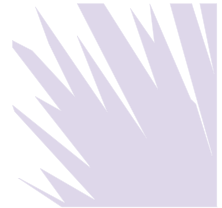


America Invents Act: The 5 New Post-Issuance Procedures

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AMERICA INVENTS ACT: THE 5 NEW POST-ISSUANCE PROCEDURES

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AUTHOR'S NOTE

Patent reform legislation has been before Congress since 2005 and has gone through many permutations and iterations as the political winds and developments in the courts have buffeted and shaped the proposed legislation. The law, America Invents Act, was finally passed on September 9, 2011, and signed into law on September 16, 2011 by President Obama. In the tradition of The Sedona Conference® on Patent Litigation of being on the cutting edge of the law, this legislation has been selected for deep dialogue on the first day, October 13, in the 2011 conference. This paper addresses the 5 provisions of the legislation that involve post issuance proceedings of a patent before the United States Patent & Trademark Office. The 5 provisions are in addition to a modified form of the current *ex parte* reexamination proceeding that continues forward from the current reexamination system. This paper subscribes to a neutral Swiss approach of presenting all sides of an issue and does not advocate for any particular view so that full and deep dialogue may ensue. Several of the authors devote substantial portions of their practices to the current reexamination procedures and/or the patent interference procedures in place at the PTO and have tapped into that experience in the preparation of this paper. However, the views expressed herein are for purposes of Sedona dialogue and do not necessarily reflect the individual views of the authors.

¹ Sterne, Ellison, Holoubek and Sterling are with Sterne, Kessler, Goldstein & Fox, PLLC, and Hadad and Spalding are with Bristol-Myers Squibb Company. The views expressed do not necessarily reflect the authors, their organizations or clients.

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I. INTRODUCTION

This paper addresses the post issuance provisions of the America Invents Act (“AIA”). There are 5 new provisions along with an extension of the current *ex parte* reexamination process that the United States Patent and Trademark Office (“Office” or “PTO”) will now have to interpret and implement. To say this is going to be a daunting task for the Office and its stakeholders is an understatement. In addition to the very substantial staffing requirements that these provisions of the AIA impose on the Office, the new discovery procedures that are created put the Office into uncharted territories it has never been in before. Moreover, despite transitional periods in the AIA for implementation, the current *ex parte* and *inter partes* reexaminations ongoing at the Office, of which there are thousands, will still have to be completed under the current reexamination procedures. New rules will have to be drafted, published for comment, and implemented in order for the new provisions to go into action. It is thus clear to see that the Office needs all of the best advice and guidance it can get from the most informed segments of the patent community. It is fortuitous that this legislation was enacted just before the final preparation for the Sedona Patent Litigation Conference 2011 to allow this paper and the Sedona dialogue that it will support on October 13-14, 2011 to generate some initial guidance that the Office can use in its implementation and rule making process. We also thank Director Kappos for being on the faculty and for his sharing of initial Office views as well as Chief Judge James Smith for being a participant of this conference views.

II. POST-GRANT REVIEW AND *INTER PARTES* REVIEW

Following enactment of the AIA, the primary vehicles for litigating patentability at the PTO are the new Post-Grant Review (“PGR”) and *Inter Partes* Review (“IPR”) proceedings. PGR and IPR proceedings share many important similarities. But the key differences highlight the different roles they were envisioned to fill. For instance, PGR has a wider scope than IPR and appears to fulfill the role of immediate and proactive review of newly-issued patents that are of potential concern to competitors. Effective use of PGR will likely require close monitoring of pending applications and issued patents. IPR, on the other hand, is narrower in scope and appears to fulfill the role of the current *inter partes* reexamination (“IPX”) as a vehicle for accused infringers or corporate competitors to challenge patentability before the PTO.

A. Overview of Post-Grant Review (PGR) Under the AIA

Post-grant review (PGR) will provide a new mechanism for challenging patents before the Office, and it expands the grounds on which a petitioner may challenge patents. With this additional opportunity for challengers comes increased vulnerability and uncertainty for patent owners. It remains to be seen what effect PGR will have on the valuation, enforcement, and licensing of patents. Will the possibility of PGR make it more difficult for patent owners to obtain venture capital funding before the end of the window for PGR? Will PGR proceedings under the AIA become such a burden on patentees that they have the unintended effect of stifling innovation or job creation? How will the impact of PGR proceedings in the U.S. compare with the impact of opposition proceedings on patents outside of the U.S.? Undoubtedly, the creation of PGR proceedings will affect the business practices of patent owners and their competitors, as they seek to minimize risks and maximize opportunities created under the AIA.

1. Grounds for PGR

By statute, the time window for initiating PGR will be limited. A petition for PGR may be filed within nine months after (i) the date of grant of a patent or (ii) of the issuance of a reissue patent. However, if a patent is reissued outside of the first nine months after grant, PGR cannot be initiated with respect to claims that were narrowed or remained of the same scope in the reissued patent. Claims that were broadened in a reissue application will be eligible for PGR. Thus, a patent owner who contemplates seeking a broadening reissue patent within the first two years following grant of the patent should remain aware of the risk created by potentially reopening the door to PGR. Such a patent owner should ask itself whether the potential benefits of a reissue outweigh the risk of exposing the patent to an additional attack via PGR. The patent owner also should consider whether its objectives could be met by seeking *ex parte* reexamination of its own patent or by requesting supplemental examination.² A potential challenger of a patent that is reissued must be poised to seize the additional opportunity that arises upon reissuance of a patent. Prior to reissuance of the patent, the challenger should consider whether its objectives could be met simply by protesting the reissue application under Rule 291. Given the greater opportunity to remain involved in a PGR proceeding than in a protest, PGR would likely be the preferred option when it is available.

PGR proceedings can first be filed at one year after enactment of the AIA, i.e., on September 16, 2012. PGR will initially be available only for a limited subset of patents, namely (i) certain business method patents³ and (ii) patents that are involved in an interference as of the September 16, 2012 effective date. PGR will later become available for patents that issue from applications filed on or after 18 months after the date of enactment, i.e., so-called “first-to-file” patents issuing from applications filed after March 16, 2013. Given that it may take 3-4 years for such patents to issue, the floodgates for PGR will not be fully open until approximately 2016 or 2017. Gradually opening the door to PGR is probably good for all involved. Patent owners and their competitors will be able to learn from the Office’s treatment of the early PGR cases. And, the Office will have more time – although not a lot of time – to establish its policies and procedures relating to PGR, as well as to build its staff and infrastructure to handle PGR proceedings.

In considering the statute, one must wonder why Congress felt it important to apply PGR essentially only to “first-to-file” patents, rather than to all patents that are issued after the effective date. If PGR is meant to create a checks-and-balances system to guard against improperly issued patents, one might argue that a need for such a system exists even with “first-to-invent” patents. If, on the other hand, switching to a first-to-file system were expected to increase the need for post-grant scrutiny of patent claims, it would beg the question as to why switch systems.

What effect will the nine-month PGR window have on patent owners and their competitors? Corporate competitors and others who may wish to challenge a patent via PGR will have increased incentive to monitor prosecution of important patent applications and reissue applications so as not to “miss the boat” for PGR. Additionally, a patent applicant will have increased incentive to ensure that original prosecution of the patent includes a thorough examination of the application and full consideration of the art. During the first nine months post-issuance, some patent owners may be more hesitant to assert their patents than they would have been in a pre-PGR era, so as to minimize the

² For a discussion of supplemental examination, see Section V below.

³ For a discussion of the transitional proceedings relating to business method patents, see Section III below.

likelihood of becoming a target for PGR. If one finds that there is a spike in the number of patent infringement suits filed just after nine months post-issuance, such data would suggest that the possibility PGR has had a chilling effect on the initiation of district court litigation. Potential infringers, on the other hand, may have increased incentives to engage in licensing discussions early on in the life of a patent or prior to issuance of the patent. Armed with information as to whether reasonable licensing terms may be available, the potential infringer can then factor such information into the calculus for determining whether to seek PGR.

PGR opens the door for challenging patentability on any ground for invalidity. Additionally, the AIA will allow PGR to be instituted to resolve novel or unsettled legal questions that are important to other patents and applications. Thus, PGR will be an attractive option for many would-be challengers.

a. PGR Based on Unpatentability

Under the AIA, a petitioner may request to cancel as unpatentable one or more claims of a patent on any ground for invalidity under 35 U.S.C. §282. Thus, PGR not only permits attacks based on prior art patents or printed publications, but it also permits attacks based on, for example, non-statutory subject matter, lack of enablement, lack of written description, lack of utility, prior public use, or prior sale or offer for sale. Accordingly, patents that fail to claim statutory subject matter or that fail to comply with the utility requirement will be vulnerable to challenges via PGR. Additionally, a reissue patent can be attacked as being improper under 35 U.S.C. §251. This new mechanism for attacking patents at the Office may, for example, lead to an increase in challenges to patents that fail to meet *Bilski's* test for patent-eligible subject matter. As the Federal Circuit and the Supreme Court address statutory subject matter and other legal requirements, PGR will undoubtedly become a vehicle to challenge patents based on recent refinements in the law.⁴

The AIA also provides that patentability may be challenged under any requirement of section 112 except for failure to disclose the best mode. Thus, unlike in current reexamination practice, a challenger will be able to directly nullify patent claims based on lack of enablement or lack of an adequate written description.⁵ The ability to challenge patent claims based on lack of enablement may be particularly attractive for competitors in the life sciences, rather than in the electrical or mechanical arts, because of the perceived higher level of unpredictability in the life sciences. The creation of PGR proceedings may incentivize patent applicants in the life sciences to obtain more scientific data prior to filing a patent application, in order better to shield against a §112 attack. On the other hand, with the shift to a first-inventor-to-file system, such an applicant may be willing to risk the §112 attack so as not to become the second-inventor-to-file. Additionally, certain patents in the life sciences are particularly prone to attack for lack of an adequate written description, e.g., patents that seek to claim a genus of compounds by describing their function without adequately describing their structures. Such patents will be attractive targets for attack via PGR. While patent reexaminations have been more prevalent in the electrical and mechanical arts than they have been in the life sciences arts,

⁴ PGR undoubtedly will become a tool for forcing modification of Office examination practice on a new point of law as an outgrowth of a PGR of a particular patent. Thus, the petitioner will be acting as a "private attorney general" urging change in examination practice and procedure that sidesteps PTO rule-making procedures.

⁵ In reexamination practice, a requester may argue that the patent claims are not entitled to an earlier priority date on the grounds that the earlier application fails to satisfy the requirements of § 112. The requester may then cite intervening prior art patents or publications that form the basis for the requester's proposed rejections. Similar priority attacks will likely be acceptable in PGR. Following claim amendments, a petitioner can also challenge the amended portion of claims or new claims under § 112.

PGR may become the post-issuance tool of choice for competitors in the life sciences, in view of the additional grounds for attacking patents.

