified the “grace period” on the ground that additional patents protection should be possible after an inventor has published or patented an invention, but only with respect to patents sought during the one-year period after such inventor Spublication or patenting. Congress justified “patent term adjustment” on the ground that it would be unfair to restrict patent life under the 20-year term because the USPTO delayed taking action on the application for patent. Similarly, Congress justified up to a five-year patent term extension in the case commercialization of a product was delayed on account of a government-imposed “regulatory review period.” Given congressional justification for the limited times in which patent protection can be secured for patents subject to the URAA, no policy justification exists for the courts to declare the URAA-based statutory term of protection under a patent is not justified—or produces an unjustified timewise-extension of the right to exclude relative to another patent that has issued.

part of the examination process—further assisting to focus the examination process on just the three D’s.

3. Requiring applicants to make more detailed information disclosures

The third significant change to the pre-grant examination process under the Act places new obligations on patent applicants in making required disclosures of “prior art” patents and printed publications to the USPTO under the duty of candor and good faith, 37 C.F.R. § 1.56. A new statutory provision under the Act mandates that such applicant submissions of information to the USPTO be accompanied by a concise description of their potential relevance to patentability.

In addition, the Act permits that USPTO to collect a new fee on each individual item of prior art submitted for consideration by an applicant during the examination of a patent application. The USPTO would, however, be authorized to make exceptions to these new description and fee requirements. The relevancy-description requirement, coupled with the per-item fees, provides incentives that operate to limit such applicant information disclosure submissions to items of prior art of significant potential relevance.

These reforms operate to induce significant changes the manner in which the patent applicant’s “duty of candor and good faith” must be executed, with the objective of encouraging a higher level of candor and more demonstrable good faith on the part of patent applicants in dealing with patent examiners. In particular, the practice of some patent applicants, *i.e.*, who disclose multiple items of prior art of little or no apparent relevance will be doubly discouraged by the requirement to set forth a concise description of the potential relevance to patentability of each individual item and the per-item fee requirement for submission.

The current practice of “over disclosing” items of prior art with an “under-explanation” of their significance—while often defended as essential to protect patent applicants from allegations of “inequitable conduct” based upon concealing items of prior art or misrepresenting their significance—singularly impairs the effectiveness of patent examination and more mocks than epitomizes any acceptable standard for candor, much less good faith.

In order to make the new requirements on patent applicant information disclosure workable, the Act abrogates the judicially imposed doctrine of unenforceability based on patent prosecution misconduct. The “inequitable conduct” unenforceability doctrine is rife with unintended consequences, including the perverse incentive to disclose large quantities of at best marginally relevant information during patent examination (to avoid allegations of “concealment”) with no explanation or characterization of their possible relevance (to avoid allegations of “misrepresentation”).

The abrogation of the unenforceability doctrine, together with the new patent applicant relevancy-description and fee requirements on submissions of prior art, quashes any motivation for submitting massive prior art disclosures during the examination process, thereby greatly enhancing patent examination focus on the most relevant prior art and the overall efficiency of the patent examination process.

Finally, the Act provides a series of additional changes that enhance the effectiveness of the enhanced duty of candor and good faith imposed on patent applicants:

- The Act further defines the subject matter that will be regarded as having been considered by the Office during examination and limits applicant-submitted prior art that will qualify as having been considered by the USPTO during patent examination to items for which a concise description of relevance is provided. Without providing to the patent examiner such a candid and accurate description of the potential relevance of an item of prior art, a patent may be more amendable to invalidation based upon such prior art since it will be treated as having been given no USPTO consideration in deciding to issue the patent.
- The Act provides that the petition fee for a post-grant review may be delayed or waived entirely when the proceeding is instituted based upon prior art not considered by the USPTO during patent examination.
- As a means of additionally encouraging use of the post-grant review procedure, the Act provides that inter partes review proceeding can invalidate a patent only if the factual predicates for invalidity are established with clear and convincing evidence.
- Similarly, the Act eliminates the judicial estoppel arising from a post-grant review to issues actually raised.

The collective impact of these changes is to complement the enhanced “duty of candor and good faith” by greatly increasing the attractiveness of the post-grant review procedure, particularly to address any prior art reference disclosed by the patent applicant, but lacking in a candid and accurate description of its relevance.

4. Eliminating “continuing” applications—examining all claims initially

The fourth major change to the examination process under the Act eliminates the ability to file all types of “continuing applications,” *i.e.*, continuation, continuation in part, and divisional patent applications. As a consequence, the Act eliminates requirements for restriction or election of claims for examination. This reform will end the piecemeal examination of the claims of all patent applications filed after the enactment of the Act.

With this change to the statute, barring “continuing applications” of all types, patent examination commence on all claims presented for examination and the examination of all pending claims continues in the originally filed patent application until all issues of patentability are resolved for all claims. In this respect, this provision of the Act goes to the heart of the imperative for promptness in a patent examination—an essential element if the examination process is to operate with a high degree of integrity.

The new statute under the Act continues to provide for requests for continued examination. Such requests serve as an alternative to the filing of continuing applications where

the patent applicant believes that the examination process has not been satisfactorily completed, such that an appeal would be unripe.⁵

Instead of restricting the examination of claims of a patent application to the “elected” subject matter, the Act creates a procedure under which the USPTO is given a new statutory authorization to require that *each individual claim* in the *same patent application* be restricted to a *single general inventive concept*. The “general inventive concept” standard is currently used by USPTO examiners in dealing international patent applications subject to the Patent Cooperation Treaty.

Where patent’s various independent claims are directed to separate general inventive concepts, the Act provides that additional claim, issue, and maintenance fees apply to any application or patent with more than three independent claims. The additional fees are respectively equal in amount to an additional application filing fee, patent issue fee, or patent maintenance fee. They are assessed on each independent claim in excess of three.

While the new requirements for *claim restrictions* and *excess fees* will not delay or defer the examination of any claim of any patent application, they will serve to generate fees for the USPTO that reflect the level of examination effort required. Thus, such “excess fees” assure a metric will be available so that patent examiners can receive appropriate credit for examining more complex applications for patent that are not confined to a single general inventive concept—and do so precisely to the same extent that the current examination practice recognizes efforts involved in examining “independent and distinct inventions.”⁶

5. Complementary changes to USPTO post-issuance patent review processes

The Act is premised in part on the belief that changes in the USPTO post-issuance processes used to determine patentability of issued patent claims are—and should remain—essential to a high-integrity patent examination system. In pursuit of this premise, the Act makes several changes in the current statute relating to post-issuance review proceedings to ensure that the preponderant role played by the public will lie in proceedings instituted in the immediate post-issuance period.

⁵ The section of the Act barring all forms of “continuing applications” also simplifies the requirements for an oath or declaration by affording the USPTO discretion by regulation to waive any requirement for a separate inventor declaration. It further eliminates redundant formalities in connection with any declaration that might be required. This allows the Director, for example, to waive the requirement in connection with international applications for patent or applications where the inventor has assigned the application to the person making the application for patent.

⁶ The section of the Act barring all forms of “continuing applications” for patent also assures more complete transparency in the patent examination process by providing for all essentially applications to be published at 18 months following the earliest patent filing for which the patent applicant seeks the benefit. It does so by eliminating the exception to publication that is possible for patent applications that are not the subject of foreign patent filings. Removing this exception will assure that patent examination can be more thorough and accurate in situations where the failure to publish the patent application at 18 months would prevent it from being available as prior art with respect to later-sought patents claiming the same or an obviously different invention from the disclosure in the earlier-filed application.

This focus is essential if errantly issued patent claims are to be addressed in such USPTO proceedings at the earliest possible time after a patent has been granted. The changes, thus, favor the use by the public of earlier-in-time “post-grant review” proceedings over “inter partes review” and “ex parte reexamination” procedures that can be sought later in time during a patent’s 20-year term of protection.

As noted above, the Act promotes making such prompt validity challenges by limiting the judicial estoppel that attaches to post-grant review proceedings, deferring or waiving fees for post-grant reviews initiated on account of prior art not considered during the original examination, and raising the burden of proving invalidity in inter partes review proceedings—brought can only be brought later in the life of the patent—to match the judicial invalidity standard of clear and convincing evidence. In addition to these changes, the Act limits ex parte reexaminations to those ordered by the USPTO, *i.e.*, removing both patentee-requested and third-party-requested reexaminations.

Additionally, the Act resets the time period for patent owners to seek broadened claims in reissued patents to seven years from the filing date of the original application for patent, instead of the current two year period from the issued date of the original patent. The new timing requirement—unlike the existing two-year period from the original issue date of a patent—imposes an absolute deadline during the 20-year term of a patent when the scope of protection is definitively set if the patent has issued and no reissue has yet been sought.

Patent reissuance is otherwise be made more readily available by removing the requirement that the original patent have been issued through an error. It suffices under the Act if the original patent grant contained some defect in the specification or the patent owner had claimed more or less than the law permitted. This change is designed to soften the impact of the categorical bar in the Act to filing continuing applications for patent of all types. Further, this change moots the need for maintaining the option in the patent statute for applicant-requested ex parte reexaminations, which the Act eliminates.

6. Complementary protection scope and other enforcement-related changes.

A final set of statutory changes under the Patent Examination Integrity Act further clarifies the scope of protection available under a patent once issued, as well provides for other enforcement-related changes to the protection that an issued patent provides. The most significant of these changes affords the right to remedies where the alleged infringing acts are not directed to the claimed invention itself but to qualifying equivalents of the claimed invention.

The new statutory protection for equivalents of a claimed invention supersedes the judge-made “doctrine of equivalents.” In addition, it replaces and extends more generally the statutory protection accorded to equivalents under 35 U.S.C. § 112(f).

The reforms in the Act simplifying patent examination underscore the need for better clarifying—through a statutory codification—the “doctrine of equivalents.” Hence, the new statutory equivalents provide an important complement to the elimination of all forms of “continuing” applications for patent. Since the practice of using serially filed continuing

applications to issue additional claims of varying scope is eliminated under the Act, the ability of a patent to cover equivalents, if done through a clear and tightly circumscribed statutory standard, partially offsets potential prejudice to patent owners of the limitation on vehicles for securing further claims based on the same patent specification.

Under the Act's codified doctrine of infringement by equivalents, patent owners have assurance that immaterial differences from a claimed invention could be protected under the patent. The new statute extends patent protection to subject matter that functions in substantially the same way to produce substantially the same result as a claimed invention, provided the equivalent could not have been claimed based on the disclosure in the specification of the patent and the equivalent would not have been merely obvious subject matter that could never have been patented had it been properly disclosed.

The Act further codifies an experimental use exception to patent infringement that assures that patents cannot provide protection for the basic tools of science and technology. In this regard the Act follows closely the 2006 recommendations of the National Academies of Science. This codification provides further assurance that, with the Act's abrogation of the "implicit exception" to subject matter eligibility for patenting, patent rights cannot block access to the basic tools of science and technology when used as the feedstock for making new discoveries promoting progress in useful arts—the *raison d'être* for the patent system.

Lastly, the Act makes changes to the prior commercial use defense to patent infringement. Under the Act, the defense applies in a non-discriminatory manner to all issued patents, recognizes the completion of substantial preparation for commercial use can suffice to trigger the defense, and recognizes that all activities prior to the effective date of the patent filing are to be considered in determining if the prior use rights had been triggered. These changes are essential to bring the U.S. statute closer to international norms as it relates to insulating prior domestic commercial uses of claimed inventions.

Collective impact of the changes driving greater integrity in the patent examination process

The above statutory changes operate to profoundly change the manner in which patent examination proceeds. In the aggregate, these changes remarkably simplify and refocus the examination process:

- Under these changes, the patent examination process begins and ends with a single (nonprovisional) patent filing. In the course of filing such an application, the patent applicant is obliged to identify the most significant prior art and describe its possible relevance. Unlike the current law, under the Act, patent applicants have few incentives to disclose prior art of little or no relevance. Such "over disclosure" of prior art is affirmatively deterred through the new fee and statement of relevancy requirements from doing so. *When the patent examiner initially commences the substantive examination, all the claims presented in the patent application are assessed for patentability.*
- The focus of examination is distilled to the "three D's" – the *key issues of disclosure sufficiency, definiteness in claiming, and differentiating in novel and non-obviousness*

ways over the most pertinent prior art. Other issues that can dominate patent examination under the current patent law—the patent eligibility “implicit exception” and “double patenting” judge-made doctrines—are no longer part of the examination process. In addition, “restriction practice” is gone—patent examiners will no longer make such “restriction requirements” at the start of the examination process that limit the claims being examined and will no longer require that claims withdrawn from examination be sought in separate patents.

- At the end of the substantive examination of the application, any and all claims found patentable issue together in a single patent. Members of the public can seek cancellation of any claim of a newly issued patent on any ground of unpatentability immediately upon patent issuance—under a lower standard of proof of invalidity than is available if such challenge were to be pursued in the courts or a in later inter partes review—and with a limited estoppel to later judicial challenges to the patent extending only to issues actually raised.
- Patent applicants retain the ability to seek changes in the claims of an issued patent, but only through reissue applications or supplemental examination. The USPTO Director retains the ability to order reexamination of an issued patent at any time, based on patentability questions arising from patents and printed publications.

When the above changes to the patenting process are aggregated and their collective impact on the patent system assessed, they form the essential predicate for a strong patent system—one on which the integrity of the examination process is beyond serious question—in which established patent rights receive due deference earned under the process. In summary:

- *Patent applicants are given a more demanding role in the process.* They not only continue to have the obligation to disclose prior art relevant to examination, but have new obligations to explain the relevance of what they disclose and new incentives to deter inundating the USPTO with prior art of little if any materiality to the examination process.
- *Patent examiners have a more focused role in conducting examination.* Armed with more informative patent applicant disclosures, the examination process focuses almost entirely on substance, *i.e.*, a limited set of rigorous, but complete, statutory standards for patentability.
- *The public has a better defined role as a check on examination quality.* After a patent issues, a reinvigorated post-grant review process allows the public a more viable and immediate opportunity to secure cancellation of patent claims that should not have been found patentable. After the period for seeking post-grant review has ended, inter partes review remains available throughout the life of the patent as the sole USPTO forum for public challenges to the novelty and non-obviousness of patent claims based on patents and printed publications—but in a proceeding where the standards for adjudication parallel those in a federal district court addressing like invalidity defenses.

