

POST GRANT PATENT CHALLENGE PROCEDURES UNDER FIRE

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I. OVERVIEW

This paper explores the post grant patent procedures to attack patents now available in the context of increasing challenges to such procedures, including a pending Supreme Court attack that such procedures may be unconstitutional – a point squarely in focus through *Oil States Energy Services* that will shortly be argued on the merits at the Supreme Court. A legislative addition to the patent law is also proposed that would *add* the possibility of a pre-grant pre-examination patent challenge.

The increasing technologically complex world coupled with the proliferation of prior art in various forms such as through the internet make it imperative that the Patent Examiner is assisted in his task by third parties through filings, once largely *prior* to grant but increasingly filed *post* grant. See § II, *The Global Movement to a Post-Grant System*.

While the major patent granting authorities of the world over the past two generation have moved to a post-grant system of inter partes review, the United States system has been *too* effective in weeding out bad patents: There are now clear challenges to the post grant review system including the trial level in the *Restasis* case (creating a clever title transfer strategy seeking to avoid a Patent Office validity challenge) as well as in merits appeals at the Supreme Court in *Oil States Energy Services* (challenging the Constitutionality of post grant invalidation procedures) and *SAS Institute v. Matal* (a second but less important challenge to such procedures.). . See § III, *Post Grant Proceedings under Judicial Challenge*.

Post Grant Review – PGR – represents the most powerful weapon for a patent challenger at the PTO particularly for highly technical issues. *See § IV, The Narrow Filter of Post Grant Review.* This is particularly true for continuing applications with prior art publications intervening between parent and actual filing date. *See § IV-A, Special Situation of Continuation Patent Validity.* Yet, public statements criticizing this procedural tool fail to mention that it is used against less than one (1) percent of issued patents. *See § IV-B, One Decision for Every 600 Patents per Year.* The relative number of petitions are also seen to be going down as the patent bar becomes more sophisticated. *See § IV-C, Maturation of the Patent Bar.* At the same time, the *need* for post grant review continues to be important as third party patent challengers act to weed out bad patents, thereby fostering competition. *See § IV-D, Need for Validity “Police” at the PTO.*

A series of cases is provided that show how and why post grant review plays a vital role in the patent system. *See § V, Case Studies.*

As a final point in conducting the study leading up to this paper it has become apparent that there is an inefficiency in the system that *discourages* third party participation at an early date. Why have third parties hold off with their patent challenges until *after* a complete examination of the patent and then the time for a Post Grant Review. It makes more sense to *encourage* a third party challenge *prior* to examination to make the overall process more efficient and clear up patents of dubious worth at the earliest opportunity. A modest proposal is made for

a simple modification of the statute to encourage pre-examination patent challenges. See § VI, *Preissuance Submissions before Examination*.

To be sure, there are there are nuanced differences between the various post grant challenge procedures. Love and Ambwani explain that the significant differences in the outcomes of the various types of post grant review options open to patent challengers.¹

II. THE GLOBAL MOVEMENT TO A POST-GRANT SYSTEM

Historically, patent offices had utilized a pre-grant opposition system as manifested by the systems of Europe and Japan, to iron out third party validity challenges *before* the grant of a patent. All this has changed in previous decades both for Europe and Japan.

¹ Brian J. Love & Shawn Ambwani, *Inter Partes Review: An Early Look at the Numbers*, 81 U. Chi. L. Rev. Dialogue 93, 101 (2014) (“[T]he rate at which petitioners have succeeded on the merits of their petitions is markedly different [comparing Inter partes review and inter partes reexamination]: *inter partes* reexaminations ended in complete victory for the petitioner just 31 percent of the time, less than half as often as for [Inter partes review]. In addition, over 60 percent of *inter partes* reexaminations ended with patentees securing new, amended claims.”)(footnote omitted)

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A. The Patent Law Treaty (1994)

Beginning in the 1980's and proceeding for most of a decade the Patent Law Treaty, the PLT, was negotiated in Geneva under auspices of the World Intellectual Property Organization. The treaty was never ratified by the United States and never entered into force.²

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² The Patent Law Treaty was killed by the unilateral action of then PTO Director Harry Manbeck.

The PLT expressly proscribes a pre-grant opposition,³ but has a grandfather clause which permits a Contracting Party with a pre-grant opposition system ten years from the date of the Patent Law Treaty to switch to a post-grant system,⁴ provided a timely notice is given to the Director General.⁵ Unfortunately, the leader of the United States PTO unilaterally refrained from acceptance of the PLT, dooming this treaty.