PGR can also be initiated on the ground that the patent fails to comply with any requirement 35 U.S.C. §251. Thus, a petitioner may challenge a reissue patent on the ground that it is a time-barred broadening reissue patent. Section 251 also recites other requirements, e.g., that there was an error in the patent. Will a petitioner be able to challenge patentability on the ground that there was no such error?⁶ More generally, will the bases for challenging patents as unpatentable in PGR *identically* align with the bases for challenging patent validity in district court?⁷

b. PGR based on a novel or unsettled legal question that is important to other patents or patent applications.

Under the AIA, PGR will also provide a forum in which the Office can bring clarity to novel or unsettled legal questions that are important to a number of patents or patent applications. Thus, PGR can be initiated when a patent presents a novel or unsettled legal question. Because the AIA identifies such questions as an “additional ground” for instituting PGR, beyond the unpatentability bases discussed above, PGR opens up a whole new avenue for initiating a post-issuance challenge to a patent. It remains to be seen what will constitute such a novel or unsettled legal question that warrants PGR. Must the petitioner establish that at least one claim is unpatentable, even though the question of law is unsettled or novel?⁸ Will the resolution of such a question lead to cancellation of the involved patent claims? Or will such resolution have only a prospective effect on future patents or applications? Should any form of compensation be provided to a patent owner who had complied with all existing laws but whose patent was subjected to PGR on this basis? One might argue that the answer should be “no,” because the patent is presumptively valid and enforceable in district court. On the other hand, will a court be more likely to stay a litigation that involves a patent that has the “cloud” of a novel or unsettled legal question hanging over it?

The AIA indicates that the novel or unsettled legal question must be important to other patents and applications. But this provision begs the question of how many other patents or patent applications must be affected by resolution of the novel or unsettled legal question. What metrics will the Office use in defining the scope of PGR challenges that can be instituted under this aspect of the AIA? How will a petitioner establish that the legal question is important to other patents and applicants? Additionally, does this provision in the AIA inherently and inadvertently give the Office the authority to *create* new law in the process of resolving such novel or unsettled legal questions? If resolution of the legal question is important to a number of other patents and applications, should the Office resolve the issue even if the involved parties settle the PGR? Although the AIA seeks to bring clarity to the law by providing for PGR on this basis, the current lack of guidance as to how this provision in the AIA will be applied leaves uncertainty for all involved.⁹

6 A tactical question is how will such evidence be adduced from the patent owner?

7 Of course two critical questions are whether the Office will use the same claim construction and burden of proof standards as used in district court?

8 Undoubtedly the Office implementing rules will require specificity to support such bases, otherwise it will be pleaded as a standard catch-all in all petitions.

9 Since the Director of the PTO and the Director of Patents are members of the new Patent Trial and Appeal Board (PTAB), they will have opportunity to directly control this decision-making. Thus, the question of how will the Solicitor's Office fit in to this process will need to be addressed.

2. *Instituting PGR*

In response to a petition for PGR, a patent owner may file a preliminary response, explaining why PGR should not be instituted. Such an explanation may be based on the failure of the petition to meet any requirement of the statute relating to PGR. Will the Office consider such a preliminary response in determining whether to initiate PGR? The AIA states that PGR will be instituted if the Director determines that the information presented in the petition, *if such information is not rebutted*, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.¹⁰ If a patent owner files a preliminary response, will the Office simply ignore it before deciding whether to institute PGR? If the Office does review the preliminary response before instituting PGR, how can the Office adequately apply the “if-not-rebutted” standard for deciding whether to institute PGR? Because a preliminary response is optional, a patent owner must decide whether to file one. Assuming the Office will consider such a response before instituting PGR, there will be significant incentives for patent owners to file the response, hoping that PGR will not be instituted. On the other hand, if the response is merely placed in the file for later consideration, a patent owner may be less inclined to file the preliminary response. Such hesitancy may be based on a concern against prematurely taking a position in the case, e.g., with respect to claim construction, prior art or novel legal theory.

The Office’s decision whether to institute PGR is final and non-appealable.¹¹ Additionally, the Office may consolidate multiple PGR proceedings into a single review. What parameters will the Office use to determine whether to consolidate multiple reviews? How will the Office juggle such multi-party “PTO litigation” so as to ensure justice for all involved parties and the public?¹²

3. *Impact of PGR*

Because PGR may be initiated on numerous grounds that do not form the basis for challenging patents in reexamination, PGR will likely be an attractive mechanism for challenging patents. PGR may shift more litigation away from district courts and to the PTO. An advantage of such PTO litigation is that the challenger does not need to meet the standing requirements of a U.S. district court. For some companies, this ability to nullify a patent at an early stage – before the company continues to invest substantially in a project – may provide a strong incentive to engage in PTO litigation. Will such an incentive be greater in the biotech and pharmaceutical areas than it is in other technical areas, because the research & development and regulatory costs for bringing a new biotech or pharmaceutical product to market can be enormous and must generally be incurred before a justiciable case or controversy arises?¹³

How will the ability to petition for PGR affect licensing discussions? During the time window for PGR, a patent owner may be hesitant to be overly aggressive in its efforts to out-license its patent in view of a concern that a potential licensee will petition for PGR.¹⁴ Conversely, a potential licensee should bear in mind the possibility of petitioning

10 Everyone is keen to know how the Office will define this threshold standard.

11 This makes administrative sense except perhaps for the novel legal theory basis.

12 It can be argued that the Office must expand the discovery and hearing process in a linear fashion based on the number of granted petitions, otherwise due process will not be met.

13 Some speculate that the dominant players in specific electronic channels may become early adopters of a PGR strategy as a way to control the IP of that channel.

14 Some argue that blanket or package licenses will not be allowed to contain prohibitions against the use of PGR of future issued patents by the petitioner.

for, or threatening to petition for, PGR in response to aggressive licensing tactics, or in anticipation of such aggressive tactics. Just as “pocket” reexamination requests sometimes are used to pressure the patent owner to agree to more generous licensing terms, “pocket” PGR petitions may be used. Moreover, PGRs can be settled more easily than reexaminations, and because they can be settled without creating an estoppel, a potential infringer will likely be more inclined to petition for PGR than it was to seek *inter partes* reexamination. Will the ability to petition for PGR and settle PGR proceedings lead to more PTO litigation involving patents held by non-practicing entities (NPEs)? An NPE who skillfully runs an out-licensing campaign without creating declaratory judgment jurisdiction may nonetheless find its patent increasingly vulnerable to attack at the PTO.¹⁵

4. Impact on Litigation

To a limited degree, the AIA seeks to control and clarify the relationship between PGR and other proceedings. The bases for this legislative construct is the real concern not to repeat the creation of the “parallel universe” that currently exists between district court and USITC enforcement and concurrent reexamination. For example, PGR may not be instituted if, before filing for PGR, the petitioner (or its real party in interest (RPII)) filed a civil action “challenging validity of a claim of the patent.” Will PGR be precluded even if the claims that are challenged in the civil action differ from those challenged in the PGR petition? A patent owner would likely argue that the answer is “yes” and that the petitioner must pick one of the two forums in which to fight. Indeed, if the petitioner or its RPII files a civil action on or after the date of filing a petition for PGR, the civil action will be automatically stayed for a period of time. Unlike a civil action challenging validity, an action asserting non-infringement or unenforceability will not preclude PGR. Similarly, a counterclaim of invalidity does not preclude PGR. Finally, a patent owner who wishes to obtain a preliminary injunction against an accused infringer is incentivized under the AIA to file suit shortly after issuance of the patent. If the suit is filed within 3 months of the grant of the patent, and if the patent owner moves for a preliminary injunction, the AIA precludes a court from staying its consideration of the motion for preliminary injunction on the basis that PGR has been sought or instituted. Will this three-month provision incentivize patent owners to bring suit quickly after issuance of a patent?¹⁶

B. Overview of Inter Partes Review (IPR)

Patents that are eligible for *inter partes* review (IPR) are those that issued before, on, or after September 16, 2012. Thus, unlike in *inter partes* reexamination (IPX), patents that issued from applications filed prior to November 29, 1999, will be included among the patents eligible for IPR.¹⁷ Additionally, the universe of patents that are eligible for IPR is larger than the universe of patents that are eligible for PGR, which mostly is limited to first-to-file patents and certain business method patents. The time window for filing a petition to institute PGR opens upon the later of (i) nine months from issuance of the patent or (ii) the date of termination of a PGR on the patent. Although widespread use of the PGR may not be feasible until around 2016 or 2017, as discussed above, IPR may be widely used as soon as it becomes available on September 16, 2012.¹⁸

15 This “nuclear winter” approach against NPEs is currently being used in reexaminations, especially *inter partes* reexaminations. Whole portfolios are being subject to reexamination. One can legitimately ask if such strategy should be condoned by the Office and allowed to occur in PGR?

16 The high standard to obtain a preliminary injunction of an unlitigated patent will undoubtedly deter the use of this provision, even though on paper it has the appearance of protecting the rights of the patent owner.

17 This will undoubtedly decrease the use of *ex parte* reexamination by third-party requesters.

18 In drafting this legislation, Senate staffers were concerned if they were opening a flood gate of IPRs after September 16, 2012. Time will tell if this was fact or fiction.

C. Comparison of Inter Partes Review (IPR) with Other Proceedings

Savvy companies need to stay on top of troublesome patents that are about to issue. Why? Unlike in PGR, a petitioner in IPR can challenge patentability only on a ground that can be raised under 35 U.S.C. §§ 102 or 103 and only on the basis of prior art patents and printed publications.¹⁹ If the best arguments against patentability arise under § 112, 101, etc, a challenger would be remiss if it missed the nine-month deadline for PGR. However, if one has missed the PGR deadline, or if the troublesome patent is not eligible for PGR, IPR may remain the best option. Additionally, if a petitioner wants to reserve certain invalidity arguments under §112 or §101 for use in a later district court action, it may wish to utilize IPR rather than PGR in view of the estoppel provisions of the AIA.

The main challenge with IPR – for now – is simply uncertainty. IPR brings with it a new standard for initiation, and the contours of this new standard have yet to be shaped by the adversarial process. While IPR will replace *inter partes* reexamination (IPX) from September 16, 2012, the Office has begun applying the IPR threshold to order IPX for requests filed after September 11, 2011.²⁰ With this shift in standard, we have ventured into waters that are somewhat uncharted.

To initiate IPR, the information presented in the petition must show that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition. Will it be easier or harder to meet the “reasonable likelihood of prevailing” standard than it was to meet the “substantial new question of patentability” (SNQ) standard that was previously used in IPX and which continues to be used in *ex parte* reexamination (EPX)? Does the new standard simply constitute a distinction without a practical difference?