Conclusions

With the above collection of changes substantially remaking and refocusing the process of patent examination, the Act greatly enhances this foundational aspect of the patent system. It provides better assurance to patent owners and the public that a high-integrity examination process will now be focused on granting the highest quality patents. The Act provides more clearly defined exclusionary rights—in the patent statute itself—that apply to an issued patent.

The changes made to the patent law will produce patents that merit greater deference and respect. Such patents will provide a more secure vehicle for spurring investments in the development and commercialization of new technologies. As such, the Act assures that the constitutional purpose of the patent laws to promote progress in useful arts can be far better served compared to the current examination processes.

PROPOSED LEGISLATIVE TEXT

116th CONGRESS
1st SESSION

S. XXXX - H.R. XXXX

IN THE SENATE - HOUSE OF REPRESENTATIVES

_____, introduced the following bill, which was referred to the Committee on the Judiciary.

A BILL

To amend title 35, United States code, to codify and simplify the patent law;
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) This Act shall be referred to as the “Patent Examination Integrity Act of 2019.”

(b) Table of Contents.—The table of contents for this Act is as follows:

- Sec. 1. Short Title; Table of Contents.
- Sec. 2. Patent Eligibility Restoration.
- Sec. 3. Non-Statutory Double Patenting Abrogation.
- Sec. 4. Patent Applicant Prior Art Disclosure Requirements.
- Sec. 5. Patent Examination Simplification.
- Sec. 6. Patent Enforcement Clarification.
- Sec. 7. Technical Clarifications.
- Sec. 8. Effect and Effective Date.

SECTION 2. PATENT ELIGIBILITY RESTORATION.

(a) SENSE OF CONGRESS—The non-statutory, implicit exception to patent eligibility, as presently imposed by the courts, has failed to provide the degree of predictability and certainty in determinations of patent validity essential to the proper functioning of the patent laws. This uncertainty frustrates the patent system’s constitutional purpose of promoting progress in useful arts and, therefore, necessitates remedial action by Congress. With the codification in this Act of new limitations on the interpretation of patent claims—so as to exclude from patent protection any law or product of nature, any natural or physical phenomenon, or any abstract idea or other concept—Congress finds it to be unnecessary to, and inconsistent with, fulfilling the constitutional purpose of the patent laws to continue the judicial imposition of a non-statutory, implicit exception relating to the subject matter for which patents may be validly granted under the statutory provisions of title 35, United States Code.

(b) LIMITATIONS ON CLAIM CONSTRUCTION.—Strike section 112(f) of title 35, United States Code, and insert:

“(f) CLAIM CONSTRUCTION.—

“(1) NATURAL PRODUCTS AND PROCESSES AND OTHER PHENOMENA OF NATURE.—A claim that would otherwise cover subject matter that exists in nature independently of and prior to any human activity, irrespective of whether or not such subject matter was known to so exist prior to the effective filing date of the claimed invention, shall instead be construed to exclude coverage for all such naturally occurring subject matter.

“(2) MENTAL OR FUNCTIONAL STEPS.—A step in a claim to a process, which step could be construed to cover the performance of the step solely in the human mind, or recites a function without also reciting acts for carrying out the function and would otherwise cover every means for achieving the function, shall instead be construed to exclude coverage for performing the step mentally and to be limited to the corresponding acts described in the specification for carrying out the step.

“(3) FUNCTIONAL ELEMENTS IN COMBINATION CLAIMS.—An element in a claim to a combination of elements, other than in a claim to a process, which element recites a function without reciting the structures or materials for achieving the function and would otherwise cover every means for achieving the function, shall instead be construed to cover only the corresponding structures or materials described in the specification.

“(4) PREEMPTIVE CLAIMS.—A claim that, notwithstanding the limitations under paragraphs (1) through (3), would nonetheless be construed to cover every useful application of a natural law or phenomenon or other abstract idea or concept shall instead be construed to cover only the specific means for implementing the idea or concept that are described in the specification and that otherwise meet each of the limitations in the claim.”

(c) CLARIFICATION OF THE RIGHT TO PATENT.—

(1) PREAMBLE CLARIFICATION.—In section 102(a), strike “A person shall be entitled to a patent unless” and insert “A patent for a claimed invention may not be obtained if”.

(2) RIGHT TO PATENT—In section 101 of title 35, United States Code, strike and insert:
“§ 101. Right to patent eligible inventions.

“Whoever invents a useful process, machine, manufacture, or composition of matter, or a useful improvement thereto, shall be entitled to a patent on such invention absent a finding that one or more conditions or requirements under this title have not been met.”

(3) CONFORMING AMENDMENT.—The item relating to section 101 in the table of sections for chapter 10 of title 35, United States Code, is amended to read as follows:

“§ 101. Right to patent eligible inventions.”

SECTION 3. NON-STATUTORY DOUBLE PATENTING ABROGATION.

(a) LIMITATION ON ANY NON-STATUTORY DOUBLE PATENTING BAR.—A claimed invention of a patent may not be held invalid with respect to a claimed invention of another patent based on any nonstatutory double patenting ground if one of the claimed inventions is prior art to the other claimed invention under section 102 of title 35, United States Code, or the claimed invention of the patent is subject to section 102 of title 35 as amended by the Leahy-Smith America Invents Act (Public Law 112–29; 125 Stat. 284).

(b) REMEDY FOR INFRINGEMENT; CIVIL ACTION LIMITATION.—Section 281 of title 35, United States Code, is amended by striking and inserting:

“§ 281. Remedy for infringement of patent.

“(a) IN GENERAL—The patentee shall have a remedy by civil action for infringement of the patentee’s patent.

“(b) ENFORCEMENT-LINKED PATENTS; INDISPENSABLE PARTY.—

“(1) IN GENERAL.—Notwithstanding subsection (a), a civil action for infringement that has been brought with respect to an enforcement-linked patent may be maintained only if the action would not have been barred by res judicata had each of the claims of the patent and the patent to which it is enforcement-linked issued jointly to the respective patentees of the two patents in a single patent.

“(2) INDISPENSABLE PARTY.—A patentee who would be barred by res judicata under the preceding paragraph, as a consequence of a civil action brought to enforce an enforcement-linked patent, shall be an indispensable party to such civil action.

“(3) ENFORCEMENT-LINKED PATENTS DEFINED.—For the purposes of this subsection, the term “enforcement-linked patent” shall mean either of the two patents in which—

“(A) for at least one pair of claimed inventions, one selected from each of the two patents, neither claimed invention constitutes prior art under section 102(a)(2) to the other; and

“(B) for at least one pair of claimed inventions under subparagraph (A), where neither is prior art to the other, one of the claimed inventions would have been obvious under section 103 in view of the other, had the other constituted prior art to it under section 102(a)(2).

(c) PATENT TERM JUSTIFICATION AND RESTORATION.—If the term of a patent is based upon the amendments made to subsection (a) of section 154 by the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4809)—

(1) the patent term as provided under subsection (a) of such section 154, United States Code, any adjustment to said term as provided under subsection (b) of such section 154, and any extension of such term as provided under section 156 of title 35, United States Code, shall not constitute, nor be deemed by the United States Patent and Trademark Office or the courts to constitute, an unjustified period of protection under the patent, or an unjustified extension of the right to exclude under the patent, relative to any earlier-expiring patent;

(2) the Office may not condition the issuance of any such patent on a disclaimer of the terminal part of the patent term otherwise permitted under sections 154 and 156, United States Code; and

(3) any disclaimer of the terminal part of the term of such a patent under section 253(b) of title 35, United States Code, pursuant to section 1.321 of title 37, Code of Federal Regulations, with respect to one or more other applications or patents, shall have no effect on the term of the patent and shall be treated as never having had effect on the term of the patent except to the extent that the patent would otherwise have expired less than one year after the date of enactment of this section.

SECTION 4. PATENT APPLICANT PRIOR ART DISCLOSURE REQUIREMENTS.

(a) MISCONDUCT-BASED DEFENSES.—Section 284 of title 35, United States Code, is amended by inserting at the end:

“(d) MISCONDUCT-BASED DEFENSE BARRED.—A claim in a patent may not be held unenforceable in a civil action based upon misconduct before the Office unless the claim is found to be invalid.”

(b) INFORMATION DISCLOSURE IN PATENT APPLICATIONS.—In chapter 12 of title 35, United States Code, insert at the end:

“§ 136. Disclosure of patents and printed publications during examination.

“(a) IN GENERAL.—A patent or printed publication that may or does constitute prior art material to patentability of a claim in an application being examined, or otherwise is of potential

or actual relevance to the patentability of a claim, may be submitted by the applicant to the Office for consideration during the examination of the application only if the applicant—

“(1) provides with the submission of such item a concise description of its potential relevance to the patentability of the claims being examined;

“(2) pays the fee established by the Director for submission of such item; and

“(3) meets such other requirements as to timing and form for the submission of the item as the Director may establish by regulation.

“(b) EXCEPTIONS.—The requirements under paragraphs (1) and (2) of subsection (a) shall not apply to any patent or printed publication—

“(1) for which the specification of the application contains a concise description of its potential or actual relevance to the patentability of the claims of the specification or

“(2) that is exempted from one or both of such requirements under regulations established by the Director.

“(c) CONSIDERATION BY THE OFFICE.—A patent or printed publication shall not be considered, or be regarded as having been considered, by the Office unless it—

“(1) meets the requirements under subsection (a),

“(2) falls within the exception under subsection (b),

“(3) is listed in an action reporting on the prior art prepared by the Office during the examination of the application or a like report prepared in connection with a related foreign or international application that has been made available during examination in a timely manner, or

“(4) is identified in a submission in connection with the application in compliance with section 122(e).”

(c) POST-ISSUANCE REVIEW PROCEEDINGS.—

(1) DEFERRAL AND POSSIBLE WAIVER OF POST-GRANT REVIEW FEE.—In section 321 of title 35, United States Code, insert at the end:

“(d) FEE DEFERRAL AND WAIVER.—If a petition seeks the institution of a post-grant review based in whole or in part on a patent or printed publication not considered by the Office during the examination of a patent under section 136(c), payment of the fee under section 322(a)(1) otherwise required to accompany the petition shall be deferred and become due only if the proceeding is instituted under section 324. If the Director determines under section 324(a) that that it is more likely than not that at least 1 of the claims challenged in a petition for post-grant review is unpatentable based in whole or in part upon a patent or printed publication that was not considered during the examination of the patent, and is not merely cumulative with respect to prior art considered during such examination, the fee otherwise required under section 322(a)(1) shall be waived. If a fee deferred under this subsection becomes due, the post-grant review shall not commence under section 324(d) unless such fee is paid by the petitioner within such time period as the Director establish by regulation for making such payment.

(2) ESTOPPEL IN POST-GRANT REVIEW.—In section 325(e)(2) of title 35, United States Code, strike “or reasonably could have raised”.

(3) STANDARD OF PROOF IN INTER PARTES REVIEW.—In section 316(e) of title 35, United States Code, strike “a preponderance of the” and insert “clear and convincing”.

(d) CONFORMING AMENDMENTS.—

(1) SUPPLEMENTAL EXAMINATION.—Strike subsection (c) of section 257 of title 35, United States Code.

(2) TABLE OF SECTIONS.—In the table of sections for chapter 12 of title 35, United States Code, insert at the end:

“§ 136. Disclosure of patents and printed publications during examination.”

SECTION 5. PATENT EXAMINATION SIMPLIFICATION.

(a) PATENT APPLICATIONS AND EXAMINATION.—

(1) RESTRICTION OF INDEPENDENT CLAIM SCOPE IN LIEU OF FILING DIVISIONAL APPLICATIONS.—Section 121 of title 35, United States Code, is amended by striking and inserting:

“§ 121. Restriction of claims.

“In an application that is otherwise in condition to be allowed under section 151, the examiner may require that each claimed invention in the application be restricted to a single general inventive concept. Before an application is allowable, the examiner may provisionally object to any claim in an application by identifying multiple general inventive concepts alleged to be encompassed by the claim. The applicant may request a review of any action under this section by petition to the Director identifying what the applicant regards as the single general inventive concept present in the applicable claims. The validity of a patent shall not be questioned for failure of any claim to be restricted to a single general inventive concept.”

(2) CONTINUED EXAMINATION AUTHORIZED IN LIEU OF FILING CONTINUATION APPLICATIONS.—Section 120 of title 35, United States Code, is amended by striking and inserting:

“§ 120. Continued examination.

“If an applicant requests continued examination of an application, accompanied by the required fee, the Director shall recommence the examination of such application under section 131. The continued examination shall be based on the specification as amended, and the examination record otherwise before the Office, at the time the request was made.”

(3) FEES.—In chapter 4 of title 35, United States Code, insert at the end:

“§ 43. Additional fees for excess claims in independent form.

“Upon filing or on presentation at any other time of each claim in independent form in excess of 3, in addition to the fee specified in section 41(a)(2), the applicant shall incur an additional excess claims fee under this section in the amount of the fee as specified in section 41(a)(1) for the original filing of the application for each such claim 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 such 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 such claim in the patent in independent form in excess of 3.”

(4) OATH OR DECLARATION.—In section 115(a) of title 35, United States Code, strike “shall execute” and insert “may be required by the Director to execute”.

(5) CONFORMING AMENDMENTS.—

(A) Section 100(i) of title 35, United States Code, is amended by striking the text after “365(b).”

(B) Section 102(d) of title 35, United States Code, is amended by striking “or to claim the benefit of an earlier filing date under section 120, 121, or 365(c).”

(C) Section 111(b)(7) of title 35, United States Code, is amended by striking this paragraph and inserting:

“(7) TREATMENT OF INTERNATIONAL AND NONPROVISIONAL APPLICATIONS FOR PRIORITY PURPOSES.—For the purpose of asserting a right of priority or securing the benefit of an earlier filing date under section 119(e), a nonprovisional application filed under subsection (a), or an international designating the United States, shall be deemed a provisional application under this subsection (b). If any claim for the priority is based on a prior international application which designated but did not originate in the United States, the Director may require the filing in the Patent and Trademark Office of a certified copy of such application together with a translation thereof into the English language, if it was filed in another language.

(D) Section 115 of title 35, United States Code, is amended by striking and reserving subsections (c) and (g) and by striking subsection (i).

(E) Section 132(b) of title 35, United States Code, is amended by striking subsection (b) and removing the subsection designation from subsection (a).

(F) Section 154(a)(2) of title 35, United States Code, is amended by striking the text after “United States”.

(G) Section 184(b) of title 35, United States Code, is amended by striking “, or division thereof”.

(H) Section 365 of title 35, United States Code, is amended by striking the subsection (c).