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³ See Wegner, PATENT HARMONIZATION, § 2160, *Administrative Revocation [Art. 18]*, p. 277 (London, Sweet & Maxwell 1993)(quoting the Patent Law Treaty, Art. 18(2)(a)(“No Contracting Party may allow any party to oppose, before its Office, the grant of patents (pre-grant opposition).”)

⁴ *Id.*, Art. 18(2)(b)

⁵ *Id.*, Art. 18(2)(c).

A member of the Patent Office involved with the creation of the treaty as a representative for the United States provides the following explanation:

Article 18(1) requires Contracting Parties to provide for the revocation of patents granted after substantive examination. With regard to such patents, “any person shall have the right to request the competent Office to revoke the patent, in whole or in part, at least on the ground that, because of one or several documents available to the public, the conditions of novelty or inventive step are not satisfied.” United States law provides an opportunity for any person at any time to file a request for reexamination by the Office of any claim of a patent on the basis of certain specified prior art. United States law, therefore, is consistent with Article 18(1)(a).

As to the time frame in which a person can request revocation, Article 18(1)(b) provides that the period “shall commence from the announcement in the official gazette of the grant of the patent and shall not be less than six months.” United States law is consistent with this provision since it provides that a request for reexamination may be filed “at any time during the period of enforceability of a patent....” Moreover, United States law is consistent with the requirement found in Article 18(1)(c) that a request for revocation may not be “based on grounds of non-compliance with formal or procedural requirements.”

More problematic are paragraphs (d) and (e) of Article 18(1) which address the procedures to follow once a person requests revocation. Under 35 U.S.C. section 304, if a third party requests reexamination, the patent owner can respond to the request. Following that, the third-party requestor is afforded an opportunity to reply to the patent owner's response. Thereafter, the proceedings before the USPTO are conducted *ex parte*, with the third-party requestor excluded. Therefore, under United States practice, even if the USPTO “departs” from the original request after the inception of the *ex parte* proceedings, the third-party requestor has no opportunity to “present his arguments on the grounds on which the office intends to depart from the request.” The third-party requestor's lack of an opportunity to present an argument is contrary to the provisions of Article 18(1)(d), thus necessitating a change to United States law.⁶

⁶ Richard C. Wilder, An Overview of Changes to the Patent Law of the United States After the Patent Law Treaty, § III-B, *Administrative Revocation Provisions of the PLT and Reexamination Practice in the United States*, 26 J. Marshall L. Rev. 497, 530-31 (1993)(footnotes omitted).

B. European Shift to A Post-Grant System

European countries through the European Patent Convention adapted their local practice to a post-grant opposition system. The European Patent Convention defines the ground rules for an opposition proceeding.⁷ As a prime example of national law integrated into the European system, prior to the EPC, the United Kingdom had a pre-grant opposition system; it was abolished in favor of a post-grant system as part of the implementation of the European Patent Convention. This is explained by Justice Henry Carr in *Fujifilm Kyowa Biologics*:

¶ 40 *** [T]he procedure for opposing a patent during the pre-grant process provided for in section 14 of the Patents Act 1949, was abolished when the Patents Act 1977 was enacted and there is no corresponding provision in the 1977 Act. It submits that the position is *a fortiori* with respect to European patents: Parliament can hardly have contemplated that despite the abolition of the pre-grant opposition with respect to 1949 Act patents regulated by UK law, the court would nonetheless take it upon itself to act as a forum for pre-grant examination of European applications under the 1977 Act. The European Patent Convention does not provide for pre-grant oppositions but instead states that opposition may be filed within nine months “from the publication of the mention of the grant of the European patent” (Article 99).

¶ 41 A clear summary of the history and structure of the European patent system, including the deliberate exclusion of pre-grant oppositions; the provision for post-

⁷ European Patent Convention, Art. 105, *Opposition*:

“(1) Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid.

“(2) The opposition shall apply to the European patent in all the Contracting States in which that patent has effect.

“(3) Opponents shall be parties to the opposition proceedings as well as the proprietor of the patent.

“(4) Where a person provides evidence that in a Contracting State, following a final decision, he has been entered in the patent register of such State instead of the previous proprietor, such person shall, at his request, replace the previous proprietor in respect of such State. Notwithstanding Article 118, the previous proprietor and the person making the request shall not be regarded as joint proprietors unless both so request.”

grant opposition proceedings; and the ability to apply for revocation of national designations of European patents whilst an opposition is continuing; was provided by Jacob LJ in *Unilin Beheer BV v Berry Floor NV* [2007] EWCA Civ 364; [2007] F.S.R 25 at [5]-[18]. This supports the conclusion that, both as a matter of UK law and under the EPC, pre-grant opposition is excluded.