Under the new standard, there is no need for a “new” question of patentability. But has that really changed the standard? Perhaps not! It is clear that an IPR petition can be based on art previously considered during original prosecution. But it would be difficult to convince the Office to initiate IPR by making bare assertions that the original Examiner erred in his or her analysis. Thus, as a practical matter, a petitioner will need to bring something “new” to the patentability analysis. In considering the IPR standard, what exactly does “prevail” mean? Does “prevail” mean that at least one claim must be rejected? Or cancelled or substantially amended? If the phrase “reasonable likelihood that the petitioner would prevail” amounts to the establishing that the Office should issue a rejection, the AIA does not significantly change the burden on the third-party challenger. In IPX, a third party requester would propose rejections over the prior art, with the hope that the PTO would adopt such rejections. In IPR the petitioner will have a similar burden to establish unpatentability of the challenged claims. In unusual instances in IPX, the petitioner established that there was an SNQ and the PTO ordered reexamination without adopting any of the proposed rejections. Under IPR, it seems that such unusual instances would be avoided, since the challenger effectively must establish unpatentability before the proceeding will be instituted.

Will potential patent challengers be inclined to wait and see how the Office handles IPX requests filed under the new IPR-like standard before deciding to initiate IPX or wait to initiate IPR? A potential challenger to a patent should ask itself whether it is

¹⁹ This parallels the basis for instituting the current IPX with the changes brought under the new first-inventor-to-file regime.

²⁰ As of the date of this paper at the end of September 2011, the Office has not yet issued guidelines for this new standard.

better off challenging a patent under IPX or under IPR. In making such a determination, the potential challenger should bear in mind that, beginning on September 16, 2012, the patent owner that potentially faces IPR will be given a chance to file a preliminary response to the petition for IPR. Thus, the patent owner will be able to provide reasons why no IPR should be instituted, and the Office must consider such a preliminary response before determining whether to institute IPR. In view of the shifting standards, some competitors may delay filing IPX until they get a sense for the new IPR-style standard, but then rush to file a request for IPX before the patent owner gains the right to file a preliminary response and before IPX proceedings disappear in favor of IPR proceedings.

A patent owner's response to a petition for IPR is optional. Should the patent owner always rush in? It may be that the patent owner can convince the Patent Trial and Appeal Board ("PTAB") that the petition is not reasonably likely to prevail, thus precluding initiation of the IPR: a great outcome for the patent owner. But what if the Office initiates IPR regardless of the patent owner's preliminary response? The response may have characterized the invention or the art in a way that can come back to needlessly disadvantage the patent owner later in the IPR or in another proceeding.

Once the switch to IPR happens, the Director has the authority to impose a limit on the number of IPRs that may be instituted during each of the first 4 years of implementation. The limit can be reached if the number of IPR implemented in each year equals or exceeds the number of *inter partes* reexamination requests filed in the last fiscal year (2010) ending before the effective date of the act.²¹ We believe that limit will be around 270. How will the Office impose the limit? What will happen to petitions on file that have not yet been implemented when the limit is reached? Will the Office publish the limit with a running total of petitions filed to date so potential petitioners can keep track? Or will the Office just let the public know when its limit has been reached, with no warning?

D. Impact of IPR on related litigation and vice versa

1. Civil action filed first, then IPR

IPR may not be instituted if, before the date on which the petition is filed, the petitioner or real party in interest filed a civil action challenging the validity of the patent. Here, it seems that the AIA seeks to ensure that a petitioner who first challenges the validity of a patent in a civil action cannot have two bites at the same apple in different forums. Of course, one party's filing of a civil action would not preclude a second party from challenging the same patent via IPR. Thus, a patent could still face multiple challenges in different forums. In addition, a civil action challenging the enforceability of a patent or asserting non-infringement has no impact on the filing of an IPR.

IPR cannot be sought more than one year after the date on which the petitioner, its real party in interest, or a privy of the petitioner has been served with a complaint alleging infringement of the patent. Thus, when IPR replaces IPX, it may foreclose the option for a PTO-based *inter partes* proceeding for defendants that are involved in suits in which the complaint was served prior to September 16, 2011. If the defendants to such suits wish to participate in an *inter partes* proceeding at the PTO, they should consider requesting IPX before September 16, 2012, provided the patent is eligible for IPX (i.e.,

²¹ This was done by Congress to make sure the PTO would be able to staff up for an unanticipated level of IPR filings. Time will tell if this IPR limit will be exceeded in the first 4 years, but with the current level of IPX filings, the limit may in fact be a big issue.

patents filed on or after November 29, 1999). So, certain defendants wishing to pursue an *inter partes* challenge at the PTO must file a request for IPX before September 16, 2012, or risk losing the option altogether. Because IPX can be based only on prior art patents and printed publications, a diligent challenger should be able to prepare its IPX request while it remains an option. Likewise, a defendant served with a complaint for patent infringement after September 16, 2011, may utilize IPR as of September 16, 2012, even for patents filed *prior* to November 29, 1999. Thus, under the AIA, accused infringers will be able to initiate *inter partes* PTO challenges to an earlier class of issued patents than they previously could, since IPR does not impose date restrictions on the patents that can be attacked. The accused infringer must remember to seek IPR within one year of service of the infringement complaint. Again, a potential challenger must stay on top of such deadlines so as not to miss out on an opportunity to engage in PTO litigation.

An accused infringer who wishes to petition for IPR within one year of being served with a patent infringement complaint may find that it has its hands tied. As discussed above, IPR cannot be instituted until after the later of nine months from issuance of the patent or the conclusion of PGR. Conclusion of the PGR proceeding may not occur until after expiration of the one-year period for seeking IPR after having been served with a complaint. Should such an accused infringer seek to be joined in any ongoing PGR if the time window for doing so is still open? Some would say “no” and that the accused infringer should just save its defenses for the civil action. Others would encourage the accused infringer to seek to be joined because of the differences in standards and technical sophistication in the PTO versus district court.

2. IPR filed first, then civil action

If a petitioner first challenges a patent in an IPR proceeding, once the IPR petition is filed, if the same petitioner then files a civil action challenging the same claims on validity, the civil action will automatically be stayed until (i) the patent owner moves the court to lift the stay; (ii) the patent owner files a suit or counterclaim alleging that petitioner infringes the patent; or (iii) the petitioner moves the court to dismiss the civil action. It is not stated what, if any, burden the movant must meet in order to convince the court to lift the stay. Is a simple request sufficient or will the court require more? Also, how might this standard differ between courts? In any event, the AIA seeks to limit the petitioner’s ability to attack the patent in multiple forums.

E. Issues Common to PGR and IPR

With new options available for post-grant challenges to patents before the PTO, a potential challenger must carefully balance the pros and cons of each available option. For example, if one’s best arguments rely upon prior art patents and printed publications, rather than §112, one should consider waiting for the IPR window to open, rather than petitioning for PGR? However, doing so is not without risk. If one waits, another party may come along and petition for PGR in the interim, thus likely pushing back the date on which IPR could be initiated. If such a date is pushed back too far, a defendant in a patent infringement suit may find that it will miss out of the opportunity to seek IPR (because of the requirement that IPR be initiated within one year of service of the complaint). Additionally, the AIA appears to give the PTO broad authority, in considering whether to institute EPX, PGR or IPR, to consider whether the same prior art or arguments previously were presented to the Office. What parameters and criteria will the PTO consider in determining whether to refuse instituting or ordering a proceeding? What recourse, if any,

will a dissatisfied petitioner have? In any event, a potential challenger likely should not assume that a proceeding it seeks to initiate will necessarily move forward at the PTO. In view of the heavy workload that the PTAB is expected to face, one must wonder whether it will freely exercise its statutorily granted authority to refuse to institute proceedings that raise old art and arguments.

1. Administrative considerations

The fee for filing a petition for PGR has not yet been set. By statute, the fee must be in an amount that the Director determines is reasonable when considering the aggregate cost of the PGR. It would not be surprising if the fee for PGR were to be similar to the fee for *inter partes* reexamination, which is currently \$8800 per request. While such a dollar amount is one of the highest fees paid to the PTO, it is modest compared with the overall costs including attorney's fees of challenging a patent via *inter partes* reexamination or compared with what the overall costs for PGR are likely to be. Moreover, the PTO is still grappling with the huge problem of fee diversion not having been stopped in the AIA. However, in setting the fee for PGR, the PTO will need to consider the costs of hiring and training an adequate corps of Administrative Patent Judges (APJs) to handle this new proceeding. Whether the PTO will be able to handle the increased workload brought upon by PGR remains to be seen and it remains one of the biggest areas of concern for practitioners. Already, the PTO has announced that it seeks to hire 100 new APJs who have a combination of professional and technical qualifications, e.g., bar membership along with a technical degree and comprehensive patent experience.²² In hiring new APJs, should the PTO maximize its talent pool by including APJs who work remotely? If so, would such telecommuting stifle communication between members of the three-judge panel adjudicating the PGR?

2. Decision on a petition to institute PGR or IPR

The Office must decide whether to institute a PGR or IPR within 3 months after receipt of the patent owner's preliminary response, or, if no patent owner response was filed, within 3 months of the last date upon which the response could have been filed. The AIA's lack of an explicit time period in which the patent owner must provide its preliminary response makes it unclear, for now, how long a petitioner will have to wait for a decision from the Office as to whether to initiate PGR or IPR. A time period of somewhere between 1-2 months seems reasonable for a patent owner's preliminary response; a patent owner currently has 2 months in which to file an optional patent owner's statement in EPX.

The Office's decision whether or not to initiate a PGR or IPR is final and not appealable. So what recourse does a petitioner have if PGR or IPR is not initiated? Like with IPX, can the petitioner request that the Director review the denial? What if PGR or IPR is sought for all claims, but the Office institutes it for only some? Can the petitioner appeal the decision on the non-rejected claims?

²² See, www.usajobs.gov, e.g., <http://jobview.usajobs.gov/GetJob.aspx?JobID=102560198&JobTitle=Administrative+Patent+Judge+%28Biotechnology%29&q=administrative+patent+judge&where=&x=0&y=0&cbid=3876&vw=b&FedEmp=N&FedPub=Y&AVSDM=2011-09-19+14%3a46%3a00> (last accessed September 27, 2011).

3. Joinder of Additional Parties

If a PGR or IPR is instituted, the Director has the discretion to join as a party to that proceeding any person who properly files a petition that the Director determines warrants institution of PGR or IPR. The AIA does not specify a time period by which the second or any additional parties must be joined. While joinder may make sense if the first proceeding has not moved too far along, we must wait to see if (and hope that) the Office takes a sensible approach here. Under the AIA, the PTO can adjust the time periods for making a final determination in a case if it has joined multiple parties in PGR or IPR. But will this provision of the AIA lead to multi-year, multi-party PGRs and IPRs? What is the likelihood that we will see multi-party PGR or IPR proceedings? In view of the estoppel provisions, would not a second potential challenger be inclined to be a “free rider” and hold off on bringing its own action?

4. Patentee’s Motion to Amend Claims

A patent owner may file, by right, only one motion to amend its claims during PGR or IPR. Such a motion may seek to cancel any challenged patent claim or propose a reasonable number of substitute claims for each challenged claim. Note, the patent owner has no right merely to amend claims, but instead has the right to file one motion to amend. What is the rationale behind making the patent owner *move* to cancel or substitute its claims? By requiring that such an amendment be made by motion, the AIA suggests a greater burden upon a patent owner who seeks to amend claims in PGR or IPR than in IPX, EPX or *ex parte* prosecution.²³ The AIA does not specify what would be a “reasonable” number substitute claims. The Act is clear that any amendment may not enlarge the scope of the claims or add new matter.