(I) Section 366 of title 35, United States Code, is amended by striking “, unless a claim for benefit of a prior filing date under section 365(c) of this section was made in a national application, or an international application designating the United States, filed before the date of such withdrawal”.

(J) The item relating to sections 120 and 121 in the table of sections for chapter 11 of title 35, United States Code, is amended to read as follows:

“§ 120. Continued examination.

“§ 121. Restriction of claims.

(K) In the table of sections for chapter 4 of title 35, United States Code, insert at the end:

“§ 43. Additional fees for excess claims in independent form.

(b) PUBLIC ACCESS.—In section 122(b)(1) of title 35, United States Code, strike subparagraph (B), strike the designation for subparagraph (A), and replace the designation of items (i)-(iv) of as subparagraphs (A)-(D), respectively.

(c) REEXAMINATION AND REISSUE.—

(1) REISSUE.—In section 251 of title 35, United States Code—

(A) In subsection (a), strike “, through error,”.

(B) In subsection (e), strike “two years from the grant of the original patent” and insert “seven years after the original nonprovisional filing date of the application for patent”

(2) REEXAMINATION.—In title 35, United States Code—

(A) In sections 302-303, strike and insert:

“§ 302. Reexamination

“To the extent authorized under sections 303 and 304, the Director may order reexamination by the Office of any claim of a patent on the basis of any prior art patents and publications discovered by the Director or cited under the provisions of section 301.”

“§ 303. Determination of issue by Director

“(a) The Director may determine a substantial new question of patentability is raised by patents and publications discovered by the Director or cited under the provisions of section 301. The existence of a substantial new question of patentability is not precluded by the fact that a

patent or printed publication was previously cited by or to the Office or considered by the Office.”

“(b) A record of the Director’s determination under subsection (a) of this section will be placed in the official file of the patent, and a copy promptly will be given or mailed to the owner of record of the patent.”

(B) In section 304, strike after the first sentence.

(D) In section 305, strike “After the times for filing the statement and reply provided for by section 304 have expired, reexamination” and insert “Reexamination”.

(E) In section 257(b), strike “except that the patent owner shall not have the right to file a statement pursuant to section 304”.

(3) In the table of sections for chapter 30 of title 35, United States Code, strike the entry for section 302 and insert:

“§ 302. Reexamination.

SECTION 6. PATENT ENFORCEMENT CLARIFICATION.

(a) CERTAIN EQUIVALENTS OF CLAIMED INVENTIONS PROTECTED.—Section 271 of title 35, United States Code, is amended by striking subsection (a) and inserting:

“(a) DIRECT INFRINGEMENT.—

“(1) IN GENERAL—Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any claimed invention or an equivalent thereof within the United States, or imports into the United States any claimed invention or an equivalent thereof, during the term of the patent therefor, infringes the patent.

“(2) EQUIVALENTS OF CLAIMED INVENTIONS.—Subject matter accused of infringing a patent represents an equivalent of a claimed invention if the patentee establishes that such subject matter—

“(A) differs at most immaterially from the each element of at least one specific embodiment disclosed in the specification that satisfies each of the limitations of the claim;

“(B) was not disclosed in the specification in a manner that would have permitted at least one claim meeting the requirements under section 112 to have covered the subject matter;

“(C) had such subject matter been specifically disclosed in the specification and been covered by one or more claims meeting the requirements under section 112, at least one such claim would not be invalid under section 103, irrespective of whether the element or elements of such subject matter that differ immaterially from the claimed invention were novel.

“(3) IMMATERIAL DIFFERENCES.—A difference between the subject matter accused of infringement and an element in a claim of a patent shall be regarded as immaterial only if a corresponding element can be identified in the subject matter accused of infringement that functions in substantially the same way to produce substantially the same result as the element of the claim. No finding of immateriality may be made under the preceding sentence if the specification of the patent describes essential limitations on the claimed invention that would be inconsistent such a finding. The immateriality of the difference shall not be negated by the foreseeability of the subject matter accused of infringement or any element thereof.”

(b) CERTAIN EXPERIMENTAL USES NOT PROTECTED BY PATENTS.—Section 271 of title 35, United States Code, is amended by inserting at the end:

“(j) EXPERIMENTAL USES OF CLAIMED INVENTIONS.—Notwithstanding subsections (a) and (g), it shall not be an act of infringement to make or use a claimed invention for experimental purposes to discern or discover—

“(1) the validity or scope of protection of a patent for the claimed invention;
“(2) any feature, property, characteristic, advantage, or dis-advantage of the claimed invention;

“(3) any method of making or using the claimed invention;

“(4) any alternative to, improvement to, or substitute for the claimed invention.”

(c) PRIOR COMMERCIAL USE DEFENSE CLARIFICATION.—

(1) In section 273 of title 35, United States Code, strike subsection (a) and insert:

“(a) IN GENERAL.—An alleged infringer shall be entitled to a defense under section 282(b) with respect to subject matter that would otherwise infringe a claimed invention if such person, acting in good faith before the effective filing date of the claimed invention, commercially used the subject matter in the United States or completed substantial preparations for such use, either in connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use.”

(2) In section 273(e) of title 35, insert at the end:

“(6) DILIGENCE REQUIRED.—Substantial preparations for commercial use of subject matter of a claimed invention shall be deemed to have been completed under subsection (a) only if prior to the effective filing date of the claimed invention —

“(A) diligent efforts had commenced and thereafter continued in the United States until the commercial use of such subject matter was accomplished and

“(B) the activities relied upon to demonstrate completion of substantial preparations were carried out in the United States and constituted the preponderance of the investments required to accomplish the commercial use of such subject matter.”

(d) CONFORMING AMENDMENTS.—In section 271 of title 35, United States Code—

(1) In subsection (b), after “(b)” insert “INDUCED INFRINGEMENT.—”.

(2) In subsection (c), after “(c)” insert “CONTRIBUTORY INFRINGEMENT.—”.

(3) In subsection (d), after “(d)” insert “LIMITATION ON INFRINGEMENT FINDING.—”.

(4) In subsection (e), after “(e)” insert “ADDITIONAL ACTS OF INFRINGEMENT.—”.

(5) In subsection (f), after “(f)” insert “COMPONENTS OF CLAIMED INVENTIONS.—”.

(6) In subsection (g), after “(g)” insert “PROCESS PATENTS.—”.

(7) In subsection (h), after “(h)” insert “STATE-RELATED ACTIONS.—”.

(8) In subsection (i), after “(i)” insert “OFFERS FOR SALE.—”.

SECTION 7. TECHNICAL CLARIFICATIONS.

(a) JOINT INVENTORS CLARIFICATION.—In sections 112(a) and 291(b) of title 35, United States Code, strike “or joint inventor” and insert “or a joint inventor”.

(b) DOMESTIC PRIORITY CLARIFICATION.—In section 119(e)(1) of title 35, United States Code, strike “by an inventor or inventors named” and inserting “naming the inventor or a joint inventor”.

(c) APPLICATION DISCLOSURE CLARIFICATION.—In section 112(a) of title 35, United States Code, strike all that follows after “same”; in section 282 of United States Code, strike “, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable”; and in section 119(e)(1) of United States Code, strike “(other than the requirement to disclose the best mode)”.

SECTION 8. EFFECT AND EFFECTIVE DATE.

(a) **EFFECTIVE DATE.**—This Act shall have effect upon enactment except as otherwise provided under this section.

(b) **EXCEPTION FOR FIRST-TO-INVENT PATENTS.**—The amendments made by Section 3(b) of the Act shall not apply to a patent unless it is subject to section 102 of title 35, United States Code, as amended by the Leahy-Smith America Invents Act (Public Law 112–29; 125 Stat. 284).

(c) **EXCEPTION FOR PATENTS ISSUED BEFORE ENACTMENT.**—Sections 2, 3, 4(a), and 6 of the Act, and the amendments made therein, shall not have effect with respect to a patent issued before the date of enactment if the patentee provides written notification to the Director within three months from the date of enactment that these sections and the amendments made therein shall not apply to the patent. Within 10 days from the date of enactment, the Director may publish a notice setting out any requirements as to form and content that shall apply to a patentee giving notice under this subsection.

(d) **EXCEPTION FOR EXTANT CIVIL ACTIONS.**— Sections 2, 3, 4(a), and 6 of the Act, and the amendments made therein, shall not have effect with respect to any civil action brought to enforce a patent before the date of enactment.

(e) **EXCEPTION FOR PATENT APPLICATIONS FILED BEFORE ENACTMENT.**—The amendments made by Section 4(b) and Sections 5(a) and 5(b) of the Act shall not apply to any application for patent filed before the date of enactment.

(f) **EXCEPTION FOR POST-ISSUANCE REVIEW PROCEEDINGS INSTITUTED BEFORE ENACTMENT.**—The amendments made by Section 4(c) and Section 5(c) of the Act shall not apply to any proceeding under chapters 30, 31, or 32 or section 251 of title 35, United States Code, instituted before the date of enactment.

SECTION-BY-SECTION ANALYSIS

Section 2. Patent Eligibility Restoration.

SUBSECTION A: SENSE OF CONGRESS.

The non-statutory, implicit exception to patent eligibility, as presently imposed by the courts, has failed to provide the degree of predictability and certainty in determinations of patent validity essential to the proper functioning of the patent laws. This uncertainty frustrates the patent system's constitutional purpose of promoting progress in useful arts and, therefore, necessitates remedial action by Congress. With the codification in this Act of new limitations on the interpretation of patent claims—so as to exclude from patent protection any law or product of nature, any natural or physical phenomenon, or any abstract idea or other concept—Congress finds it to be unnecessary to, and inconsistent with, fulfilling the constitutional purpose of the patent laws to continue the judicial imposition of a non-statutory, implicit exception relating to the subject matter for which patents may be validly granted under the statutory provisions of title 35, United States Code.

Subsection (a) sets out the sense of Congress that the Supreme Court's jurisprudence on the issue of subject matter eligibility for patenting has not achieved the acceptable level of predictability in its application that is necessary for the proper functioning of the patent laws. Moreover, as expressed in Subsection (a), continuing the judicial imposition of the implicit exception is unnecessary to and inconsistent with fulfilling the constitutional purpose of the patent system to promote progress in useful arts. Most particularly, the vagueness, if not arbitrariness, of this judicial standard, renders this jurisprudence unworkable to an extent that now requires legislative intervention.

Under Subsection (b), Congress has placed into the statute a codified limitation on the rights available under a patent that categorically precludes patents subject to it from protecting a law/product of nature, natural/physical phenomenon, or other abstract idea or concept. This new statutory limitation supersedes any policy or other rationale for the continued application of the judicially imposed "implicit exception" to the statutory categories of subject matter eligibility for patenting. Hence, Subsections (a) and (b), taken together, constitute a legislative abrogation of any "implicit exception" to subject matter eligibility for patenting, thereby rendering the issue of subject matter eligibility one that is addressed in its entirety through explicit limitations on eligibility contained in § 101 of the patent statute for any patent to which Subsection (b) is applicable.⁷

⁷ The amendment to the patent statute under Subsection (b), if nothing else, has mooted the "implicit exception" jurisprudence through claim construction limitations since the issue addressed in the jurisprudence will no longer arise for any claim properly construed under Subsection (b).

SUBSECTION B: LIMITATIONS ON CLAIM CONSTRUCTION.

Strike section 112(f) of title 35, United States Code, and insert:

“(f) CLAIM CONSTRUCTION.—

“(1) NATURAL PRODUCTS AND PROCESSES AND OTHER PHENOMENA OF NATURE.—A claim that would otherwise cover subject matter that exists in nature independently of and prior to any human activity, irrespective of whether or not such subject matter was known to so exist prior to the effective filing date of the claimed invention, shall instead be construed to exclude coverage for all such naturally occurring subject matter.

“(2) MENTAL OR FUNCTIONAL STEPS.—A step in a claim to a process, which step could be construed to cover the performance of the step solely in the human mind, or recites a function without also reciting acts for carrying out the function and would otherwise cover every means for achieving the function, shall instead be construed to exclude coverage for performing the step mentally and to be limited to the corresponding acts described in the specification for carrying out the step.

“(3) FUNCTIONAL ELEMENTS IN COMBINATION CLAIMS.—An element in a claim to a combination of elements, other than in a claim to a process, which element recites a function without reciting the structures or materials for achieving the function and would otherwise cover every means for achieving the function, shall instead be construed to cover only the corresponding structures or materials described in the specification.

“(4) PREEMPTIVE CLAIMS.—A claim that, notwithstanding the limitations under paragraphs (1) through (3), would nonetheless be construed to cover every useful application of a natural law or phenomenon or other abstract idea or concept shall instead be construed to cover only the specific means for implementing the idea or concept that are described in the specification and that otherwise meet each of the limitations in the claim.”

Subsection (b) contains an amendment to title 35, United States Code, that assures no claim of an issued patent can be interpreted in a manner that would preempt access to (or otherwise provide exclusivity over) a law or product of nature, a natural or physical phenomenon, or an abstract idea or other abstract concept. The amendment replaces existing 35 U.S.C. § 112(f)⁸ with an entirely new subsection that expands upon and clarifies the application of the repealed subsection in the patent statute.

⁸ Under the 1952 Patent Act, 35 U.S.C. § 112(f) limited the interpretation of combination claims in patents containing elements setting forth only a means for carrying out a function to the structures, materials, or acts set out in the patent’s specification (and their equivalents) for performing that function.

New § 112(f) sets out a set of four limitations on the interpretation of claims in four separate paragraphs.⁹ Under paragraph (1), for a claim that could otherwise be construed to cover a law or product of nature or a natural or physical phenomenon (*i.e.*, any claimed subject matter that exists in nature independently of and prior to any human activity, irrespective of whether or not such subject matter was known to so exist), the claim must be interpreted to categorically exclude the subject matter existing in nature from patent protection.

Under paragraph (2), for a process claim containing a step that is drafted in an abstract or conceptual manner (*i.e.*, such that the step could be construed to cover the performance of the step solely in the human mind or the step otherwise recites a function without also reciting acts for carrying out the function and would otherwise cover every means for achieving the function), the step must be interpreted to include only the corresponding acts described in the patent's specification for carrying out the step.

Under paragraph (3), for a combination claim, other than a process claim, setting forth multiple discrete elements in which any element is drafted in an abstract or conceptual manner (*i.e.*, such that the claim element recites a function without also reciting the structures or materials for achieving the function and would otherwise cover every means for achieving the function), such element in the claim must be interpreted to include only the corresponding structures or materials described in the patent's specification.