AbbVie submits that, in effect, the Arrow judgment impermissibly introduces such pre-grant opposition by way of declaratory relief.

¶ 42 I agree that there is no provision for pre-grant oppositions, either in respect of UK or European patents. That is why, in common with Kitchin J., I agree that the UK Court cannot conduct a pre-grant opposition to European Patent applications, as this would usurp the function of the EPO, which would be inconsistent with the framework of the EPC and the Act. This is why Kitchin J. stated at [60] that “I find it hard to conceive of any circumstances in which it would be appropriate for this court to grant a declaration that no valid patent could be granted on a divisional application which is being prosecuted before the EPO.”⁸

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⁸ *Fujifilm Kyowa Biologics Co., Ltd. v. Abbvie Biotechnology Limited*, [2016] EWHC 425 (PAT), 2016 WL 00750567 (High Court 2016)(Carr, J.).

The opinion in *Unilin Beheer BV v Berry Floor NV* relied upon in *Fujifilm Kyowa Biologics* is explained by Heath:

[*Unilin Beheer v Berry Floor* is] concerned [with] a (successful) infringement claim that became final before the patent on which it was based was invalidated by the European Patent Office. The court flatly denied any remedy by the defendant in the absence of a statutory provision that would allow a retrial or even the estoppel of unenforceability: ‘Where a final decision has been made on a fair context between the parties, that should stand as the final answer between them’ (point 45). This principle of *res judicata* should stand ; unless an intention to exclude that principle can properly be inferred as a matter of construction of the statutory provisions’ (point 54). And in fact no such intention could be found either in English domestic law or in the EPC whose *travaux préparatoires* ‘give a firm indication that national procedural law ... is to apply to European patents when litigated in a national court’ (point 69). Thus, the decision is not about the precedence of UK proceedings over those of the European Patent Office's, but rather about the absence of an estoppel or the possibility of a retrial under UK law.⁹

Dr. David Lancaster provides further helpful information in his analysis of *Virgin Atlantic Airways Ltd v Zodiac Seats*:

In July 2007, Virgin Atlantic Airways Ltd (Virgin) brought an action against Zodiac Seats UK Ltd (Zodiac) for infringement of the UK designation of the patent (the EP(UK)). Zodiac denied infringement and alleged that, to the extent that the EP(UK) covered its products, it would be invalid in view of the prior art and for added matter. Virgin appealed against the decision on infringement, and Zodiac cross-appealed on validity.

⁹ Christopher Heath, *Wrongful patent enforcement: threats and post-infringement invalidity in comparative perspective*, 2008 IIC 307, 316 (2008)

In February 2008, Zodiac, along with a number of companies who had bought its seats, commenced opposition proceedings against the patent at the EPO, relying on the same prior art that was before the Patents Court in England.

In January 2009, following a trial in the Patents Court, Lewison J. held that Zodiac had not infringed the EP(UK) and that, if the claims had been wide enough to cover Zodiac's seating system, the EP(UK) would be invalid for added matter. In March 2009, the Opposition Division of the EPO upheld the validity of the patent. Zodiac and other opponents of the patent appealed the decision to the [Technical Boards of Appeal,] the TBA. Zodiac proposed that if the appeal on validity succeeded in England, the making of any final order by the Court of Appeal should be stayed pending the final determination of the opposition proceedings at the EPO. Virgin did not agree to a stay. In May 2009, Jacob L.J. gave a direction that the Court of Appeal would not grant a stay of the English proceedings.

In October 2009, the Court of Appeal gave judgment reversing Lewison J.'s earlier decision on validity, holding the EP(UK) to be valid and infringed.

In December 2009, following an application by Zodiac, the Court of Appeal refused to stay the order on the appeal, mainly on the ground that it was pointless to do so because the effect of the decision in *Unilin Beheer BV v Berry Floor NV* was that any later decision of the TBA revoking the patent would make no difference because the decision of the Court of Appeal would bind the parties *per rem judicatam*.

On January 12, 2010, the Court of Appeal therefore sealed an order making a declaration that the EP(UK) was valid and infringed, together with an injunction and an order for an inquiry as to damages. The damages Virgin wished to recover exceeded £49 million.

In September 2010, the TBA decided that all claims of the patent that had been held to be infringed by the English courts were invalid in view of the prior art. By the time the TBA gave its decision, the English appeal proceedings had been concluded and permission to appeal the Court of Appeal's decision on validity had been refused by the Supreme Court.