Once the patent owner has used its right to one motion to amend, additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of the IPR proceeding. Additional motions to amend the claims may also be permitted by “regulations prescribed by the Director.” Whether such regulations will exist and what form they may take, remains to be seen.

5. Discovery

IPR and PGR will both be adjudicated by the PTAB, and it is clear there will be discovery in both proceedings. However, the AIA has distinct differences in what discovery is available in each case.

Under the AIA, the Director must set forth standards and procedures for discovery of relevant evidence in both PGR and IPR. That discovery will be limited to evidence directly related to factual assertions advanced by either party during PGR. Thus, the AIA seeks to confine the scope of discovery to something narrower than what is available in a typical district court proceeding. In contrast, for IPR, discovery will be limited to (a) depositions of witnesses who submitted affidavits or declarations; and (b) what is otherwise necessary in the interests of justice. This contrasting language suggests that discovery could be broader in PGR than in IPR.

²³ This is one of the most controversial provisions of the AIA.

If interferences are any example, it seems likely that the PTAB will essentially limit discovery in IPR to depositions of affiants or declarants. Although additional discovery may be available in current interferences, the BPAI has generally been loath to grant it, begging the question as to whether the PTAB will similarly be unlikely to grant additional discovery. Parties to PGR or IPR might argue that the PTAB should be more liberal in granting discovery than the BPAI typically has been in interferences. In interferences, a dissatisfied party can seek judicial review in U.S. district court and seek additional discovery in that tribunal. In contrast, a party dissatisfied with the outcome of PGR or IPR has recourse only at the CAFC and thus will not have a further opportunity for discovery and to build the administrative record. It is difficult to imagine that discovery will be granted at the Office as leniently as it is in district court. But if it were, that would seem to defeat one of the purposes of PGR and IPR, *viz.* to provide a forum for litigating the patent at less expense and greater speed than in district court.

For IPR, discovery will be limited to (a) depositions of witnesses who submitted affidavits or declarations; and (b) what is otherwise necessary in the interests of justice. With regard to (b), it will be interesting to see what may be deemed to be “otherwise necessary in the interests of justice.” If interference practice is illuminating, then, for the reasons discussed above for PGR, option (b) will provide little, if any, avenue to obtain discovery.

With regard to (a), the Office may choose to mirror interference practice for depositions, for example, limiting objections in the same way as in an interference. Additionally, attorney-expert communications may also enjoy the same privilege afforded in interference practice. An automatic privilege, of course, fosters easier discussions with expert witnesses. It also prevents nit-picking discovery, or other minimally productive practices that arise from attempting to delve into attorney-expert discussions.

Will the PTAB style depositions like those in district court? Is a petitioner more likely for example to video depositions (a practice uncommon in interferences)? And if so, how likely is the PTAB to watch those videos? Again, will the PTAB impose time constraints on deposition length like the limits under the FRCP? Or will it follow interference practice where no such time limit exists? If the PTAB does choose to follow deposition practices akin to those of interferences, will a deposition only be for discovery purposes, or will it become part of the “trial record” as it is in interferences?

If PGR and IPR practice parallels that of interference practice, requests for discovery will be made by motion. Additionally, the AIA provides for the possibility of sealing evidence. How successfully can one seal evidence filed at the Office? What safeguards can the Office put in place?

6. Protective orders

Under the AIA, the Director must prescribe regulations providing for protective orders governing the exchange and submission of confidential information. What kind of protectable information might be relevant to adjudication of the PGR or IPR? Perhaps a patent owner will wish to provide sensitive business information that is germane to the issue of commercial success or other non-obviousness objective evidence. What protectable information might a petitioner wish to use in a PGR or IPR? Providing for protective orders represents a new paradigm for the PTO, which over the years has become increasingly transparent in its interactions. The provision for protective orders must be

carefully balanced against the public's need to understand the bases for confirming (or canceling or amending) the rights of a patent owner. From the public's perspective, such a need may be just as great, if not greater, during PGR or IPR than it is during original *ex parte* prosecution, because the stakes will generally be higher in PGR and IPR and the patent is of significant commercial importance. From the public's perspective, a patent owner or third party petitioner arguably should have to "pay the price" of playing the patent game by publicly disclosing the information that is relied upon for determining the patentability or unpatentability of the patent under review. The AIA states that the Director shall prescribe regulations ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d) of the AIA is made available to the public as part of the prosecution history of the patent. Such a provision seems to cut against widespread use of protective orders. However, from the patent owner's and challenger's perspectives, such protective orders may prove necessary to render the PTO a viable alternative forum to district courts for adjudicating patent issues.

7. Time limits for resolution of PGR or IPR

By statute, and with few exceptions, a final determination in PGR or IPR must be made within one year from institution of the proceeding. Where good cause is shown, the Director may extend the period for an additional 6 months. In situations in which multiple parties have been joined together into a single PGR, the Director may further adjust the time periods for making a final determination of the PGR. Many patent owners and potential challengers question whether the PTO will be adequately staffed to meet the one-year deadline in a manner that provides justice and due process to the involved parties and the public. Also, what will constitute "good cause" that will permit extension of the deadline by 6 months? Will the parties have the opportunity to argue that such good cause exists or will it be determined just by PTO fiat? The parties may find that there is a need for additional discovery or for the production of laboratory test results that takes time; perhaps such grounds constitute good cause. Will an extension of the final deadline allow for an extension of intermediate deadlines for obtaining discovery, or filing motions, oppositions, etc.? Will the one-year standard time limit for resolution of the case cause district courts to be more likely to stay a litigation pending resolution of the PGR or IPR than they have been to stay a litigation pending resolution of a reexamination? Such a short time for resolution of PGR and IPR suggests that the proceedings must move swiftly once they are initiated. Accordingly, an owner of a valuable patent in a competitive field should be prepared to face an attack immediately upon issuance of the patent. Such preparation may involve ensuring that the owner has a strong professional relationship with the inventor(s), retaining potential experts (who typically will be distinct from experts used in other related proceedings), and securing any additional evidence that may be germane to patentability (e.g., commercial success, unexpected results, etc.).

8. Estoppels

As with *inter partes* reexaminations, estoppels may arise in both PGR and IPR. The speed with which such estoppel arises is likely to be a significant factor in determining whether potential challengers are willing to utilize either new form of PTO litigation. The estoppel may arise against the petitioner, the real party in interest (RPII), or a privy of the petitioner. The estoppel may arise in later actions before the PTO, in civil actions in district court and/or in proceedings before the U.S. International Trade Commission ("USITC"). At the PTO, the petitioner, RPII or privy of a petitioner who institutes PGR or IPR of a claim that results in a final written decision may not request or maintain a

proceeding before the PTO with respect to that claim on any ground the petitioner raised or reasonably could have raised during the PGR or IPR. Given that the estoppel provision refers to grounds that *reasonably* could have been raised, and this language differs from the “raised or could have raised” standard used during *inter partes* reexamination, one must ask how the two standards are meant to differ. For example, could one have “reasonably” raised a prior art challenge based on a difficult-to-find, obscurely catalogued foreign dissertation or commercial document? If, during the course of a PGR, a petitioner uncovers through discovery information that may form the basis for challenging a claim on a ground not presented in its original petition, must the petitioner seek to raise the unpatentability ground at that time? If so, the petitioner risks running afoul of the estoppel? If not, arguably the petitioner reasonably could have raised the ground and would also create an estoppel.

Because written description and enablement, for example, cannot be challenged via IPR, unlike in PGR, an IPR petitioner is still free to challenge the patent in a later civil action based on invalidity for lack of written description, lack of enablement, lack of utility, prior public use, etc. The patent could also be challenged as unenforceable in civil litigation. Of course, non-infringement also remains as a defense in a civil litigation.

One interpretation of the plain language of the AIA is that the estoppel arises as soon as the PTO issues its final written decision, without consideration of any appeals. If such an interpretation is the correct interpretation, the estoppel would arise much sooner in PGR or IPR than it has in *inter partes* reexamination, where the estoppel arises only after all appeals are final. The AIA states that a petitioner “may not assert” in a civil action or at the ITC that a claim is invalid on any ground the petitioner raised or reasonably could have raised during PGR or IPR. Does this language preclude a petitioner from *maintaining* such a ground if it had previously been asserted? Note that the estoppel before the PTO precludes the petitioner from requesting *or maintaining* a proceeding before the PTO on such a ground. Thus, a petitioner may point to this difference in language to argue that the AIA does not preclude maintaining such a ground in district court or at the ITC. The speed with which the estoppel takes effect will be an important consideration for parties that contemplate seeking PGR or IPR. While the statute may be intended to preclude a petitioner from having two bites at the apple, potential petitioners will certainly seek to maximize their opportunity to make similar arguments in multiple forums.

Unlike in *inter partes* reexamination, the parties to PGR or IPR may file a joint request to settle and terminate the proceeding prior to the PTO deciding the merits of the proceeding.²⁴ Such settlement and termination of the proceeding will prevent any estoppel from arising as to the settling petitioner, its RPII or privies. It will be interesting to see whether such settlement provisions that preclude estoppel will lead to the increased use of PGR or IPR as negotiating tools, as compared with reexaminations. A party to *inter partes* reexamination had little incentive to settle once the reexamination “bomb” had been dropped, since the PTO typically would simply continue the reexamination as a *de facto ex parte* reexamination if the third party requester abandoned the case. Thus, potential third-party requesters of reexaminations sometimes showed up at the negotiation table with a reexamination request in their pockets (i.e., a so-called “pocket reexam”) to pressure the patent owner into offering more reasonable licensing terms. Will the possibility of settling PGR or IPR without estoppel make the potential petitioner more likely to file the petition rather than to keep it in his or her back pocket? Because the PTO will terminate settled

²⁴ This is a major change from current reexaminations which cannot be terminated by the parties unless the concurrent litigation has reached a certain point concerning the bases for the reexamination.

proceedings, provided that a final decision had not yet been made, one must wonder whether such settlements will be more likely to be collusive. Access to settlement agreements for PGR and IPR will be limited to Federal agencies and persons showing good cause. Should an agency such as the Federal Trade Commission review settlement agreements for PGR and IPR proceedings in high-stakes cases (e.g., as it does for ANDA litigations)? For PGR that is instituted based on a novel or unsettled legal question that is important to other patents, should a timely settlement between the parties lead to an automatic termination of the PGR? Would the public's interests be better served by continuing the proceeding to resolve the novel or unsettled legal question?

F. Parallels with Interference Practice

Interference proceedings likely provide the best paradigm for how PGR and IPR will be adjudicated. Interferences are contested cases that are adjudicated by the BPAI, the predecessor tribunal for the PTAB, which will adjudicate PGR and IPR. All three proceedings are held before a three-judge panel of Administrative Patent Judges (APJs). Most day-to-day proceedings in interferences are handled by one of the APJs, whereas the remaining two APJs typically do not become heavily involved until late in the proceeding.