Finally, under paragraph (4), a catch-all provision precludes other drafting techniques that could produce preemptive claims. It does so by limiting the interpretation such claims. If a claim would be interpreted to cover every useful application of a natural law or phenomenon or other abstract idea or concept, § 112(f) requires that the claim must instead be construed to cover only the specific means for implementing the idea or concept that are described in the specification and that otherwise meet each of the limitations set out in the claim.

As enacted under the 1952 Patent Act, § 112(f) was intended to allow claims that otherwise would have been invalid for lack of a sufficient description¹⁰ to be found valid by limiting the manner in which such claims could be interpreted. New § 112(f) builds on the original remedial purpose of subsection (f) by providing that claims that would otherwise have been found judicially invalid under on subject matter eligibility grounds¹¹ may be found valid given that such claims could no longer be interpreted as directed to subject matter held implicitly ineligible for patenting under 35 U.S.C. § 101 under the judicially imposed implicit exception.

⁹ These new limitations incorporated into 35 U.S.C. § 112(f) are broadly consistent with proposals adopted by the Intellectual Property Law Section of the American Bar Association, the American Intellectual Property Law Association, and the Intellectual Property Owners Association. These associations have collectively urged that patent protection should be unavailable for (1) preemptive claims, (2) claims that could be carried out solely in the human mind, and (3) claims that directed to subject matter existing in nature independently of and prior to any human activity.

¹⁰ See *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946).

¹¹ Invalidity has been found under a judicially imposed "implicit exception" in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), *Mayo Collaborative v. Prometheus Labs.*, 132 S. Ct. 1289 (2012), *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347 (2014).

In sum, in the same manner that claims interpreted so as to be subject to original § 112(f) could not be invalidated for insufficient disclosure,¹² amended § 112(f) now moots the implicit exception the courts have imposed to invalidate claims on the ground such claims encompassed subject matter implicitly ineligible for patenting under § 101. Such subject matter is now statutorily beyond the scope of protection under any patent claim, once properly construed under amended § 112(f).

SUBSECTION C: CLARIFICATION OF THE RIGHT TO PATENT.

(1) PREAMBLE CLARIFICATION.—In section 102(a), strike “A person shall be entitled to a patent unless” and insert “A patent for a claimed invention may not be obtained if”.

(2) RIGHT TO PATENT—In section 101 of title 35, United States Code, strike and insert:

“§ 101. Right to patent eligible inventions.

“Whoever invents a useful process, machine, manufacture, or composition of matter, or a useful improvement thereto, shall be entitled to a patent on such invention absent a finding that one or more conditions or requirements under this title have not been met.”

(3) CONFORMING AMENDMENT.—The item relating to section 101 in the table of sections for chapter 10 of title 35, United States Code, is amended to read as follows:

“§ 101. Right to patent eligible inventions.”

Subsection (c) clarifies provisions of the America Invents Act relating to the right to patent. The three paragraphs of Subsection (C) provide a technical correction to 35 U.S.C. § 102(a)’s preamble under the American Invents Act, (2) replace 35 U.S.C. § 101 with a new provision clarifying the inventor’s right to a patent, and (3) make a conforming amendment.

Paragraph (2) of Subsection (c) incorporates into § 101 an unambiguous statutory “right to patent” that, before the America Invents Act, was present in 35 U.S.C. § 102’s preamble,¹³ as enacted under the 1952 Patent Act. Under the 1952 Patent Act, § 102 provided that an inventor

¹² Federal Circuit precedents relating to the implementation of § 112(f) appear to have failed at least in part to implement this subsection in a manner consistent with its remedial purpose of addressing claims that would be invalid under the *Haliburton* decision. One aspect of this failure to fully implement the original § 112(f) fully consistent with its remedial purpose arises from the court’s continuing insistence on employing dueling “presumptions” to determine whether a claim element is subject to the § 112(f) limitation. Under Federal Circuit precedents, the § 112(f) limitation on claim scope presumptively applies or presumptively does not apply depending on whether or not the words “means for” or “step for” appear explicitly in a claim element. *Williamson v. Citrix Online, LLC*, 792 F. 3d 1339 (Fed. Cir. 2015). In effect, these precedents exalt the form in which a claim is drafted (*e.g.*, with or without the words “means for” or “step for”) rather than the substance (*e.g.*, whether or not the claim was actually limited to disclosed structures, materials, or acts). New § 112(f) has been drafted to eliminate any presumptive effect depending on the actual words used in the claim and requires instead that the claim be construed as a matter of law, *e.g.*, see *Phillips v. AWH Corp.*, 415 F. 3d 1303 (Fed. Cir. 2005).

¹³ Under § 102(f) enacted under the 1952 Patent Act, “A person shall be entitled to a patent unless ... he did not himself invent the subject matter sought to be patented”

has a right to a patent absent some finding that one or more of the conditions and requirements for patentability has not been met. This is best illustrated in the text of § 102(f) of the 1952 Patent Act that obligated the United States Patent and Trademark Office to allow a patent to be granted to an inventor on an inventor's claimed invention.¹⁴

Since the enactment of the America Invents Act in 2011, there has been no cogent provision in the patent statute providing the inventor the same categorical right to patent formerly appearing in the pre-AIA § 102(f).¹⁵ The above text of § 101 remedies this drafting deficiency in the America Invents Act. In addition, it is a confirmation that the conditions and requirements for patentability are all statutory and a claimed invention cannot be held invalid on a non-statutory, judicially imposed ground.

Section 3. Non-Statutory Double Patenting Abrogation.

SUBSECTION A: LIMITATION ON ANY NON-STATUTORY DOUBLE PATENTING BAR.

A claimed invention of a patent may not be held invalid with respect to a claimed invention of another patent based on any nonstatutory double patenting ground if one of the claimed inventions is prior art to the other claimed invention under section 102 of title 35, United States Code, or the claimed invention of the patent is subject to section 102 of title 35 as amended by the Leahy-Smith America Invents Act (Public Law 112–29; 125 Stat. 284).

Subsection (a) prevents any non-statutory double patenting ground for invalidity from being applied in two situations. First, no non-statutory double patenting invalidity can apply to a claimed invention in one patent based on a claimed invention in any other patent if either claimed invention is prior art to the other. The rationale for this limitation is that both claimed inventions can be validly patented only if the prior art invention does not render the other invention obvious under the existing statutory requirement for non-obviousness under 35 U.S.C. § 103. In the situation where statutory non-obviousness bars the issuance of two valid patents, there is no conceivable policy justification for nonetheless declaring either claimed invention to be double patenting.¹⁶

¹⁴ *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) and *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992), “If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.”

¹⁵ Specifically, in rewriting § 102 as an entirely new provision of title 35, the AIA left the opening clause of subsection (a) of this section unchanged from the text of § 102 as enacted under the 1952 Patent Act. However, under the AIA, each of the loss of right to patent provisions were removed from § 102, including § 102(f). As a result, the current opening clause of § 102(a) has no readily apparent purpose and affords no predicate—including appropriate antecedents—for the substantive text that follows.

¹⁶ This provision would expressly overrule the recent expansion by the Court of Appeals for the Federal Circuit of non-statutory double patenting as reflected in *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013), which followed earlier holdings if the same ilk in *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) and *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly and Co.*, 611 F.3d 1381 (Fed. Cir. 2010). In such cases, the court had held that double patenting was possible even though the statutory non-obviousness requirement under

The second exclusion prevents non-statutory double patenting from applying to any first-inventor-to-file patent.¹⁷ The amendments made under subsection (b) to 35 U.S.C. § 281 obviate any conceivable policy rationale for the courts to impose a non-statutory double patenting bar by imposing limitations on the enforcement of first-inventor-to-file patents that remove the potentially for harassment from infringement actions brought by multiple patentees seeking to enforce claims on patentably indistinct inventions.

SUBSECTION B: REMEDY FOR INFRINGEMENT; CIVIL ACTION LIMITATION.

Section 281 of title 35, United States Code, is amended by striking and inserting:

“§ 281. Remedy for infringement of patent.

“(a) IN GENERAL—The patentee shall have a remedy by civil action for infringement of the patentee’s patent.

“(b) ENFORCEMENT-LINKED PATENTS; INDISPENSABLE PARTY.—

“(1) IN GENERAL.—Notwithstanding subsection (a), a civil action for infringement that has been brought with respect to an enforcement-linked patent may be maintained only if the action would not have been barred by res judicata had each of the claims of the patent and the patent to which it is enforcement-linked issued jointly to the respective patentees of the two patents in a single patent.

“(2) INDISPENSABLE PARTY.—A patentee who would be barred by res judicata under the preceding paragraph, as a consequence of a civil action brought to enforce an enforcement-linked patent, shall be an indispensable party to such civil action.

“(3) ENFORCEMENT-LINKED PATENTS DEFINED.—For the purposes of this subsection, the term “enforcement-linked patent” shall mean either of the two patents in which—

“(A) for at least one pair of claimed inventions, one selected from each of the two patents, neither claimed invention constitutes prior art under section 102(a)(2) to the other; and

“(B) for at least one pair of claimed inventions under subparagraph (A), where neither is prior art to the other, one of the claimed inventions would have been obvious under section 103 in view of the other, had the other constituted prior art to it under section 102(a)(2).”

35 U.S.C. § 103 would have assured that two valid patents could not have issued unless the claims of the respective patents had been patentably distinct.

¹⁷ “First-inventor-to-file patents” is a reference to patents that are subject to the prior art provisions of 35 U.S.C. § 102(a) enacted in § 3(b) of the Leahy-Smith America Invents Act (Public Law 112–29), 125 Stat. 284.

35 U.S.C. § 281(a): Reenactment of the Patentee’s Right to a Civil Action to Enforce

Subsection (b) repeals existing 35 U.S.C. § 281¹⁸ and substitutes a new § 281 to replace it. Under the transition provisions set out in Subsection (e), amended § 281 applies only to patents that are subject to the first-inventor-to-file provisions under the Leahy-Smith America Invents Act. New § 281 consists of two subsections.

New § 281(a) is substantively unchanged from the repealed § 281. The only difference between the new text of § 281(a) and the repealed text of § 281 is that the possessive noun “patentee’s” is substituted for the pronoun “his” to render new subsection (a) gender-neutral. New § 281(a) reaffirms that patent owners have the right to bring a civil action as a remedy for infringement of their respective patents.

35 U.S.C. § 281(b): Overview

Subsection (b) of § 281 imposes new limitations on the enforcement of certain first-inventor-to-file patents, defined in § 281 as “enforcement-linked patents.” It does so by limiting in certain circumstances the right to bring a separate civil action on an enforcement-linked patent once the patent to which it is linked for enforcement purposes has been the subject of a separate cause of action for patent infringement. Additionally, it imposes a new “indispensable party”¹⁹ requirement on enforcement-linked patents that are not owned by the same patentee. The new limitations relating to such enforcement-link patents have no counterpart in the current statute.

New subsection (b) consists of three paragraphs. The first paragraph is the one that bars certain civil actions involving enforcement-linked patents under a *res judicata* principle. The second paragraph then imposes the new requirement relating to the indispensable parties to a civil action alleging the infringement of such an enforcement-linked patent. The third paragraph defines the enforcement-linked patents to which the new *res judicata* bar and indispensable party requirements apply for first-inventor-to-file patents apply.

The overall objective of new § 281(b) is to link the enforcement of a first-inventor-to-file patent with another patent containing at least some *patentably indistinct* claims. The enforcement linkage, if such patents are separately owned or become separately owned, prevents multiple civil actions alleging infringement of enforcement-linked patents to be brought by separate patentees who might otherwise be entitled to separate damages, thereby eliminating any potential for harassment arising from patentably indistinct claims. Eliminating the potential for such harassment obviates one of the two justifications for the imposition by the courts of the non-statutory “double patenting” grounds for invalidating patent claims.²⁰

¹⁸ 35 U.S.C. § 281 current has the title “Remedy for infringement of patent” and reads “A patentee shall have remedy by civil action for infringement of his patent.”

¹⁹ Under Rule 19(b) of the Federal Rules of Civil Procedure, an “indispensable party” is a “necessary party” to a civil action under Rule 19(a) who, if unable to be joined as a party to the action, mandates dismissal of the lawsuit. See *A123 Systems, Inc. v. Hydro-Quebec*, 626 F. 3d 1213, 1220 (Fed. Cir. 2010), dismissing a § 281 civil action based on the failure to join the patentee who “was not only a necessary party but also an indispensable party, making dismissal appropriate.”

²⁰ In this regard, the Federal Circuit has “recognized a ‘concern over potential harassment of an infringer by multiple assignees asserting essentially the same patented invention...’” *In re Hubbell, supra*, at 709 F. 3d 144.

35 U.S.C. § 281(b)(1): Limitation on Civil Actions for Enforcement-Linked Patents

Under new § 281(b)(1), a civil action for infringement, once brought, may be maintained with respect to an enforcement-linked patent only if the new “res judicata” requirement set out in this paragraph is satisfied. Under this new requirement, such a civil action with respect to an enforcement-linked patent may not go forward if the allegations of infringement therein would have been barred by res judicata had both enforcement-linked patents instead issued as a single patent, *i.e.*, had each of the claims of the asserted patent and the patent to which it is enforcement-linked been originally issued as a single patent that was granted to jointly to the respective patentees (or, in the case of commonly owned patents, the common patentee) of the two patents.

Thus, a civil action can only be barred under new paragraph (1) in the circumstance where the two patents containing patentably indistinct claims would not have supported multiple causes of action under the established principles of res judicata, but for the issuance of such claims in two patents instead of a single patent. In this respect, the new limitation on civil actions with respects to enforcement linked claims vindicates the policy objective under non-statutory “double patenting” principles without the need for intervention by the United States Patent and Trademark Office to condition the grant of patents with indistinct claims on maintaining common ownership of the patents with such claims—or disclaiming the right to separately enforce two such patents.

35 U.S.C. § 281(b)(2): New Indispensable Party Requirement.

Under new § 281(b)(2), a patentee who would be barred by res judicata under paragraph (1)—as a consequence of a civil action brought to enforce one of two enforcement-linked patents—is made an indispensable party to such civil action brought to enforce the other of the two enforcement-linked patents. This new requirement removes any possibility that one of the two patentees holding enforcement-linked patents could be denied the remedy of a civil action to enforce its patent because of a unilateral infringement action by the other patentee had triggered the res judicata bar under § 281(b)(1).