In interferences, the APJs do not issue office actions the way that patent examiners do in *ex parte* prosecution or at the CRU. Rather, the APJs decide motions filed by the parties and consider oppositions and replies thereto. Because the AIA states that a patent owner may file a response to a petition after PGR or IPR has been instituted, and the patent owner may *move* to amend its claims, the statute suggests that PGR and IPR will also involve a process akin to motions practice used in interference proceedings. An additional similarity comes via the use of affidavits or declarations to provide factual evidence and expert opinions. The practice of filing such motions, oppositions and replies, supported by factual evidence and expert opinions, is routine in interference practice. In this regard, interferences can be very litigious in nature, and it seems likely that PGR and IPR will be similarly litigious.

The PTAB will likely look to interference practice as a model for obtaining and handling evidence. In interferences, the Federal Rules of Evidence apply, but the Federal Rules of Civil Procedure do not. It seems logical that PGR and IPR will be similar in this regard. But will the new corps of APJs be adequately trained to consider whether the evidence of record complies with the Federal Rules of Evidence? In interferences, evidence is almost never excluded from the record. Will the same be true in PGR and IPR? Will the APJs be adequately trained and sufficiently experienced to assess the credibility and reliability of competing witnesses? In nearly every PGR or IPR proceeding, one can expect that at least two well-credentialed experts will offer conflicting opinions. PGR and IPR will be viewed as viable alternatives to district court litigation only if the PTO handles the evidence it receives in a logical, just and predictable manner. Will depositions in PGR and IPR more closely resemble those in interferences or those in district court litigation? In interferences, there are notable constraints on communicating with the witness and on making objections. Will the PTAB impose similar constraints in PGR and IPR? Additionally, an entire interference proceeding is considered to be "trial," and there is rarely live testimony before an APJ. Instead, essentially all testimony is provided via a written affidavit or declaration, with subsequent cross-examination at deposition. Thus, depositions in interferences are not pre-trial exercises to prepare one for trial. Will depositions in PGR and IPR be treated in the same manner? Given the short timeframe for reaching a final determination in PGR and in IPR, it seems that it would be necessary to treat the entire proceeding as trial, just as it is in interference practice.

Just as in interferences, PGR and IPR will culminate in an oral hearing before the Board. Each party in an interference is typically allotted 20-30 minutes for presentation and questioning related to its entire case, which generally has played out of the course of the previous year.²⁵ Thus, an interference decision is founded heavily on the paper record provided to the Board. As with interferences, it seems unlikely that oral hearings in PGR or IPR will involve live testimony. Given the substantial time pressures the APJs will be under to resolve PGR and IPR proceedings, it seems unlikely that the PTAB will be able to allow lengthy hearings.

G. Conclusion

We are entering into a brave new world in which valuable patents will be subjected to new forms of post-issuance scrutiny at the PTO. As always, change brings uncertainty and uncertainty generally has a negative impact on business. As stakeholders in the patent system, we must work together to assist the PTO and courts in working through the myriad issues and unintended consequences that may arise in the wake of the AIA.

III. TRANSITIONAL PROCEEDINGS UNDER SECTION 18

Section 18 of the AIA provides a post-grant review proceeding specifically for certain types of business method applications. Proponents of Section 18 believe that the AIA will solve the problem of overly broad method patents that issued within the first several years after the Federal Circuit's 1998 decision in *State Street*.²⁶ At that time, proponents of the legislation argue, the PTO was still building its prior art databases and determining best practices to use in the examination of business methods. Combined with the PTO's allowance-friendly culture at the time, it is argued that the lack of readily available prior art resulted in a large number of business method patents being inappropriately issued. Opponents of Section 18 argue that the AIA singles out a certain area of technology for additional scrutiny using art that is unavailable to a petitioner in other types of post-grant review in an unprecedented manner. They argue that this goes against the traditional understanding that all patents carry equal weight. Further, due to the uncertainty surrounding patent enforceability, opponents argue that Section 18 essentially degrades business method technology to second class status and strips appropriately granted patents of their value.

Interestingly enough, even though Section 18 has been referred to by many as the "business method review" section, the Section 18 proceeding is actually limited to only a particular type of business method patent that affects a particular type of petitioner in particular circumstances. Section 18 is widely considered to be a "bailout" to the financial sector in response to the \$400 million judgment awarded to Data Treasury against large banks and other financial institutions who were accused of infringing its patents, even after reexamination of those patents.

If Section 18 was meant as to be an avenue for defendants to continue challenging patents that have already survived reexamination, then Section 18 will succeed in providing those defendants with yet another weapon in their arsenal for attacking their accusers and

25 Some practitioners may argue that if the PTAB limits the oral hearing to such a short time, the essential nature of a fact-finding hearing will be lost and the parties will be deprived of their ability to put on their case in a full and complete manner. This arguably would undermine the whole purpose of these new proceedings. Thus, the PTO should create rules that foster full and complete hearings and not the super short interference-type hearings of the BPAI.

26 *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).¹ 35 U.S.C. § 257(a).

discouraging litigation by patentees. If Section 18 was intended to solve the bigger problem of overly broad and abstract business method patents, however, it likely does not achieve that goal because of the narrow scope of patents that are actually eligible for the Section 18 proceeding. The following sections explore the eligibility requirements for a Section 18 proceeding, the grounds for which a Section 18 proceeding can be initiated, and Section 18's effect on litigation.

A. Eligibility for Transitional Proceeding

Indeed, when considering the large number of patents that are traditionally thought of as “business method patents,” the patents that can actually be reexamined via a Section 18 proceeding are a small subset of that group.

1. Petitioner qualifications

To use the Section 18 proceeding, a petitioner must meet a stringent set of requirements. First, the petitioner must have been sued for infringement of the patent, or at least charged with infringement under that patent. It is unclear where the line will be drawn regarding who has been “charged with infringement.” At one end of the spectrum, “charged with infringement” may mean that a petitioner has been served with process, even if the actual civil action has not yet been filed. At the other end of the spectrum, “charged with infringement” may simply mean that a petitioner has been threatened by a patentee's implication of infringement, similar to the current standard for finding a basis for a declaratory judgment action.

Assuming that the petitioner meets that first hurdle, the availability of the proceeding also depends on whether the petitioner started the battle, or was just brought into the battle by virtue of the lawsuit. That is, to use a Section 18 proceeding, the petitioner cannot have filed a civil action challenging the validity of the patent. For example, if the petitioner filed a declaratory judgment action against the patent holder, the Section 18 proceeding would not be available to the petitioner. The Section 18 proceeding *is not* barred by a counterclaim challenging validity, though, so a defendant in a lawsuit is not required to choose between the Section 18 proceeding and pursuing what is often an important defense in the co-pending infringement suit.

2. Timing qualifications

Section 18 of the AIA goes into effect on September 16, 2012 (one year from the date of enactment), so the procedure is not available to petitioners before that date. Section 18 also includes a sunset provision, meaning that it will expire on September 16, 2020 (8 years from the effective date), unless Congress extends this provision.

Even if the petitioner meets the requirements for filing a Section 18 proceeding, a Section 18 proceeding cannot be requested when a PGR procedure is available to the petitioner. As discussed above, PGR is available for all patents for the first nine months after a patent issues, and any issue provided for by paragraphs (2) and (3) of section 282(b) can serve as the basis for the post-grant review. Given the wide scope of PGR, Congress is clearly trying to incentivize challenging a patent early on instead of later through a Section 18 proceeding. After 9 months have passed after issuance, though, a Section 18 proceeding may be instituted. Importantly, Section 18 applies to all issued patents, not just those that issued after the enactment date or the effective date of the AIA.

3. Applies only to a “covered business method patent”

Even if the petitioner meets all the qualifications set out by the AIA, and satisfies the required timing, the patent itself must meet its own set of qualifications in order for the petitioner to take advantage of the Section 18 procedure. For the 8-year period in which Section 18 proceedings will be available, any “covered business method” patent will be susceptible to this proceeding. This includes any patent that was already issued as of the effective date. For newly issued patents, as discussed above, the Section 18 proceeding will not be available for the first nine months after grant.

By far, the biggest question raised by the language of the Act is “what is a ‘covered business method?’” According to the Act, a “covered business method patent” is “a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.” This bears repeating: A covered business method patent is for an invention that involves data processing, but which is not considered to be a technological invention.

The AIA itself provides little guidance regarding what would be considered a data processing invention without being considered a technological invention. Perhaps recognizing the difficulties inherent in defining “a technological invention,” Section 18 leaves the definition up to the Director. Specifically, the Director is tasked with issuing regulations for determining whether a patent is for a technological invention. Congress takes the further step of distancing itself from any controversy as to how this definition might affect examination based on §101, remarking that “nothing in this section shall be construed as amending or interpreting categories of patent-eligible subject matter set forth under §101.”

It is unclear how the Director might define a technological invention, and it is likely that any definition will bleed over to applications under initial examination by the PTO, and affect how they are treated under §101. Traditionally in the PTO, a business method patent was considered to be any patent classified in class 705, which is defined by the PTO as “data processing: financial, business practice, management, or cost/price determination.” The specific definition given by the PTO for class 705 is “machines and methods for performing data processing or calculation operations in the: 1) practice, administration or management of an enterprise; 2) processing of financial data; or 3) determination of the charge for goods or services,” so this seems like a logical place to start. The Director could simply define a technological invention as any patent classified outside of class 705. Since a patent applicant likely cannot challenge the classification of a patent, such a solution offers a fairly impartial way of determining which patents will be subject to the Section 18 proceeding. Such a definition could lead to gamesmanship on the part of the patent applicant, though, who may try to draft the claims such that the application would be classified outside of class 705. For example, a patent applicant could focus the claims on a non-financial feature of the invention, causing the application to be classified outside of class 705, yet still claim financial aspects of the invention as secondary features. Further, the PTO has long recognized that some business methods are classified outside of class 705 anyway. These patents are typically not financial patents, but may prove unwise in the long term for the PTO to define something as broad and far-reaching as a “technological invention” without considering the definition’s effect on patents outside Section 18’s limited purview of financial services and products.

In another scenario, the Director may choose a definition of “technological invention” that follows the lines of 35 U.S.C. §101. That is, a technological invention may be defined as any invention whose claims satisfy the requirements of 35 U.S.C. §101. The PTO already has a set of factors in place for examining claims under §101, so both examiners and patentees would be advantageously familiar with such a standard. One difficulty with such a definition, however, is that the law around §101 is in flux and may be changed by the courts. It may be difficult, then, for a patent owner to predict whether its claims will be subject to a Section 18 proceeding or not. Even if the patent may not currently be susceptible to a Section 18 proceeding, a new court case related to §101 could change that susceptibility fairly quickly, if Section 18 availability depended on the interpretation of §101. Similarly, a Section 18 proceeding may begin when a patent is vulnerable under current laws, but there is a question of what would happen when the patent under review no longer presents an issue under §101 due to a change in the law. Additionally, it is questionable as to whether this would go against Congress’s stated intent of trying to limit the impact of Section 18 on 35 U.S.C. §101.

The PTO may also look to the European Patent Office as a model for defining technological inventions. In Europe, the term “invention” is interpreted to imply “a requirement of technical character or technicality to be fulfilled by an invention as claimed in order to be patentable. Thus, an invention may be an invention [under the European patent laws] if, for example, a technical effect is achieved by the invention or if technical considerations are required to carry out the invention.” (Decision of the European Patent Office Board of Appeal Case No. T0931/95, OJ 2001,441 (Sept. 8, 2000)). This definition is somewhat circular, however, in that it defines a technical invention using the word technical, which itself is prone to many interpretations. Additionally, the European Patent Convention has carved out a number of technologies as being non-statutory, including methods for doing business and programs for computers, so the question of whether they would be considered technical is never reached. Following the EPO, then, could be problematic since the EPO’s rules for patent eligibility are, at their core, different than the PTO’s standards.

It is possible that the PTO may consider simply returning to some version of the oft-maligned “technological arts test” for patent-eligibility that fell out of favor several years ago after the Board’s precedential decision in *Lundgren*. The Federal Circuit explicitly rejected the “technological arts test” in its decision in *In re Bilski*, but that decision was overturned by the Supreme Court, which did not explicitly discuss the technological arts test in its decision. Further, the change in the law could provide a springboard for reviving this test.

Of note is that the AIA does not make the Section 18 proceeding available for patents that are considered business methods but which do not involve data processing. Yet, these patents are the kinds that are most vilified by the public, and which give the term “business method” a bad name (e.g., a non-data-specific method of hedging risk).

To recap, if all patents that are traditionally seen as “business method patents” are identified as a set, a smaller set can be identified as “data processing” patents, leaving untouched the business method patents that do not include any type of data processing. A still smaller set of the data processing patents can be identified as relating to financial services or products, leaving untouched any data processing patent that does not have a financial component. Finally, the subset of financial data processing patents can be further split into technological financial data processing patents and non-technological financial

data processing patents. Section 18 is relevant only to that final subset of non-technological financial data processing patents. Although this subset is not insubstantial, the AIA still leaves a large swath of business method patents unaffected by Section 18.

There is the further question of when a business method patent can be categorized as being directed to a financial service or product. There are some patents that would clearly fall within this description, because they involve, for example, capturing and storing images of consumer checks to speed up processing by a bank. But there are a number of patents that may only tangentially claim some financial aspect. For example, would a method for advertising be considered a financial product or service, since advertising is ultimately directed to generating business for a company? Would a novel method of delivering data to a user over the Web be considered a financial product or service, simply because the data could include financial data? And where would patents related to the insurance industry fall? Would those be considered financial products or services for the purposes of Section 18? If a patent included both financial and non-financial claims, would the non-financial claim be excluded from reexamination under the Section 18 proceeding? One thing is clear – any ambiguity in the definition of a “covered business method patent” will likely result in defendants trying to apply the definition to patents outside the intended subject matter to take advantage of the effects Section 18 has on stays in related civil litigation, discussed in further detail below.

B. Grounds for Transitional Proceeding

Similarly to IPR, a Section 18 proceeding may be based only on the grounds of lack of novelty and obviousness. Despite the focus on business methods in Section 18, the Section 18 proceeding is not intended to address issues under 35 U.S.C. §101, although such issues can likely be raised if the claims are amended during the proceeding. The primary difference between IPR and a section 18 proceeding involves the prior art that serves as the basis for the proceeding.

The art available for IPR under the AIA includes patents and printed publications, much like the current requirements for *ex parte* and *inter partes* reexamination. In contrast, the availability of art in a Section 18 proceeding depends on the pre-AIA version of 35 U.S.C. 102(a). Specifically, Section 18 art includes art that is known or used by others in this country before the invention by the patentee, as well as patents and printed publications that were published in any country before the invention by the patentee. Under the new 35 U.S.C. 102, any printed publication available to the public prior to the filing date of the patent is considered prior art. So, any *printed* document that was available prior to the invention date (and thus the filing date) could be used to support a petition under the regular IPR proceeding. Given that printed publications are able to be handled under the regular IPR proceeding, it appears that Section 18 was included in the AIA to give defendants an opportunity to provide evidence of non-printed knowledge or use of the invention as support for reexamination of an issued patent.

For art that “disclosed the invention more than one year before the application filing date,” Congress opens the door further. Section 18 art can *also* include art that *would have been* described by the pre-AIA version of 35 U.S.C. 102(a) “if the disclosure had been made by another before the invention thereof by the applicant for patent.” There are a number of ways that this clause can be interpreted, because it is unclear which part of the sentence modifies the phrase “if the disclosure had been made.”

If the clause is read with emphasis on “if the disclosure had been made by another,” then the likely meaning of the clause is that the inventor’s own work can be used against him. If the inventor’s own written work was disclosed a year prior to the invention date (and thus the filing date), the art would be 102(b) art, and the regular IPR proceeding would apply. The Section 18 proceeding can therefore be supported by any non-printed disclosure by the inventor, such as an oral disclosure at a conference proceeding or a discussion the inventor may have had with friends regarding his development of the invention.

If the clause is read with emphasis on “if the disclosure had been made...before the invention,” then it is possible that a post-invention disclosure can be used as long as the disclosure was made more than one year before the filing date. Again, since a written disclosure by another would be considered 102(b) art and could be used in a regular IPR proceeding, this provision in Section 18 could be interpreted as allowing for a non-printed disclosure by someone other than the inventor to form the basis of the Section 18 petition, even if the disclosure was made after the date of invention. Section 18 does not provide any exception for derivation. So, if the inventor disclosed the invention to a third party under an NDA, and the third party violates the NDA by speaking openly about the invention, the third party’s actions could form the basis for a Section 18 petition if they took place more than a year before the patent’s filing date.

It is also possible that the primary emphasis could simply be on the phrase “if the disclosure had been made.” The “known or used” language in the pre-AIA version of 35 U.S.C. 102(a) has long been understood to mean “publicly known or used.” This portion of Section 18 clearly is intended to include art that would not traditionally have been considered prior art under 102(a). So, one interpretation of the new language is that secret, non-public use can also serve as a basis for a Section 18 proceeding. Such an interpretation would take the prior user defense a step further, rendering a patent invalid over secret use rather than simply acting as a defense to infringement.

For each of these interpretations there are, of course, questions as to how such prior art would be presented to the PTO. Since the art may not be printed art, some other mechanism must be used to put the art before the examiner in the initial petition. One option may be to include an affidavit or declaration, such as the current practice under 37 CFR 1.132. This raises the further questions of whether the declaration would need to be corroborated, what evidence would be required to support such a declaration, and whether the patentee would have any recourse to question the validity of the declaration, particularly if the declaration references secret knowledge or use that cannot be easily confirmed.

C. Effect on Co-Pending Litigation

A petitioner requesting a Section 18 proceeding would, of course, have to decide whether the proceeding fits into their overall litigation strategy, but the limitations on litigation imposed by Section 18 are not as stringent as those imposed by regular PGR or IPR.

1. Effects on ability to file civil actions

If a claim examined in a Section 18 proceeding is ultimately found to be patentable over the cited art, then the petitioner is prevented from raising in a civil action the same invalidity contentions that were raised in the Section 18 proceeding. Interestingly,

this is less limiting than the typical limitation on petitioners in a standard IPR proceeding. In a standard IPR proceeding, the petitioner is prevented from raising at trial any invalidity contention that *could have been raised* during the IPR proceeding. The Section 18 proceeding is thus less likely to endanger a litigation strategy than the typical IPR proceeding. Because the estoppel resulting from a Section 18 proceeding is less than that resulting from a regular IPR proceeding, a defendant may opt to request a Section 18 proceeding instead of the regular IPR proceeding when the patent is clearly a “covered business method patent.”

2. Effects on ability to stay civil action

In another departure from the typical IPR proceeding, the Section 18 proceeding changes the standards for how a court decides whether a civil action should be stayed pending review at the PTO. The AIA does not go so far as to actually require that the court stay the civil action pending the outcome of the Section 18 proceeding, but the factors to be considered – whether the trial date is set, whether discovery is complete, whether the stay will reduce the burden of litigation, etc. – could be interpreted as weighing more heavily in favor of a stay.

Section 18 also grants an immediate right of appeal on the issue – if a stay in a civil action related to a Section 18 proceeding is requested in a district court, the losing party can make an immediate interlocutory appeal to the Federal Circuit. The Federal Circuit is required take the appeal, and may review the issue *de novo*. Proponents of this feature argue that Section 18 provides a path to dispense with frivolous infringement suits in a cost-effective manner, because invalidating the patent at the PTO results in significant savings of time and money for both the courts and the parties to a lawsuit. Opponents of the legislation counter that a defendant may now file a frivolous Section 18 proceeding on questionable art that may or may not have been available at the time the patent was filed and examined, and in doing so may tie up a valid infringement suit for years by appealing a motion for stay submitted early in the litigation. Since there is little downside for a defendant who files a motion for stay as a delay tactic, opponents of the legislation worry that Section 18 will present such a serious barrier to patentees trying to enforce their patents that they will be discouraged from pursuing those infringers at all, thus denigrating the value of their legitimately held IP.

IV. DERIVATION PROCEEDINGS

The AIA replaces interference proceedings with so-called “derivation proceedings.” In a system that awards priority on the basis of filing dates instead of invention dates, inventive activity before to the filing of a patent application has little bearing on priority. Thus, interference proceedings are largely unnecessary. Derivation proceedings address the limited situation in which two applicants file for the same invention but the earlier-filing applicant derived the invention from the later-filing applicant. A strict application of first-to-file principles would award priority to the earlier-filing applicant, but derivation proceedings allow the later-filing applicant to prevail on the issue of priority.

Such priority disputes appear to be the only context in which derivation arises under the AIA. Previously, derivation was a prior art basis for invalidity but it no longer appears to be so. The AIA eliminates 35 USC § 102(f), which precluded anyone from patenting subject matter that “he did not himself invent,” i.e., subject matter derived from someone else. The invalidity defense of 35 USC § 102(f) was available to any accused

infringer, but derivation now becomes a matter strictly between the owners of competing patent applications.

A consequence of this change is that patents based on derived subject matter can be valid and enforceable. This will occur, for example, when “true” inventors either do not file a competing patent application or do not seek to institute a derivation proceeding. In such situations, the owner of a derived patent may block the public from practicing subject matter that he did not invent. Even true inventors may find themselves blocked from practicing their own inventions. This possibility might prompt inventors to file patent applications when they would otherwise forego patent protection.