Most commonly, enforcement-linked patents will be commonly owned and the indispensable party requirement will only apply if ownership of one of the two patents has been subsequently alienated, an action that has been heretofore barred under the terminal disclaimer practice under 37 C.F.R. § 1.321(c) relating to commonly owned patents. Under 37 C.F.R. § 1.321(c), the United States Patent and Trademark Office requires a “terminal disclaimer” in the situation where the two patents involved in the “double patenting” are commonly owned that requires maintenance of such common ownership for the disclaimed patent to remain valid. This rule specifically requires “any patent granted ... shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting.”

In the case of patents subject to non-statutory double patenting that were not initially commonly owned, 37 C.F.R. § 1.321(d) imposes a similar requirement to effectively bar separate

enforcement. For these patents, the USPTO rule requires “waiving the right to separately enforce any patent granted on that application ... and the patent ... which formed the basis for the double patenting, and that any patent granted ... shall be enforceable only for and during such period that said patent and the patent ... which formed the basis for the double patenting are not separately enforced.” Subsequent to the enactment of the Leahy-Smith America Invents Act, both patentees of the two separately owned patents must jointly disclaim separate enforcement for the double patent for the USPTO to accept the terminal disclaimer as being legally sufficient to redress the double patenting.²¹

With the enactment the amendment in subsection (b), enforcement-related disclaimers required under 37 C.F.R. § 1.321 for first-inventor-to-file patents would be superseded by the enforcement-related limitations in 35 U.S.C. § 281(b). In combination, §§ 281(b)(1) and (2) remove the any basis for continuing to require such disclaimers relating to continued common ownership or separate enforcement with respect to first-inventor-to-file patents. Together, these two paragraphs preclude any possibility that two enforcement-linked patents, *i.e.*, patents containing patentably indistinct claims, could be separately enforced in a manner that could be regarded as harassment by multiple patentees.

35 U.S.C. § 281(b)(3): Statutory Definition for Enforcement-Linked Patents

Under paragraph (3), a definition is provided for an “enforcement-linked patent.” The definition imposes two separate requirements that must be met by each of a pair of patents for the two patents to be regarded as enforcement-linked patents. Those requirements appear in separate subparagraphs, *i.e.*, subparagraphs (A) and (B).

Under subparagraph (A), the first of the two requirements is met if, for at least one claimed invention selected from each of two patents, neither such claimed invention constitutes prior art under 35 U.S.C. § 102(a)(2) to the other. If each claimed invention of either of the patents is prior art to each of the claimed inventions of another patent, neither patent constitutes an enforcement-linked patent with respect to the other. In such a circumstance, none of the limitations of new § 281(b) apply to either patent.

In general, therefore, the requirement under subparagraph (A) will not apply unless patent applications were filed on the same day (*i.e.*, neither is “prior” to the other and cannot constitute “prior art”) or one of the exceptions to prior art set out in 35 U.S.C. § 102(a)(2) or § 102(b)(1)

²¹ For a discussion of the disclaimer of the right to separately enforce patents, see H.R. Rep. No. 108-425 at p. 6 and the Hatch colloquy at Cong. Rec. S7521 (June 25, 2004), discussing the requirements of a disclaimer relating to separate enforcement as part of the legislative history of the Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596, which permitted separately owned patents with patentably indistinct claims to be validly issued, subject to such disclaimers: “To meet the requirements of the [CREATE Act], the parties to the joint research agreement must agree to accept the conditions concerning common term and the prohibition against separate patent enforcement *and all involved parties must agree to be signatories to any required terminal disclaimer.*” [Emphasis supplied.] Under the Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284, the above requirement expressed in the CREATE Act legislative history has been enacted into law. See AIA § 3(b)(2), “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.”

apply. These exceptions are limited to claimed inventions (1) in patents naming the same inventor or joint inventor or (2) that were commonly assigned or (3) subject to a joint research agreement.

Under subparagraph (B), the second of the two requirements is met if a modified form of the so-called “one-way” test²² for determining if the claims of a patent represent “obviousness-type” double patenting by undertaking a claim-to-claim comparison as between respective claims of the two patents.²³ However, subparagraph (B) modifies this “one-way” test by considering each of the claimed inventions being assessed for patentable distinctness as though they were prior art under § 102(a)(2) to the other. For the purpose of applying paragraph (3), the term “claimed invention” refers to the subject matter defined by the claim.²⁴

Under § 281(b)(3)(B), the patentable distinctness in light of such assumed “prior art” is assessed through a statutory obviousness analysis under 35 U.S.C. § 103. Thus, subparagraph (B) provides that, for each claimed invention that forms a pair of claimed inventions in which neither claimed invention would otherwise be prior art to the other under subparagraph (A), the modified “one-way” test is satisfied if one or more of such claimed inventions would have been obvious in view of the other as § 102(a)(2) prior art under section 103’s requirement for non-obviousness.

Since the provisions of new § 281(b) do not apply to patent applications being examined or patents that have issued under the first-to-invent conditions for patentability, the examinations of such applications and the validity of any patents issued on such applications will continue to depend on a disclaimer of separate enforceability, including—when applicable—through a disclaimer of enforceability to the extent the patents involved in the non-statutory double patenting do not remain common owned. As noted above, however, such requirements for disclaimer are superseded for all patent applications—and patents issued on such applications—that have been, are being, and will be examined under the first-inventor-to-file conditions for patentability, save for the possibility that certain first-inventor-to-file patents granted prior to enactment will not be subject to section 2 pursuant to the applicable transition provisions.

²² The Federal Circuit has used both a “one-way” and a “two-way” test to assess patentable distinctness of claimed inventions from each of two patents. The respective claims can be patentably distinct under the “one-way” test if obviousness would be found running the comparison of the claimed inventions “either way”—by considering either claimed invention prior art to the other to determine if obviousness would exist either way. In contrast, the claims of the respective patents can qualify as patentably distinct under the “two-way” test only if obviousness would be found running the comparison “both ways.” The Federal Circuit has progressively limited the applicability of the more limited “two way” or “both ways” test for patentability indistinctness in favor of more expansive “one-way” or “either way” test. See *In re Berg*, 140 F. 3d 1428, 1432 (Fed. Cir. 1998), “Generally, a ‘one-way’ test has been applied to determine obviousness-type double patenting. ... [W]hen the two-way test applies, some claims may be allowed [as patentably distinct] that would have been rejected [as patentably indistinct] under the one-way test.”

²³ See *Geneva Pharmaceuticals v. GlaxoSmithKline*, 349 F. 3d 1373, 1385 (Fed. Cir. 2003), “because nonstatutory double patenting compares earlier and later claims, an earlier patent’s disclosure is not available to show nonstatutory double patenting.”

²⁴ This is the statutory definition for the term “claimed invention” found in 35 U.S.C. § 100(j).

SUBSECTION C: PATENT TERM JUSTIFICATION AND RESTORATION.

If the term of a patent is based upon the amendments made to subsection (a) of section 154 by the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4809)—

(1) the patent term as provided under subsection (a) of such section 154, United States Code, any adjustment to said term as provided under subsection (b) of such section 154, and any extension of such term as provided under section 156 of title 35, United States Code, shall not constitute, nor be deemed by the United States Patent and Trademark Office or the courts to constitute, an unjustified period of protection under the patent, or an unjustified extension of the right to exclude under the patent, relative to any earlier-expiring patent;

(2) the Office may not condition the issuance of any such patent on a disclaimer of the terminal part of the patent term otherwise permitted under sections 154 and 156, United States Code; and

(3) any disclaimer of the terminal part of the term of such a patent under section 253(b) of title 35, United States Code, pursuant to section 1.321 of title 37, Code of Federal Regulations, with respect to one or more other applications or patents, shall have no effect on the term of the patent and shall be treated as never having had effect on the term of the patent except to the extent that the patent would otherwise have expired less than one year after the date of enactment of this section.

Under Subsection (c), two rules of construction are provided in paragraphs (1) and (2). In addition, a third paragraph provides for the restoration of the term of certain patents that are subject to disclaimers. Each of these three provisions of Section 3(c) applies only to patents that have terms of protection determined under the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4809), *i.e.*, have a statutory patent term under 35 U.S.C. § 154(a) that ends 20 years after the original, nonprovisional filing date of the patent application, subject to any patent term adjustment or patent term extension that might be justified under § 154(b) or 35 U.S.C. § 156.

Paragraph (1): Bar to Judicial Finding Statutory Term Is Unjustified Timewise

Paragraph (1) bars either the United States Patent and Trademark Office or the courts from deeming the available statutory exclusivity for a patent subject to the URAA to produce an unjustified timewise extension of such exclusivity relative to the term of any other issued patent. This rule of construction assures a patent owner that the new statutory prohibition on considering patent exclusivity to be unjustified includes exclusivity based upon the 20-year patent term authorized under 35 U.S.C. § 154(a), as well as any adjustment to that term authorized under § 154(b) or any extension of that term under 35 U.S.C. § 156.

Since these provisions of the patent law authorize exclusive rights under any individual patent for the limited time for which Congress is authorized to provide for the grant of patents, Congress has directed under Section 3(c)(1) that there is no basis for the Office or the courts to limit or negate such protections for limited times on a non-statutory double patenting ground or otherwise. This rule of construction precludes the Office or the courts from determining that a claimed invention in any URAA patent is unpatentable or is invalid based upon the failure of a patent owner to disclaim the terminal part of the term of the patent.

Paragraph (2): USPTO Bar on Requiring a Disclaimer of Term.

Paragraph (2) specifically addresses the “terminal disclaimer” practices of the United States Patent and Trademark Office to the extent those provisions are applied to URAA patents. It expressly bars the Office from conditioning the issuance of a URAA patent on disclaiming the terminal part of the term of such a patent.

This paragraph overruling one aspect of the current USPTO disclaimer practice applies to the first-to-invent patents that remain subject to non-statutory double patenting. The first-to-invent patents that remain subject to non-statutory double patenting are those that contain patentably indistinct claims under non-statutory double patenting law as limited under Subsection (a) and, therefore, will remain subject to disclaimers of separate ownership or separate enforcement under 37 C.F.R. §§ 1.321(c) or (d)—but will no longer be subject to disclaimers of term pursuant to the amendments under paragraph (2).

Paragraph (3): Nullification of Disclaimers of Term Pursuant to 37 C.F.R. § 1.321

The third paragraph nullifies the effect on patent term of certain terminal disclaimers filed under 35 U.S.C. § 253(b) pursuant to 37 C.F.R. § 1.321 with respect to patents whose terms are subject to 35 U.S.C. § 154(a) as amended by the URAA. This includes all patents subject to the first-inventor-to-file provisions of the Leahy-Smith America Invents Act. This provision is limited by one exception. The nullification is inapplicable to any patent that, pursuant to a terminal disclaimer, would expire within one year from the date of enactment of the Act.

Section 4. Patent Applicant Prior Art Disclosure Requirements.

SUBSECTION A: MISCONDUCT-BASED DEFENSES.

Section 284 of title 35, United States Code, is amended by inserting at the end:

“(d) MISCONDUCT-BASED DEFENSE BARRED.—A claim in a patent may not be held unenforceable in a civil action based upon misconduct before the Office unless the claim is found to be invalid.”

Subsection (a) amends 35 U.S.C. § 284 to bar any unenforceability defense based upon misconduct before the USPTO.²⁵ This Subsection overrules the so-called “inequitable conduct” defense in which concealing or misrepresenting information material to patentability with an intent to deceive the patent examiner can result in the patent being held permanently unenforceable. This type of defense to infringement is unique to U.S. patent law and its abolition was recommended by the National Academies of Science in its 2004 report on the patent system. The National Research Council of the National Academies concluded that subjective elements should be removed from U.S. patent litigation, *i.e.*, “In view of its cost and limited deterrent value the committee recommends the elimination of the inequitable conduct doctrine or changes in its implementation.”²⁶

New § 284(d) does not affect remedies under the antitrust laws arising from the fraudulent procurement of an invalid patent²⁷ and does not affect the “unclean hands” doctrine under which a patent can be held unenforceable based upon litigation misconduct.²⁸ Other substantial deterrents to misconduct before the USPTO are similarly unaffected.²⁹

The elimination of the unenforceability defense removes the incentive for patent applicants to “over disclose” to patent examiners information of little or no relevance to patentability in order to avoid later allegations of concealment of such information with an intent

²⁵ The Federal Circuit has recently considered the continued viability of the “inequitable conduct” doctrine that can result in a patent being held permanently unenforceable based on misconduct before the USPTO in connection with an application for patent and reaffirmed and rearticulated the boundaries of this judicially imposed ground of unenforceability. See *Therasense, Inc. v. Becton, Dickinson & Company*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc). It noted: “Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system. Because allegations of inequitable conduct are routinely brought on ‘the slenderest grounds [citation omitted], patent prosecutors constantly confront the specter of inequitable conduct charges. With inequitable conduct casting the shadow of a hangman’s noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value.” *Id.* at 1289.

²⁶ National Research Council, *A Patent System for the 21st Century* (2004), p.123, available to download at <https://www.nap.edu/read/10976/chapter/6#123>. See <http://www.nap.edu/html/patentsystem/0309089107.pdf> and https://download.nap.edu/cart/download.cgi?record_id=10976. As further articulated by the National Academies at p. 122: “If invalidity, [State Professional Responsibility and USPTO] disciplinary action, and reputational concerns are not sufficient deterrent to misconduct, other civil and even criminal remedies exist—antitrust, unfair competition, common law fraud, and tortious interference. Moreover, since the creation of the inequitable conduct doctrine by the courts, other safeguards have been adopted by Congress and the USPTO to support the integrity of the patent system. These include third-party and USPTO-initiated re-examination on withheld prior art, publication of pending applications, and third-party access to pending prosecution papers and the ability to submit material information.”

²⁷ *Walker Process Equip., Inc. v. Food Mach. and Chem. Corp.*, 382 U.S. 172 (1965).

²⁸ *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), and *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 245 (1944), where the Supreme Court found the patentee had engaged in “a deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals.”

²⁹ In the case of an individual registered to practice before the USPTO, the Director of the USPTO may take action to suspend or exclude the individual from practice under 35 U.S.C. § 32 based upon misconduct before the Office. In the event an individual is the subject of such a proceeding under § 32, the Director may communicate any findings by the USPTO to disciplinary bodies of professional organizations in which the individual is a registered to practice for the purpose of exacting similar sanctions. All remedies for violation of the antitrust laws remain, including the first section of the Clayton Act and section 5 of the Federal Trade Commission Act relating to unfair methods of competition, based upon misconduct before the Office. Lastly, criminal prosecution for misconduct before the USPTO is possible under 18 U.S.C. § 1001(a).

to deceive the USPTO. The abolition of the defense removes one of the most significant contributors to the phenomenon of “over-disclosure” of prior art during patent examination.

Second, it removes the most important barrier to requiring that patent applicants explain the relevance of prior art that they submit for consideration by the patent examiner during the patent examination process. The specter that a patent might be held permanently unenforceable based upon a mere misrepresentation of the significance of the prior art is removed, thereby opening the door to requirements *mandating* that prior art that is disclosed to the USPTO be accompanied by a concise description of its possible relevance.

SUBSECTION B: INFORMATION DISCLOSURE IN PATENT APPLICATIONS.

In chapter 12 of title 35, United States Code, insert at the end:

“§ 136. Disclosure of patents and printed publications during examination.

“(a) IN GENERAL—A patent or printed publication that may or does constitute prior art material to patentability of a claim in an application being examined, or otherwise is of potential or actual relevance to the patentability of a claim, may be submitted by the applicant to the Office for consideration during the examination of the application only if the applicant—

“(1) provides with the submission of such item a concise description of its potential relevance to the patentability of the claims being examined;

“(2) pays the fee established by the Director for submission of such item; and

“(3) meets such other requirements as to timing and form for the submission of the item as the Director may establish by regulation.

“(b) EXCEPTIONS.—The requirements under paragraphs (1) and (2) of subsection (a) shall not apply to any patent or printed publication—

“(1) for which the specification of the application contains a concise description of its potential or actual relevance to the patentability of the claims of the specification or

“(2) that is exempted from one or both of such requirements under regulations established by the Director.

“(c) CONSIDERATION BY THE OFFICE.—A patent or printed publication shall not be considered, or be regarded as having been considered, by the Office unless it—

“(1) meets the requirements under subsection (a),

“(2) falls within the exception under subsection (b),

“(3) is listed in an action reporting on the prior art prepared by the Office during the examination of the application or a like report prepared in connection with a related foreign or

international application that has been made available during examination in a timely manner, or
“(4) is identified in a submission in connection with the application in compliance with section 122(e).”

Subsection (b) amends chapter 12 of title 35 by enacting an entirely new section addressing the disclosure of patents and printed publications by the patent applicant to the patent examiner for consideration during the examination of a patent application. This new section is 35 U.S.C. § 136 and it contains three subsections. New § 136(a) provides a general rule for making such submissions. New § 136(b) provides three exceptions by identifying submission of patents and printed publications that are not subject to subsection (a)’s requirements. Finally, new § 136(c) offers a definition for prior art to be considered by the USPTO during examination.

35 U.S.C. § 136(a) – Requirements for Information Disclosure Submissions

New § 136(a) provides requirements for patent applicants submitting patents and printed publications for consideration by patent examiners during the examination of a patent. Any item submitted under § 136(a) must provide a concise description of the potential relevance to patentability of the claims being examined and a fee to be established by the Director for the submission. The requirement for a concise description is substantively identical to the existing requirements for submissions of items of prior art by third parties under 35 U.S.C. § 122(e)(2)(A).³⁰ In addition, unless the subject of an exception under new § 136(b)(2), a fee is required to submit each item.³¹

These new requirements serve two objectives. First, with the abrogation of the unenforceability defense based on misconduct in the USPTO, patent applicants can submit information of potential relevance to examination without the need for concern that the failure to indiscriminately disclose information of little or no possible relevance might give rise to misconduct allegations based on intentional concealment of known information. Similarly, the imposition of a fee will affirmatively dissuade disclosure of large numbers of prior art disclosures that can do no more than complicate the process of the patent examiner of identifying the most relevant items of prior art relevant to patentability.

35 U.S.C. § 136(b) – Exceptions to Concise Description and Fee Requirements

New § 136(b) contains two exceptions to the requirements under 35 U.S.C. § 136(a) for a concise description of the relevance of an item of prior art and a fee for submission. The first relates to any item of prior art for which a concise description of relevance appears in the specification of the patent. This first exception encourages drafting patent specifications completely identifying and characterizing the most pertinent prior art.

The second exception applies to any submissions that the USPTO determines to exempt from the concise description and fee requirements. Under this provision, the USPTO can

³⁰ “Any submission under [of a patent or printed publication of potential relevance] shall ...set forth a concise description of the asserted relevance of each submitted document.” 35 U.S.C. § 122(e)(2)(A).

³¹ A similar fee is required under 35 U.S.C. § 122(e)(2)(B).

provide that a limited number of items of prior art may be submitted for consideration without a concise description of relevance or a fee.

35 U.S.C. § 136(c) – Items of Prior Art Considered by the USPTO

New § 136(c) explicitly defines the circumstances where a patent or printed publication is to be regarded as having been considered by the USPTO during the examination of an application for patent. This new statutory definition is of relevance to the presumption that a patent is valid and the evidence necessary to invalidate a patent claim.³²

Four categories of patents and printed publications are identified in new § 136(c) that are to be regarded as having been before the USPTO during examination of a patent. First, any items meeting the requirement under subsection (a). Second, any items that are the subject of an exception under subsection (b). Third, any items that are listed in “search reports” before the examiner during examination qualify as being considered. Fourth, any items submitted by the public in compliance with 35 U.S.C. § 122(e).

SUBSECTION C: POST-ISSUANCE REVIEW PROCEEDINGS.

(1) DEFERRAL AND POSSIBLE WAIVER OF POST-GRANT REVIEW FEE.—In section 321 of title 35, United States Code, insert at the end:

“(d) FEE DEFERRAL AND WAIVER.—If a petition seeks the institution of a post-grant review based in whole or in part on a patent or printed publication not considered by the Office during the examination of a patent under section 136(c), payment of the fee under section 322(a)(1) otherwise required to accompany the petition shall be deferred and become due only if the proceeding is instituted under section 324. If the Director determines under section 324(a) that that it is more likely than not that at least 1 of the claims challenged in a petition for post-grant review is unpatentable based in whole or in part upon a patent or printed publication that was not considered during the examination of the patent, and is not merely cumulative with respect to prior art considered during such examination, the fee otherwise required under section 322(a)(1) shall be waived. If a fee deferred under this subsection becomes due, the post-grant review shall not commence under section 324(d) unless such fee is paid by the

³² “[I]f the PTO did not have all material facts before [it, its considered judgment [on patentability] may lose significant force. . . . And, concomitantly, the challenger’s burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain. In this respect, although we have no occasion to endorse any particular formulation, we note that a jury instruction on the effect of new evidence can, and when requested, most often should be given. When warranted, the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity to evaluate before granting the patent.” *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238, 2251 (2011).

petitioner within such time period as the Director establish by regulation for making such payment.

(2) ESTOPPEL IN POST-GRANT REVIEW.—In section 325(e)(2) of title 35, United States Code, strike “or reasonably could have raised”.

(3) STANDARD OF PROOF IN INTER PARTES REVIEW.—In section 316(e) of title 35, United States Code, strike “a preponderance of the” and insert “clear and convincing”.

Under Subsection (c), the provisions in each of its three paragraphs offer new incentives for members of the public to undertake prompt challenges to patents once issued. Specifically, these provisions encourage greater use of the post-grant review procedure under chapter 32 of title 35, United States Code, in preference to the provisions of inter partes review (found in chapter 32 of title 35) that are available later in the life of a patent.

Under paragraph (1), a petitioner in a post-grant review procedure may defer the payment of the fee for the post-grant review petition if the petitioner seeks the review based on patents or printed publications that had not been considered during the examination of the patent. Such fees may be waived by the USPTO if the petition is granted and a post-grant review is instituted based upon such a non-considered item of prior art.

Under paragraph (2), the judicial estoppel arising from a final written decision in a post-grant review proceeding is limited to the issues determined in the review. This amendment to 35 U.S.C. § 325(e)(2) corrects a legislative error in the enactment of the America Invents Act and serves to increase the attractiveness of the post-grant review procedure.

Under paragraph (3), the standard of proof in inter partes review is raised to “clear and convincing evidence” to align the standard with the judicial standard for determining invalidity of issued patent claims. This amendment provides an additional incentive for use of the post-grant review proceeding in preference to the inter partes review.

SUBSECTION D: CONFORMING AMENDMENTS.

(1) SUPPLEMENTAL EXAMINATION.—Strike subsection (c) of section 257 of title 35, United States Code.

*(2) TABLE OF SECTIONS.—In the table of sections for chapter 12 of title 35, United States Code, insert at the end:
“§ 136. Disclosure of patents and printed publications during examination.”*

Subsection (d) provides a set of conforming amendments.

Section 5. Patent Examination Simplification.

SUBSECTION A: PATENT APPLICATIONS AND EXAMINATION.

Subsection (a) contains six paragraphs, each of which provides a simplification of the process of examining applications for patent.

Paragraph (1): RESTRICTION OF INDEPENDENT CLAIM SCOPE IN LIEU OF FILING DIVISIONAL APPLICATIONS.

Section 121 of title 35, United States Code, is amended by striking and inserting:

“§ 121. Restriction of claims.

“In an application that is otherwise in condition to be allowed under section 151, the examiner may require that each claimed invention in the application be restricted to a single general inventive concept. Before an application is allowable, the examiner may provisionally object to any claim in an application by identifying multiple general inventive concepts alleged to be encompassed by the claim. The applicant may request a review of any action under this section by petition to the Director identifying what the applicant regards as the single general inventive concept present in the applicable claims. The validity of a patent shall not be questioned for failure of any claim to be restricted to a single general inventive concept.”

Paragraph (1) repeals the existing provision in title 35 referencing “divisional applications.”³³ Under the existing § 121, patent examiners may enter requirements for restriction that mandate the filing of divisional applications for patent to secure patent protection for “independent and distinct inventions.” In addition, under existing § 121, a requirement for restriction may be accompanied by a requirement that the patent applicant elect a single independent and distinct invention to which the examination of the application may be limited. Under new § 121, these practices will end.

³³ The text of the section being repealed reads:

“§ 121 Divisional applications.

“If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.”

New § 121 permits the USPTO to require that each individual claim that is directed to multiple *general inventive concepts* to be restricted to a *single general inventive concept*. Unlike the prior law, such a requirement for restriction may be made only if the examination of all claims presented in the application is complete and claims in the application are otherwise allowable, such that a notice of allowance could be issued to the patent applicant under 35 U.S.C. § 151. Imposing the new requirement that each claim in the application be restricted to a single general inventive concept will not defer or otherwise delay the examination of any of the claimed subject matter in the application.

Patent examiners are permitted to provisionally object to a claim in a patent application during the examination of the application on the ground that one or more application claims are directed to multiple general inventive concepts. Such provisional objections permit patent applicants to amend the claims in independent form in the application or present new such claims during the examination process. When such amendments restrict each claim in independent form to a single general inventive concept that is consonant with an objection made by the examiner under new § 121, the objection is obviated and the patent application can be allowed to issue as a patent once patentability is established.

If a requirement for restriction is made under § 121, the patent applicant may petition the Director of the USPTO for relief from the requirement—or a provisional objection—under new § 121 by identifying what the applicant regards as the single general inventive concept to which each claim subject to the requirement has been limited. The petitioning process under new § 121 may be implemented by the Director in a manner analogous to the process under the prior statute in the case of requirements for restriction.³⁴

The terms “inventive concept” and “single general inventive concept” are new to title 35. This terminology is being incorporated into title 35 based on the use of the terms “single general inventive concept” and “common inventive concept” in title 37, Code of Federal Regulations. This terminology appears in the USPTO regulations implementing the Patent Cooperation Treaty obligations of the United States.³⁵ New § 121 will permit the USPTO to apply the regulations

³⁴ The current petitioning process is governed by the following rule:

37 C.F.R. 1.144 Petition from requirement for restriction.

After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see § 1.181).

³⁵ The concept of “single general inventive concept” is relevant to determining “unity of invention” under the Patent Cooperation Treaty, as set out in 37 C.F.R. §§ 1.475(a) and (e), “An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (‘requirement of unity of invention’). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression ‘special technical features’ shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. ... The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.”

and practices that have been developed with respect to the implementation of the “unity of invention” standard under the PCT to implement the new requirements for claim restriction. In this regard, the implementation by the USPTO of new § 121 should parallel procedures used in the current examination of international patent applications filed under the PCT, where patent examiners may invite the patent applicant to pay a supplemental search fee per additional invention.³⁶

Paragraph 2: CONTINUED EXAMINATION AUTHORIZED IN LIEU OF FILING CONTINUATION APPLICATIONS.

Section 120 of title 35, United States Code, is amended by striking and inserting:

“§ 120. Continued examination.

“If an applicant requests continued examination of an application, accompanied by the required fee, the Director shall recommence the examination of such application under section 131. The continued examination shall be based on the specification as amended, and the examination record otherwise before the Office, at the time the request was made.”

Paragraph (2) repeals existing 35 U.S.C. § 120³⁷ and enacts a new § 120 to replace it. Under § 120 as enacted under the 1952 Patent Act, patent applicants were entitled to file new nonprovisional patent applications that—for patentability purposes—could be entitled to the benefit of the filing date of the previously filed application from which it represented a

³⁶ See 37 C.F.R. § 1.476(b) (“If the International Searching Authority considers that the international application does not comply with the requirement of unity of invention, it shall inform the applicant accordingly and invite the payment of additional fees...”) and “PCT Fees in U.S. Dollars,” <https://www.uspto.gov/patents-getting-started/international-protection/patent-cooperation-treaty/pct-fees-us-dollars>. Under the new § 43, additional fees may apply to applications and patents claiming multiple general inventive concepts under new § 121.

³⁷ 35 U.S.C. § 120 current reads:

§ 120 Benefit of earlier filing date in the United States.

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 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. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the requirement for payment of the fee specified in section 41(a)(7), to accept an unintentionally delayed submission of an amendment under this section.

continuation. Under new § 120, such continuing applications are no longer authorized. Instead, new § 120 specifically authorizes requests for continued examination to be made. These requests must be accompanied by the required fee under 35 U.S.C. § 41(a)(3)(C).

When a request for continued examination is made, the examination of the application recommences under 35 U.S.C. § 131. In this regard, a request for continued examination can be filed in lieu of the filing of a notice of appeal under 35 U.S.C. § 134. The specification and examination record of the application at the time of the request for continued examination are used as the basis for the recommended examination.

Taken together, new § 120 and § 121 entirely eliminate the practice of filing continuation, continuation-in-part, and divisional applications for patent. Upon filing of a nonprovisional application that is not subsequently abandoned, patent examination will result in all claims presented for examination being examined simultaneously on the merits, in order to determine patentability, and will permit patent applicants to secure a single patent on any invention disclosed in the application.