A. Administrative Proceedings – Institution of Derivation Proceedings Involving a Pending Patent Application

Administrative derivation proceedings are governed by 35 USC § 135, which allows patent applicants to petition the U.S. Patent and Trademark Office (PTO) to institute a derivation proceeding. The petition must contain substantial evidence of the alleged derivation, including factual bases (1) for finding that an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner’s application, and (2) for finding that the earlier application was unauthorized. There is a strict time limit for filing such petitions – within one year of the first publication of a patent claim directed to the same invention or an invention that is substantially the same as the invention claimed in the earlier application. Depending on the regulatory implementation, this strict time limit may force later-filing applicants to sacrifice their provisional year of patent term in order to get a non-provisional application into a derivation proceeding. This will depend on whether “applicant for a patent” is interpreted to include the owner of a provisional patent application. If not included, such owners will have to file a non-provisional patent application early, thereby shortening their effective patent term in order to address a derivation issue.

Patent applicants bear the responsibility to identify competing patent claims and to prompt the PTO to institute derivation proceedings. The AIA does not authorize the PTO to institute derivation proceedings *sua sponte* as it currently may institute interference proceedings. Thus, patent applicants must monitor patent publications regularly in order to meet the one-year filing deadline. Otherwise, the opportunity for remedy via a derivation proceeding may be lost entirely. This creates a conundrum for the PTO when an earlier-filed application claiming derived subject matter is alleged prior art to a later-filed application, but it is too late for the later-filing applicant to petition for a derivation proceeding. Presumably, the later-filing applicant can overcome a prior art rejection by showing that the contents of the earlier-filed application was obtained directly or indirectly from an inventor on the later-filed application (see 35 USC 102(b)(2)(a)), but the PTO cannot issue two patents claiming the same subject matter. It is unclear how this possible scenario will be resolved under the AIA.

Upon receiving a petition under 35 USC §135, the PTO determines whether the standards for instituting a derivation proceeding are met. If it determines that the standards are met, the PTO “may” institute a derivation proceeding. The AIA’s use of “may” in lieu of a more definitive word appears to give the PTO discretion as to whether or not it institutes a derivation proceeding. Additionally, the AIA identifies at least two situations in which the PTO might defer taking any action on a petition. First, when two pending patent applications are at issue, the PTO can defer action on a petition until three months

after one of the applications issues with claims directed to subject matter of the petition. Second, when the earlier-filed case is an issued patent that is involved in ex-parte reexamination, inter-partes review or post-grant review, the PTO can defer action on a petition until such other proceeding is terminated. In both of these situations, and perhaps in others, deferrals help the PTO to preserve its resources until a derivation issue is ripe. To accomplish this result, a deferral may mean waiting to institute a derivation proceeding or even suspending a derivation proceeding that is already in process.

The PTO's determination about whether to institute a derivation proceeding is final and non-appealable. Thus, it appears that petitioners who disagree with a PTO determination in that regard have no recourse to the courts.

B. Administrative Proceedings – Conduct of Derivation Proceedings and Remedies Available

When the PTO initiates a derivation proceeding, the PTAB determines (1) whether an inventor named in the earlier application derived the claimed invention from an inventor named in the petitioner's application, and (2) whether filing of the earlier application was unauthorized. The AIA does not define what it means to "derive" an invention. In an interference proceeding, a party alleging derivation had to prove both a prior conception of the claimed invention and an enabling communication of the invention to the accused party. Whether the same requirements will apply in derivation proceedings is currently unknown.

The AIA also does not set forth detailed procedures for the conduct of derivation proceedings, but charges the PTO to prescribe regulations setting forth standards for conducting derivation proceedings. The standards shall include requiring parties to provide sufficient evidence to prove and rebut a claim of derivation. Presumably, they also will address the types and extent of discovery available for obtaining evidence. The effectiveness of derivation proceedings will heavily depend on the quality of PTO regulations governing them.

If the PTAB determines that derivation occurred, it may correct the inventorship on any application or patent at issue under "appropriate circumstances." Additionally, it may reject or cancel patent claims that cover derived subject matter. A final decision of the PTAB, if adverse to the claims in a pending patent application, will constitute a final refusal of those claims by the PTO. A final decision of the PTAB, if adverse to the claims in an issued patent will constitute cancellation of those claims, unless appeal or other review of the decision is possible. In those cases where the claims in a patent are cancelled, future copies of the patent will contain notice to that effect.

It is interesting to consider what might be "appropriate circumstances" for amending inventorship rather than canceling/rejecting the derived claims. In every derivation proceeding, the prevailing party will have its own patent application. Canceling or rejecting all the derived claims will allow the prevailing party to pursue its own claims in its own patent application. Of course, intervening prior art or some other validity issue may mean that claims to the derived subject matter are not be patentable in the prevailing party's later-filed application. That would be one reason for amending inventorship on the earlier-filed application. However, the result might be joint ownership of the amended patent – a result neither party really wants.

C. Administrative Proceedings – Settlements and Arbitration

With respect to settlements and arbitration, the AIA treats derivation proceedings much the same as interference proceedings previously were treated.

Parties to a derivation proceeding may settle and terminate the proceeding. To do so, they must file a written statement reflecting their agreement as to the correct inventors of the invention in dispute. Unless the PTAB finds the agreement to be inconsistent with evidence of record, it will accept the agreement and take action consistent with it. At the request of either party, the PTO will treat a settlement agreement as confidential information, keep it separate from the file of the involved patents or applications, and make it available only to government agencies or persons showing good cause.

In lieu of a proceeding before the PTO, parties may submit their dispute to arbitration. Arbitration proceedings are governed by Title 9 of the U.S.C. and any specific regulations promulgated by the PTO. Parties involved in arbitration must give notice of any arbitration award to the PTO, and such award shall be dispositive of the relevant issues, as between the parties. However, the PTO still has authority to determine any issues of patentability relating to the claimed inventions.

D. “Appeal” to District Court

As was the case with interference proceedings, a party dissatisfied with a decision of the PTAB in a derivation proceeding may seek remedy in district court. Thus, 35 U.S.C. § 146 is amended to refer to the PTAB instead of the former Board of Patent Appeals and Interferences and to refer to derivation proceedings instead of interferences. Other than those substitutions, the substance of 35 U.S.C. § 146 is unchanged.

E. Court Proceedings – Derivation Proceedings that Involve Issued Patents Only

Derivation proceedings that involve only issued patents (i.e., that do not involve a pending application) are handled by the federal courts and are governed by 35 U.S.C. §291. According to that statute, the owner of a patent may seek relief in a civil action against the owner of another patent that claims the same invention and has an earlier effective filing date, if the invention claimed in the other patent was derived from an inventor of the invention claimed in the first patent. Such cases are expected to be rare. The law is designed to preclude multiple patents claiming the same invention, so this will occur only in the event of a PTO error.

As with administrative proceedings, there is a strict time period for bringing an action under 35 U.S.C. §291 – within one year after issuance of the first patent to contain a claim to the allegedly derived invention and to name as an inventor someone who allegedly derived the invention. Thus, patentees need to monitor the patent literature regularly. Otherwise they risk losing the opportunity to seek a remedy via derivation proceeding.

A result of patentees missing their opportunity to invoke a derivation proceeding is that two patents claiming the same invention will exist. Not only will the patent owners be subject to each other, but the public will be subject to two different patent holders. This result is contrary to public policy because it drives up cost and limits access to patented technology.

F. Patent Term Adjustments for Successful Derivation Proceedings

Delays in the issuance of a patent caused by derivation proceedings will give rise to a patent term adjustment. 35 USC § 154 governs such adjustments and is unchanged except for the substitution of derivation proceedings in place of interference proceedings.

V. SUPPLEMENTAL EXAMINATION

Supplemental examination permits a patent owner to request that the PTO “consider, reconsider, or correct information believed to be relevant” to a granted patent.²⁷ If the submitted information does not raise a “substantial new question of patentability,” or the patent is deemed valid over the information at the close of the proceeding, the defense of inequitable conduct cannot be raised in a subsequent litigation unless certain exceptions are met. This new post-grant proceeding provides an opportunity to improve the quality of issued patents and, by doing so, improve and streamline the litigation process.

Following a brief review of the legislative background around Supplemental Examination, this paper will provide an overview of the statutory language and potential practice issues that may emerge following implementation.

A. Legislative Background

While the AIA follows from several bills introduced in the House and Senate over the last six years, an early public discussion linking patent quality enhancement goals of the legislation with inequitable conduct reform was presented in the Supplemental Comments by Senator Hatch accompanying the Committee Report upon introduction of S.515 during the 111 Congress. These comments recognized that the “inequitable conduct defense is frequently pled, rarely proven, and always drives up the cost of litigation” and that there is “virtually no downside for the infringer to raise this type of defense, even if it lacks a true basis.” The comment further acknowledged the over-disclosure of prior art to the PTO and the counterproductive effect that has on quality patent examination, and that “anything an applicant does to help an examiner focus on the most relevant information during examination becomes the target of an inequitable conduct challenge in court.” The comments conclude that inequitable conduct reform has the “potential to single handedly revolutionize the manner which patent applications are prosecuted” and “will have the most favorable impact on patent quality, and will give the PTO the ability to reduce its pendency, thereby fostering a strong and vibrant environment for all innovation and entrepreneurship.”²⁸

On March 4, 2010, a bipartisan group of Senators announced they had agreed to the details of a Manager’s amendment to S.515. These changes included the introduction of the Supplemental Examination provision designed to “permit the patent holder to provide additional, potentially material prior art regarding the patent to the PTO. If the PTO considers the information and determines that it has no effect on patentability, that additional information cannot serve as the basis for an inequitable conduct claim later in court.”²⁹

²⁷ 35 U.S.C. § 257(a).

²⁸ Senate Judiciary Committee Report on S.515 (May 12, 2009).

²⁹ Senate Press Release, Leahy, Sessions, Hatch, Schumer, Kyl, Kaufman Unveil Details of Patent Reform Agreement, March 4, 2010.

On January 25, 2011, the “Patent Reform Act of 2011,” which included the Supplemental Examination provision, was introduced in the Senate and it passed on March 8, 2011. The corresponding House bill, H.R. 1249, was introduced in June 2011. The House Judiciary Report provides further insight into the goal of supplemental examination:

The Act addresses the inequitable conduct doctrine by authorizing supplemental examination of a patent to correct errors or omissions in proceedings before the Office. Under this new procedure, information that was not considered or was inadequately considered or was incorrect can be presented to the Office. If the Office determines that the information does not present a substantial new question of patentability or that the patent is still valid, that information cannot later be used to hold the patent unenforceable or invalid on the basis for an inequitable-conduct attack in civil litigation.³⁰

The final House Bill passed on June 23, 2011, and included an amendment to the supplemental examination relating to the PTO’s discovery of fraud during the supplemental examination process.

B The Supplemental Examination Request and Procedure

35 U.S.C. § 257 (a) provides the basis for requesting supplemental examination.

Request for Supplemental Examination- A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish. Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability.