Paragraph 3: FEES.

In chapter 4 of title 35, United States Code, insert at the end:

“§ 43. Additional fees for excess claims in independent form.

“Upon filing or on presentation at any other time of each claim in independent form in excess of 3, in addition to the fee specified in section 41(a)(2), the applicant shall incur an additional excess claims fee under this section in the amount of the fee as specified in section 41(a)(1) for the original filing of the application for each such claim 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 such 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 such claim in the patent in independent form in excess of 3.”

Paragraph (3) provides additional fees for patents and applications for patent that contain more than three claims in independent form. The additional fees are incurred upon the presentation of such an excess claim in an application for patent, the issuance of such a claim in a patent, and the presence of such a claim in a patent in which a maintenance fee is due.

Under these requirements for an additional fee, each excess claim incurs either an additional patent filing fee, an additional patent issue fee, or an additional patent maintenance fee. These fees only impact patents in which the applicant seeks a multiplicity of claims in

independent form directed to the same general inventive concept or the patent claims multiple general inventive concepts for which a requirement for restriction was made under 35 U.S.C. § 121 as amended by this Act.

Paragraph 4: OATH OR DECLARATION.

In section 115(a) of title 35, United States Code, strike “shall execute” and insert “may be required by the Director to execute”.

Paragraph (4) affords the USPTO authority to waive the requirement for the execution of an oath or declaration in connection with some or all applications for patent. Most specifically, the Director would have authority to do so in connection with international applications filed under the Patent Cooperation Treaty.

Paragraph (5): CONFORMING AMENDMENTS.

(A) Section 100(i) of title 35, United States Code, is amended by striking the text after “365(b).”

(B) Section 102(d) of title 35, United States Code, is amended by striking “or to claim the benefit of an earlier filing date under section 120, 121, or 365(c),”.

(C) Section 111(b)(7) of title 35, United States Code, is amended by striking this paragraph and inserting:

“(7) TREATMENT OF INTERNATIONAL AND NONPROVISIONAL APPLICATIONS FOR PRIORITY PURPOSES.—For the purpose of asserting a right of priority or securing the benefit of an earlier filing date under section 119(e), a nonprovisional application filed under subsection (a), or an international designating the United States, shall be deemed a provisional application under this subsection (b). If any claim for the priority is based on a prior international application which designated but did not originate in the United States, the Director may require the filing in the Patent and Trademark Office of a certified copy of such application together with a translation thereof into the English language, if it was filed in another language.

(D) Section 115 of title 35, United States Code, is amended by striking and reserving subsections (c) and (g) and by striking subsection (i).

(E) Section 132(b) of title 35, United States Code, is amended by striking subsection (b) and removing the subsection designation from subsection (a).

(F) Section 154(a)(2) of title 35, United States Code, is amended by striking the text after “United States”.

(G) Section 184(b) of title 35, United States Code, is amended by striking “, or division thereof”.

(H) Section 365 of title 35, United States Code, is amended by striking the subsection (c).

(I) Section 366 of title 35, United States Code, is amended by striking “, unless a claim for benefit of a prior filing date under section 365(c) of this section was made in a national application, or an international application designating the United States, filed before the date of such withdrawal”.

(J) The item relating to sections 120 and 121 in the table of sections for chapter 11 of title 35, United States Code, is amended to read as follows:

“§ 120. Continued examination.

“§ 121. Restriction of claims.

(K) In the table of sections for chapter 4 of title 35, United States Code, insert at the end:

“§ 43. Additional fees for excess claims in independent form.

Paragraph (5) contains a set of conforming amendments. Several conforming amendments strike text from title 35 to reflect that the “effective filing date” of a claimed invention will no longer account for the filing of continuation applications, including divisional applications, under 35 U.S.C. §§ 120 and 121 . These amendments are found in subparagraphs (A), (B), (D), (F), (G), (H), and (I). Subparagraph (C) provides a similar conforming amendment by replacing 35 U.S.C. § 111(b)(7) with a new provision that permits the treatment of nonprovisional applications and PCT applications designating the United States as provisional applications for the purpose of asserting the right to the benefit of the filing date of such applications for patentability purposes under 35 U.S.C. § 119(e).

Subparagraph (E) repeals 35 U.S.C. § 132(b) relating to requests for continued examination. New § 120 supersedes this subsection.

Subparagraph (J) conforms the table of sections to the amendments made to §§ 120 and 121. Subparagraph (K) makes a similar conforming amendment to the table of sections in chapter 4 of title 35.

SUBSECTION B: PUBLIC ACCESS.

In section 122(b)(1) of title 35, United States Code, strike subparagraph (B), strike the designation for subparagraph (A), and replace the designation of items (i)-(iv) of as subparagraphs (A)-(D), respectively.

Subsection (b) removes the exception provided in 35 U.S.C. § 122(b)(2)(B) under which an applicant who did need seek foreign patent protection was permitted to retain secrecy of a patent application until the application issued as a patent. Removal of this exception will provide greater transparency in the patent procurement process.

SUBSECTION C: REEXAMINATION AND REISSUE.

(1) *REISSUE.*—In section 251 of title 35, United States Code—

(A) In subsection (a), strike “, through error,”.

(B) In subsection (e), strike “two years from the grant of the original patent” and insert “seven years after the original nonprovisional filing date of the application for patent”

(2) *REEXAMINATION.*—In title 35, United States Code—

(A) In sections 302-303, strike and insert:

“§ 302. Reexamination

“To the extent authorized under sections 303 and 304, the Director may order reexamination by the Office of any claim of a patent on the basis of any prior art patents and publications discovered by the Director or cited under the provisions of section 301.”

“§ 303. Determination of issue by Director

“(a) The Director may determine a substantial new question of patentability is raised by patents and publications discovered by the Director or cited under the provisions of section 301. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.”

“(b) A record of the Director’s determination under subsection (a) of this section will be placed in the official file of the patent, and a copy promptly will be given or mailed to the owner of record of the patent.”

(B) In section 304, strike after the first sentence.

(D) In section 305, strike “After the times for filing the statement and reply provided for by section 304 have expired, reexamination” and insert “Reexamination”.

(E) In section 257(b), strike “except that the patent owner shall not have the right to file a statement pursuant to section 304”.

(3) In the table of sections for chapter 30 of title 35, United States Code, strike the entry for section 302 and insert:

“§ 302. Reexamination.

Subsection(c) makes changes to the reissue and reexamination proceedings under § 251 and chapter 30 of title 35. These changes reduce the redundancies among inter partes review, reissue, and reexamination. They further reflect the elimination of opportunities for the filing of continuation, continuation-in-part, and divisional patent applications by broadening access to patent reissue proceedings, including proceedings in which the scope of the claims of a patent may be enlarged.

Under Paragraph (1), two changes are made to the reissue statute. Under subparagraph (A), the limitation on reissue proceedings to situations where there is an “error” in the original examination of the patent is removed. Under amended § 251(a), reissue is available to a patentee whenever there is a defect in the specification or drawings of the patent or the patentee has claimed more or less than the patentee had a right to claim.

Under subparagraph (B), the limitation on seeking broadened claims in a reissue patent is changed from two years from the issue date of the original patent to seven year from the filing date of the original nonprovisional application. The seven-year period, unlike the two-year period assures that no broader claims in an issued patent can be sought during the final 13 years of the 20-year patent term. The two-year limitation, when coupled with the ability to file continuing applications for patent, created the potential for broadening reissues to be sought much later during the 20-year patent term.

Under Paragraph (2), ex parte reexaminations under chapter 30 of title 35 are limited to Director-ordered reexaminations. The need for patentee-sought reexaminations has been superseded by the amendments to § 251 that have broadened access to reissues, obviating the need for patentee-sought reexaminations. In addition, patentees will continue to have access to supplemental examination. Finally, third-party requested reexaminations have been eliminated in light of the availability of inter partes review.

Section 6. Patent Enforcement Clarification.

SUBSECTION A: CERTAIN EQUIVALENTS OF CLAIMED INVENTIONS PROTECTED.

Section 271 of title 35, United States Code, is amended by striking subsection (a) and inserting:

“(a) DIRECT INFRINGEMENT.—

“(1) IN GENERAL—Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any claimed invention or an equivalent thereof within the United States, or imports into the United States any claimed invention or an equivalent thereof, during the term of the patent therefor, infringes the patent.

“(2) EQUIVALENTS OF CLAIMED INVENTIONS.—Subject matter accused of infringing a patent represents an equivalent of a claimed invention if the patentee establishes that such subject matter—

“(A) differs at most immaterially from the each element of at least one specific embodiment disclosed in the specification that satisfies each of the limitations of the claim;

“(B) was not disclosed in the specification in a manner that would have permitted at least one claim meeting the requirements under section 112 to have covered the subject matter;

“(C) had such subject matter been specifically disclosed in the specification and been covered by one or more claims meeting

the requirements under section 112, at least one such claim would not be invalid under section 103, irrespective of whether the element or elements of such subject matter that differ immaterially from the claimed invention were novel.

“(3) IMMATERIAL DIFFERENCES.—A difference between the subject matter accused of infringement and an element in a claim of a patent shall be regarded as immaterial only if a corresponding element can be identified in the subject matter accused of infringement that functions in substantially the same way to produce substantially the same result as the element of the claim. No finding of immateriality may be made under the preceding sentence if the specification of the patent describes essential limitations on the claimed invention that would be inconsistent such a finding. The immateriality of the difference shall not be negated by the foreseeability of the subject matter accused of infringement or any element thereof.”

Subsection (a) repeals and replaces 35 U.S.C. § 271(a). New § 271(a) retains the provisions of the repealed statute dealing with literal infringement of a patent and adds new provisions providing that a patent may be infringed by accused subject matter that differs only immaterially from the claimed subject matter that would literally infringe the patent. In new § 271(a), this immaterially different subject matter is termed an “equivalent” of a claimed invention.

The new statutory provision providing for infringement through “equivalents” supersedes the judicially created “doctrine of equivalents.”³⁸ It provides a statutory basis for infringement that is more consistent with internationally recognized norms under which equivalents of claimed inventions are protected. Both the superseded “doctrine of equivalents” and the new “statutory equivalents” focus is on protecting subject matter accused of infringement that lacks any substantial difference from a claimed invention.³⁹

³⁸ *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950) and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002)

³⁹ See *Actavis UK Limited and others v. Eli Lilly and Company* ([2017] UKSC 48) by the United Kingdom Supreme Court, <https://www.supremecourt.uk/cases/docs/uksc-2015-0181-judgment.pdf>, holding (at p. 25) that—consistent with the European Patent Convention—the United Kingdom recognized infringement via an equivalent of a claimed invention, given that two question could be affirmatively answered and a third question could be answered in the negative:

i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e., the inventive concept revealed by the patent?

ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

New § 271(a) is divided into three paragraphs. The first paragraph effectively reenacts 35 U.S.C. § 271(a). As reenacted, new § 271(a) contains each of the bases under which the repealed statute provided that activities might infringe a patent. In addition, new § 271(a) provides an explicit statutory reference to infringement based upon an “equivalent” to a claimed invention.

Paragraph (2) of new § 271(a) sets out the new statutory requirements for subject matter accused of infringing a patent to constitute an “equivalent” of a claimed invention. Under new § 271(a)(2), three specific requirements are set out for subject matter accused of infringement to constitute an equivalent to a claimed invention.

These three requirements appear in subparagraphs (A), (B), and (C). Each represents a separate element of proof that the patentee has the burden to establish for a statutory equivalence allegation of infringement to succeed.

Under subparagraph (A), an immateriality requirement is imposed. The immateriality requirement under subparagraph (A) provides that each element of the subject matter accused of infringement must differ in at most immaterial respects from at least one specific embodiment of the claimed invention that was disclosed in the specification, .e.g., through an example describing subject matter constructively or actually reduced to practice for some practical application. Equivalence may then be established for such a specific embodiment if the requirements under the definition provided in § 271(a)(3) for immateriality are met.

Under subparagraph (B), a separate requirement is set forth that requires the patentee to demonstrate that the subject matter alleged to infringe as a statutory equivalent could not have been patented based on the disclosure in the specification of the patent. Specifically, subparagraph (B) states that the subject matter alleged to infringe must not have been disclosed in the specification in the sense that a claim complying with the requirements under 35 U.S.C. § 112 could have covered such subject matter.

This requirement is established to preclude the possibility that unclaimed subject matter disclosed in a patent could be protected as a statutory equivalent. In effect, this item clarifies and simplifies a form of the “disclosure-dedication” rule currently applied by the courts.⁴⁰ If the patent specification’s disclosure provided a proper basis (sufficient disclosure under § 112) for a claim that would have constituted literal infringement of a claimed invention, then there is no possibility of infringement based on an equivalent that could have been so claimed.⁴¹

The final subparagraph bars any finding of statutory equivalence in the situation where the sole manner in which the subject matter accused of infringement could be found to literally

⁴⁰ See *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005), limiting the disclosure-dedication rule, “the public notice function of patents suggests that before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation.”

⁴¹ As noted above, this statutory requirement effectively supersedes any inquiry into the prosecution history to determine if a limiting amendment might estop reliance on statutory equivalents as a basis for an infringement allegation.

infringe would be based upon a claim that would not be found non-obvious over the prior art. Subparagraph (C) sets forth a standard for implementing this requirement by mandating that at least one claim that could meet the requirements under § 112 would need to cover the subject matter accused of infringement and be valid under 35 U.S.C. §§ 102 and 103 irrespective of whether an immaterially different element of the accused subject matter would have been novel as of the effective filing date of the claimed invention.

The standard for immateriality is set out in paragraph (3). It permits a finding of infringement even if there is a difference between the accused subject matter and the subject matter defined by an individual element of the claim. Where such a difference exists, it is immaterial when a corresponding element in the accused subject matter can be identified for each claim limitation and it can be shown that this corresponding element in the accused subject matter functions in substantially the same way to produce substantially the same result as the corresponding limitation set for in the claim.⁴²

The test under paragraph (3) enacts a statutory version of the “all-elements” rule under which all elements of a claimed invention must be found in subject matter accused of infringing a patent under the “doctrine of equivalents.”⁴³ If no element in the accused subject matter can be identified that corresponds to a limitation in the claim of the patent, the test for immateriality cannot proceed further and no infringement based on statutory equivalence can arise.

Under the second sentence of paragraph (3), for infringement through equivalency to be established, the patent specification of the patent cannot describe essential limitations on the claimed invention that would be inconsistent such a finding of equivalence. This limitation prevents the inventor from effectively disavowing in the specification that subject matter the asserted to infringe can be fairly regarded as an equivalent to the claimed invention.

Inconsistency could include, for example, a disclosure in the specification of the patent stating or implying that the equivalent, if practiced, might or would be inoperative or otherwise inconsistent with the teachings with respect to the claimed invention. In effect, a patent specification cannot teach one thing about the potential limitations on an invention and allow the patentee to subsequently assert as an equivalent subject matter that would be inconsistent with the reading of the patent specification by a person skilled in the art.

⁴² This standard was crafted to both reflect historic use of the function-way-result analysis under *Graver Tank*, and be consistent with international norms, e.g., the *Actavis v. Lilly* holding of the UK Supreme Court, “Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e., the inventive concept revealed by the patent.”

⁴³ The “doctrine of equivalents” includes an “all-elements” rule because “[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention” and “the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). In order to find infringement has taken place, “the doctrine of equivalents, by definition, recognizes that an element is missing that must be supplied by the equivalent substitute” *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1347 (Fed. Cir. 2013).

In certain respects, the requirement under the second sentence of new § 271(a)(3) is similar to the requirement under the patent laws of the United Kingdom where, if a patentee ... intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention,” infringement via equivalents is unavailable. However, § 271(a)(3) is specific that the new statutory “inconsistency” requirement depends wholly in a reading of the specification of the patent and is unaffected by any activity extrinsic to an ordinarily skilled artisan’s understanding of the teachings in the specification of the patent.⁴⁴

Under the last sentence of paragraph (3), foreseeability of the subject matter accused of infringement has no continuing relevance to any analysis for equivalency. To the extent the judicial “doctrine of equivalents” found any relevance in a foreseeability inquiry, any such holdings are legislatively overruled under § 271(a)(3).⁴⁵

The statutory equivalence provisions under § 271(a), entirely supersede the judicially created “doctrine of equivalents” and should provide a more predictable and fair remedy for the patent owner, while limiting any uncertainty for members of the public as to the full scope of protection secured under the patent. Importantly, the scope of protection under the patent—at least with respect to equivalents—should be discernable in its entirety from the specification of the patent, without the necessity of referencing the prosecution history of the patent.

SUBSECTION B: CERTAIN EXPERIMENTAL USES NOT PROTECTED BY PATENTS.

Section 271 of title 35, United States Code, is amended by inserting at the end:

“(j) EXPERIMENTAL USES OF CLAIMED INVENTIONS.— Notwithstanding subsections (a) and (g), it shall not be an act of infringement to make or use a claimed invention for experimental purposes to discern or discover—

“(1) the validity or scope of protection of a patent for the claimed invention;

“(2) any feature, property, characteristic, advantage, or dis-advantage of the claimed invention;

“(3) any method of making or using the claimed invention;

“(4) any alternative to, improvement to, or substitute for the claimed invention.”

⁴⁴ In this respect, the various holdings of the courts as they relate to “prosecution history estoppel” are overruled. See *Festo*, *supra*. While considerations relating to prosecution history were of some relevance to the judicially created “doctrine of equivalents,” the new statutory basis for infringement based on the equivalents of a claimed invention do not require reference to claim-limiting amendments made during prosecution history because the statute requires in subparagraph (3), as noted *infra*, that the statutory equivalents cannot extend to subject matter disclosed, but not claimed, including any subject matter that could have been claimed.

⁴⁵ See *Festo*, 535 U.S. at 738, where the Supreme Court opened the door to foreseeability being a bar to a finding of equivalence by stating that “[t]here is no reason why a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered.”

Subsection (b) amends 35 U.S.C. § 271 by adding a new subsection (j) to prevent a patent owner from enforcing a patent where the alleged acts of infringement constitute certain research or other experimental uses of an invention claimed in the patent. The exception in § 271(j) contains four separate categories of such uses. Each of these categories is set out in terms that are broad enough to assure that patents cannot block access to the basic tool of science and technology. Taken together, the scope of the exception assures that patents cannot operate to frustrate their constitutional purpose to promote, rather than impede, progress in the useful arts.

The text follows closely the 2004 and 2006 recommendations of the National Academies of Science.⁴⁶ In general, § 271(g) creates an infringement exception that encompasses any philosophical or scientific inquiries where the object is gaining knowledge regarding the patented invention. Exemplary activities of this type include efforts to discover, identify or discern the (1) validity of the patent or the scope of protection afforded under the patent; (2) any features, properties, inherent characteristics, or advantages of the patented subject matter; (3) methods of making or using the patented subject matter; and, (4) alternatives to the patented subject matter. The latter can encompass any type of improvement or other alternative to the patented subject matter.

These exclusions are premised on the understanding that the public must be able to develop a complete understanding of the patented subject matter and be able to use that understanding to advance the useful arts, *e.g.*, by using the patent's disclosure as a starting point for making further discoveries. Without this freedom, a patent grant could be used to stop further progress in the useful arts during the term of protection afforded under the patent, inconsistent with the constitutional purpose of the patent system.

SUBSECTION C: NON-INFRINGEMENT PRIOR COMMERCIAL USES.

(1) In section 273 of title 35, United States Code, strike subsection (a) and insert:

⁴⁶ See *A Patent System for the 21st Century*, Stephen A. Merrill, Richard C. Levin, and Mark B. Myers, Eds., Committee on Intellectual Property Rights in the Knowledge-Based Economy, Board on Science, Technology, and Economic Policy, Policy and Global Affairs, National Research Council of the National Academies (2004), <https://www.nap.edu/download/10976>, and more particularly *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*, Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation, National Research Council, National Academies of Science (2006), <https://www.nap.edu/download/11487>, at p. 14:

The committee believes that there should be a statutory exemption from infringement for experimentation on a patented invention.

Recommendation 10:

Congress should consider exempting research “on” inventions from patent infringement liability. The exemption should state that making or using a patented invention should not be considered infringement if done to discern or to discover:

- a. the validity of the patent and scope of afforded protection;
- b. the features, properties, or inherent characteristics or advantages of the invention;
- c. novel methods of making or using the patented invention; or
- d. novel alternatives, improvements, or substitutes.

“(a) IN GENERAL.—An alleged infringer shall be entitled to a defense under section 282(b) with respect to subject matter that would otherwise infringe a claimed invention if such person, acting in good faith before the effective filing date of the claimed invention, commercially used the subject matter in the United States or completed substantial preparations for such use, either in connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use.”

(2) In section 273(e) of title 35, insert at the end:

“(6) DILIGENCE REQUIRED.—Substantial preparations for commercial use of subject matter of a claimed invention shall be deemed to have been completed under subsection (a) only if prior to the effective filing date of the claimed invention —

“(A) diligent efforts had commenced and thereafter continued in the United States until the commercial use of such subject matter was accomplished and

“(B) the activities relied upon to demonstrate completion of substantial preparations were carried out in the United States and constituted the preponderance of the investments required to accomplish the commercial use of such subject matter.”

Subsection (c) makes two amendments to 35 U.S.C. § 273. First, it repeals § 273(a) and then replaces it with a new subsection that makes three substantive changes to the repealed subsection. Second, it adds a new paragraph to § 273(e) addressing diligence issues in asserting the defense. Both these amendments are designed to simplify the ability to qualify for the defense of prior commercial use under § 273 and to adopt aspects of the defense that are more consistent with international norms.

New § 273(a) permits assertion of the defense against a claimed invention of a patent if, before the effective filing date of the claimed inventions, substantial preparations for commercial use of the claimed invention had been completed by the accused infringer asserting the defense. Under new § 273(e)(6), two specific requirements are set out for determining whether substantial preparations for commercial use have been completed. First, commercial use must have commenced following diligent efforts that began in the United States before the effective filing date of the claimed invention and continued in the United States until the commencement of the commercial use. Second, whatever United States activities are relied upon in demonstrating completion of substantial preparations must have constituted the preponderance of the investments required for commercialization.

In addition, new § 273(a) allows the defense to be asserted against any claimed invention in a patent. The former limitation of the defense to a claimed invention “consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process” has been eliminated.

Finally, the 1-year “hold back” provision and the reference back to the date of public disclosure of a claimed invention⁴⁷ have been eliminated from new § 273(a). The defense under the amended subsection now follows the international norm of utilizing the effective filing date of the claimed invention as the reference point for the assessing whether an alleged commercial use or preparations therefor qualify for the defense.

These amendments assure that technology can be commercialized free from patent infringement in situations where a business has completed either commercial use or substantial preparations for commercialization in the United States before a potentially infringed patent related to the technology was initially sought. The remaining constraints on the defense will continue to apply. Thus, the defense remains strictly limited such that (1) the accused infringer asserting the defense must demonstrate its actions were in good faith, (2) the accused infringer must itself have originally created the technology eventually patented by another, (3) clear and convincing evidence must be marshalled to establish entitlement to the defense, and (4) attorney fees can be recovered whenever the defense is unreasonably asserted.

SUBSECTION D: CONFORMING AMENDMENTS.

In section 271 of title 35, United States Code—

(1) In subsection (b), after “(b)” insert “INDUCED INFRINGEMENT.—”.

(2) In subsection (c), after “(c)” insert “CONTRIBUTORY INFRINGEMENT.—”.

(3) In subsection (d), after “(d)” insert “LIMITATION ON INFRINGEMENT FINDING.—”.

(4) In subsection (e), after “(e)” insert “ADDITIONAL ACTS OF INFRINGEMENT.—”.

(5) In subsection (f), after “(f)” insert “COMPONENTS OF CLAIMED INVENTIONS.—”.

(6) In subsection (g), after “(g)” insert “PROCESS PATENTS.—”.

(7) In subsection (h), after “(h)” insert “STATE-RELATED ACTIONS.—”.

(8) In subsection (i), after “(i)” insert “OFFERS FOR SALE.”.

Subsection (d) provides a set of conforming amendments. These amendments provide descriptive subsection titles for subsections (a) through (i) of 35 U.S.C. § 271.

⁴⁷ The limitation found in § 273(a)(2)(B), referencing “the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b)” was designed to eliminate a basis for qualification for the prior commercialization defense for someone that did not originate the patented technology, but derived it from the inventor’s public disclosure. Thus, this provision was redundant in view of § 273(e)(2), “A person may not assert a defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.”

Section 7. Technical Clarifications.

(a) DOMESTIC PRIORITY CLARIFICATION.—In section 119(e)(1) of title 35, United States Code, strike “by an inventor or inventors named” and inserting “naming the inventor or a joint inventor”.

(b) JOINT INVENTORS CLARIFICATION.—In sections 112(a) and 291(b) of title 35, United States Code, strike “or joint inventor” and insert “or a joint inventor”.

(c) APPLICATION DISCLOSURE CLARIFICATION.—In section 112(a) of title 35, United States Code, strike all that follows after “same”; in section 282 of United States Code, strike “, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable”; and in section 119(e)(1) of United States Code, strike “(other than the requirement to disclose the best mode)”.

Section 7 makes three technical clarifying amendments to title 35. Two of the amendments correct the text of 35 U.S.C. § 119(e)(1) and 35 U.S.C. § 291 to conform these sections to the amendments made under the America Invents Act elsewhere in title 35. The third amendment removes vestigial text from title 35 relating to the so-called “best mode” requirement that subsequent to the America Invents Act no longer serves any remaining function, *i.e.*, no longer has any bearing on the validity or enforceability of an issued patent.

Section 8. Effect and Effective Date.

(a) EFFECTIVE DATE.—This Act shall have effect upon enactment except as otherwise provided under this section.

(b) EXCEPTION FOR FIRST-TO-INVENT PATENTS.—The amendments made by Section 3(b) of the Act shall not apply to a patent unless it is subject to section 102 of title 35, United States Code, as amended by the Leahy-Smith America Invents Act (Public Law 112–29; 125 Stat. 284).

(c) EXCEPTION FOR PATENTS ISSUED BEFORE ENACTMENT.—Sections 2, 3, 4(a), and 6 of the Act, and the amendments made therein, shall not have effect with respect to a patent issued before the date of enactment if the patentee provides written notification to the Director within three months from the date of enactment that these sections and the amendments made therein shall not apply to the patent. Within 10 days from the date of enactment, the Director may publish a notice setting out any requirements as to form and content that shall apply to a patentee giving notice under this subsection.

(d) EXCEPTION FOR EXTANT CIVIL ACTIONS.—Sections 2, 3, 4(a), and 6 of the Act, and the amendments made therein, shall not

have effect with respect to any civil action brought to enforce a patent before the date of enactment.

(e) EXCEPTION FOR PATENT APPLICATIONS FILED BEFORE ENACTMENT.—The amendments made by Section 4(b) and Sections 5(a) and 5(b) of the Act shall not apply to any application for patent filed before the date of enactment.

(f) EXCEPTION FOR POST-ISSUANCE REVIEW PROCEEDINGS INSTITUTED BEFORE ENACTMENT.—The amendments made by Section 4(c) and Section 5(c) of the Act shall not apply to any proceeding under chapters 30, 31, or 32 or section 251 of title 35, United States Code, instituted before the date of enactment.

Section 8 provides for effective date and effect for Sections 2-7 of the Act. In general, the Act takes effect upon enactment under Subsection (a). The only exceptions to the immediate effect of the Act are set out in Subsections (b) through (f).

Under Subsection (b), the enforcement-related provisions of Section 3 relating to enforcement-linked patents exclude first-to-invent patents from applicability thereto. Only certain first-inventor-to-file patents are subject to this provision.

Under Subsection (c), several sections of the Act are not applicable to patents issued before the date of enactment if the patentee provides written notice to the Director within three months from the date of enactment electing that such subsections of the Act will be inapplicable. The sections of the Act for which these opt-out provisions are applicable are Sections 2, 3, and 6 and Subsection (a) of Section 4 relating respectively to patent eligibility restoration, non-statutory double patenting, infringement via equivalents, experimental uses, prior domestic commercial uses, and misconduct-based unenforceability.

Under Subsection (d), the provisions of Sections 2, 3 and 6 and Subsection (a) of Section 4 are rendered inapplicable to any civil action for infringement pending as of the date of enactment. Under Subsection (e), Section 4(b) and Section 5 relating to patent application disclosures and patent examination are rendered inapplicable to applications filed before the date of enactment. Under Subsection (f), the amendments made by Section 4(c) is rendered inapplicable to post-grant review and inter partes review proceedings instituted before the date of enactment.