One significant difference between supplemental examination and existing post-grant proceedings is the scope of information that may be considered by the PTO. The statute confirms that information that was not previously submitted may be “considered,” that previously submitted information may be “reconsidered” presumably in a new context or given potentially greater significance, or that information may be “corrected.” The scope of information considered is far broader than the “patent and printed publications” limitation of *ex parte* reexamination, and appears intended to encompass any information believed to be potentially relevant to the patent.

Accordingly, in addition to the traditional submission of prior art publications, patent holders may request supplemental examination of, *e.g.*, positions taken in co-pending or related foreign prosecution that may be considered inconsistent with positions taken in the original examination, statements made in the specification, prosecution or declarations that are unclear, were erroneous at the time of filing, or have been subsequently established to be incorrect based on new data, and/or any other information that could potentially be considered relevant during subsequent litigation. It is difficult to envision

³⁰ House Judiciary Report on H.R. 1249, Dated June 1, 2011.

information that would not be considered an appropriate basis of a supplemental examination request under this standard.

The scope of information is also broader than allowed via existing reissue proceedings, which require that the patent owner admit that the patent is “deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent.”³¹ While this requirement has been recently construed in a liberal manner in *In re Tanaka*, 640 F.3d 1246 (Fed. Cir. 2011) with respect to adding additional claims, patent holders are hesitant to admit to a defect, and the scope of review is relatively limited to defects in the specification or claims.

The PTO is required to review the submitted information and complete the supplemental examination within three months of receiving a request. The supplemental examination shares the “substantial new question of patentability” standard with *ex parte* reexamination, and the procedure concludes with the PTO issuing a certificate confirming whether the submitted information meets this standard. 35 U.S.C. § 257 (b) provides the basis for the potential *ex parte* reexamination procedure following supplemental examination.

(b) Reexamination Ordered - If the certificate issued under subsection (a) indicates that a substantial new question of patentability is raised by 1 or more items of information in the request, the Director shall order reexamination of the patent. The reexamination shall be conducted according to procedures established by chapter 30, except that the patent owner shall not have the right to file a statement pursuant to section 304. During the reexamination, the Director shall address each substantial new question of patentability identified during the supplemental examination, notwithstanding the limitations in chapter 30 relating to patents and printed publication or any other provision of such chapter.

If the submitted information meets the substantial new question of patentability standard, there is an ensuing *ex parte* reexamination that differs from current procedure in two ways. First, there is no limitation to patents and printed publications given the broader scope of information that may be submitted to the PTO for consideration, reconsideration, or correction during the supplemental examination. Second, since the patent holder initiates this proceeding, there is no opportunity for a patent owner statement following the determination that there is a substantial new question of patentability but preceding a first office action on the merits during the reexamination.

According to the USPTO statistic as of June 30, 2011, the PTO grants 92% of *ex parte* reexamination requests. It remains to be seen whether this trend will continue when considering this broader category of information in supplemental examination requests, or whether a significant number of patents will emerge from the supplemental examination within three months of the request without a full reexamination procedure.

31 35 U.S.C. § 251.

C. The Effect of Supplemental Examination On A Subsequent Inequitable Conduct Defense

35 U.S.C. § 257(c)(1) confirms the effect of the supplemental examination process on subsequent litigation.

IN GENERAL- A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.

Thus, the same information considered during supplemental examination cannot be used a basis for an inequitable conduct defense. This potential bar on the inequitable conduct defense following supplemental examination is a further distinction from existing post-grant procedures. The Federal Circuit has held that the submission of information during reexamination or reissue does not bar a subsequent inequitable conduct defense based on that information.³² When a patent owner submits information for consideration by the PTO during reexamination or reissue, there is an effective admission of the materiality of this information. Even if a patent is maintained as valid by the PTO, this admission could be used in subsequent litigation as part of an inequitable conduct defense designed to render an otherwise valid patent unenforceable. This possibility discouraged patent owners from submitting information and addressing issues in the PTO, and instead incentivized patent owners to “take their chances” in court. The supplemental examination process appears designed to encourage patent owners to seek PTO review by removing concerns surrounding the potential admission and providing an incentive through this inequitable conduct bar.

D. The Exceptions to the Inequitable Conduct Bar

There are two exceptions to the inequitable conduct bar triggered by supplemental examination. The first exception is set forth in § 257(c)(2)(A):

(A) PRIOR ALLEGATIONS- Paragraph (1) shall not apply to an allegation pled with particularity in a civil action, or set forth with particularity in a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv)(II)), before the date of a supplemental examination request under subsection (a) to consider, reconsider, or correct information forming the basis for the allegation.

Accordingly, the inequitable conduct bar will not apply to information pled with particularity in a civil action, or set forth with particularity in a “Paragraph IV certification letter” submitted pursuant to the Hatch-Waxman Act, before the date of the supplemental examination request.

³² See, e.g., *Bristol-Myers Squibb Company v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003).

35 U.S.C. § 257(c)(2)(A) encourages a patent holder to initiate supplemental examination significantly prior to a time when it can receive information from potential infringers as to their substantive defenses in either a civil action or during the Hatch Waxman process. At a minimum, a patent holder could initiate supplemental examination three months prior to litigation, and hope the PTO finds no substantial question of patentability, prior to receiving any substantive allegations in a pleading or Paragraph IV certification. More likely, patent holders will initiate supplemental examinations several years prior to initiating litigation to take into account the potential *ex parte* reexamination process should a substantial question of patentability be found.

However, since subsection (A) applies to information pled with particularity in a civil action, it is possible that declaratory judgment action could trigger this exception and thus provide a certain degree of uncertainty as to when a supplemental examination should be filed. The situation is different for Paragraph IV certifications. Declaratory judgment actions cannot be filed during the Hatch-Waxman process. Moreover, the timing of these certifications is generally predictable, *e.g.* four years following FDA approval of a new chemical entity, with litigation following within forty five days after, so a pharmaceutical patent holder would have more clarity as to the timing for initiating supplemental examination.

In both instances, the “information” would have to be “pled with particularity,” which suggests the standard for pleading fraud under Fed.R.Civ.P. 9(b). The Federal Circuit recently clarified the standard for pleading inequitable conduct with particularity in *Exergen Corp. v. Wal-Mart Stores, Inc.*,³³ and one possibility is that courts will adopt aspects of this standard in analyzing whether the “information” was pled with particularity in a sufficient way to trigger the 35 U.S.C. § 257(c)(2)(A) exception.

The second exception to receiving the inequitable conduct bar is set forth in § 257(c)(2)(B):

(B) PATENT ENFORCEMENT ACTIONS- In an action brought under section 337(a) of the Tariff Act of 1930 (19 U.S.C. § 1337(a)), or section 281 of this title, paragraph (1) shall not apply to any defense raised in the action that is based upon information that was considered, reconsidered, or corrected pursuant to a supplemental examination request under subsection (a), unless the supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which the action is brought.

Accordingly, the bar will also not apply as a defense raised in a patent infringement or ITC action brought before the conclusion of the supplemental examination/reexamination proceeding. This provision appears designed to discourage patent holders from initiating supplemental examination shortly before or during litigation, regardless of whether the relevant information was provided by the defendant. Based on the reference to 35 U.S.C. § 281 and Section 337, this exception is limited to actions brought by the patent holder, rather than declaratory judgment actions, and therefore the patent holder has some control on its impact. Given that the current average pendency for an *ex parte* reexamination is about two years, however, it is likely that supplemental examinations will be brought significantly in advance of likely infringement if possible.

While these statutory exceptions are designed not to prejudice defendants during patent litigation, or from sharing their defenses, there are no other exceptions to the inequitable conduct bar following supplemental examination. Accordingly, information provided by third parties in other post-grant proceedings in the PTO will not trigger this exception, nor would information provided in the context of licensing negotiations, or ex-US litigation/administrative proceedings. It remains to be seen whether the potential for such information to be used in a supplemental examination will reduce the pre-litigation sharing of information between parties.

E. PTO Regulations, Transition & Disciplinary Power

The PTO shall issue regulations establishing fees relating to supplemental examination, and governing the “form, content, and other requirements” of the supplemental examination request, and procedures for reviewing the information submitted in such requests.³⁴ This section takes effect upon expiration of the one year period beginning on the date of the enactment of this Act, and shall apply to any patent issued before, on or after that effective date.³⁵ Presumably, the PTO will issue regulations during that interim period.

If the PTO becomes aware that a material fraud may be committed on the Office in connection with the patent that is the subject of the supplemental examination, then in addition to the other actions that the PTO is authorized to take, included cancellation of claims found invalid under section 307, the PTO shall also refer the matter to the Attorney General. Such a referral would remain confidential unless a person is charged with a criminal offense in connection with the referral.³⁶ Moreover, the statute confirms that sanctions under the criminal or antitrust laws remain available, as well the ability of the PTO to investigate, regulate, and impose sanctions for misconduct before the PTO.³⁷

F. Conclusion

The *Therasense* decision should reduce the overuse of the inequitable conduct defense, and thus raises the question of whether the supplemental examination process will be broadly used to address this concern. However, in addition to the benefit of eliminating potential inequitable conduct allegations, patent holders also may find supplemental examination a helpful tool for enhancing patent quality, as it broadens the scope of information considered, and the ability of the PTO to consider, reconsider, or correct information, over previously existing procedures.

For example, a patent owner may become aware of information during product development, or during a pre-litigation review that was not apparent during the original examination process. Relevant prior art may have been cited in related prosecution, or statements in the specification, declarations, or prosecution history may now be considered incorrect or inadvertently misleading. Supplemental examination now provides a platform for patent holder to obtain PTO consideration of these potential concerns and emerge with a stronger patent prior to litigation. Moreover, patents owners are now incentivized to review their commercially important patents and seek supplemental examination where issues are identified during this review due to the inequitable conduct bar.

34 35 U.S.C. § 257(d).

35 35 U.S.C. § 257(c).

36 35 U.S.C. § 257(e).

37 35 U.S.C. § 257(f).

Another area where this tool may be particularly useful is in the context of patent licensing and acquisition. Small companies and academic institutions often rely on licensing or selling their technology to other companies for continued development and commercialization. Potential partners will perform extensive due diligence on the relevant intellectual property to ensure that sufficient exclusivity is provided to warrant the investment. It is not uncommon for these reviews to uncover potential defects in the relevant patent, which may in part be due to the limited resources and experience of the patent holder. Supplemental examination gives the patent holder and partners an option to consider where concerns are identified. Potential partners now have an alternative to simply refusing the opportunity when they become aware of a possible defect in a patent.

By encouraging patent owners to obtain stronger patents, the patent litigation process should be more narrowly focused on key validity and non-infringement issues, and provide more predictable results.

VI. CONCLUSION

This article shows the enormous complexity that the AIA brings to U.S. patent law. There are many unanswered questions, concerns and dilemmas both for patent owners and requesters. The PTO is faced with a daunting task of creating the new rules and regulations and staffing the new laws. The stakeholders in the patent community will need to master the strategy and tactics of this new regime as will the courts. But this is the new world and all will need to come to grips with how to live in it.