The question on appeal

The question on appeal to the Supreme Court was whether Zodiac was entitled to argue in an inquiry for damages that no damages were payable to Virgin on the basis that the claims held to have been infringed by the Court of Appeal were subsequently invalidated by the TBA. It was accepted that the injunction would cease following the TBA's decision, since amendment to the patent in EPO opposition proceedings was deemed to be retrospective as from the date of grant. To answer the question, it was necessary for the Supreme Court to assess whether the Court of Appeal was right to say that its Order of January 12, 2010 continued to bind the parties *per rem judicatam* despite the fact that the relevant claims were later held to be invalid by the TBA.

The decision of the Supreme Court

Lord Sumption gave the leading judgment, with Lord Neuberger giving a concurring judgment. The other three judges agreed with both judgments. The Supreme Court reviewed the law of *res judicata* and concluded that Zodiac was not precluded from relying on the decision of the TBA in the inquiry as to damages. The court affirmed the principle that the patent in the form as upheld by the TBA must be treated as the one that existed at the relevant time. Accordingly, the EP(UK) in the form upheld by Court of Appeal had to be treated as if it had never existed. Further, *res judicata* did not apply to the ongoing damages inquiry because Zodiac was not seeking to reopen the validity of the relevant claims, which was one of the questions determined by the Court of Appeal. Rather, Zodiac sought to rely on the fact that the patent had been amended, not the reasons for its amendment.

The Supreme Court also held that the authorities that had been followed by the Court of Appeal in reaching its decision were wrongly decided, primarily on the basis that those cases held cause of action estoppel to be absolute generally rather than being absolute only as regards points actually determined by the earlier decision. Further, those cases were wrong to suppose that taking into account the subsequent revocation of a patent by the EPO would be rehearing the question of validity that had been decided by the court. The effect of revocation by the EPO meant that the patent in that form is deemed never to have existed.¹⁰

¹⁰ Dr David Lancaster, *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd: implications for stays in English patent proceedings*, 2013 E.I.P.R. 609, 610-11 (2013)(explaining *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* [2013])

C. British Shift to a Post-Grant System

The United Kingdom formerly had a pre-grant opposition system which was abolished in favor of a post-grant system as part of the implementation of the European Patent Convention as explained by Justice Henry Carr in *Fujifilm Kyowa Biologics*:

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The Supreme Court also held that the authorities that had been followed by the Court of Appeal in reaching its decision were wrongly decided, primarily on the basis that those cases held cause of action estoppel to be absolute generally rather than being absolute only as regards points actually determined by the earlier decision. Further, those cases were wrong to suppose that taking into account the subsequent revocation of a patent by the EPO would be rehearing the question of validity that had been decided by the court. The effect of revocation by the EPO meant that the patent in that form is deemed never to have existed.¹³

D. Japan-U.S. Agreement to End Pre-Grant Oppositions

The conventional wisdom concerning the perceived evils of a pre-grant review process is expressed by Wolfson in a student note which accurately portrays the general view of American industry at the time (whether or not it corresponds to the reality in Japan of the time):

Publication of a patent application in Japan, a necessary part of the Japanese pre-grant opposition procedure, is required eighteen months after filing. Unlike the EPO, which has a post-grant opposition system, Japan is the only country in the world that allows pre-grant oppositions. The European post-grant opposition system allows competitors to oppose patents in an adversarial hearing for nine months following publication of the patent grant. Alternatively, the United States has no adversarial opposition system. Instead the United States chooses to use a post-issuance reexamination procedure in which the U.S. PTO reexamines issued patents in an ex parte hearing upon the request of any party.

¹³ Dr David Lancaster, *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd: implications for stays in English patent proceedings*, 2013 E.I.P.R. 609, 610-11 (2013)(explaining *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* [2013] UKSC 46; [2013] 3 W.L.R. 299)(footnotes omitted).

Under the Japanese system, any person may file written opposition to a patent application within three months of its publication. *This pre-issuance publication system [in Japan] allows large Japanese firms to profit by flooding the JPO with hundreds of applications for competing patents after they view U.S. and other foreign companies' patent applications.* The newly signed Letters of Agreement will eliminate the Japanese pre-grant opposition system and its serial hearings, in favor of a consolidated post-grant opposition hearing system.¹

The letter agreement between Japan and the United States is reproduced below:

**Japan-United States: Exchange of Letters
Concerning Patent Systems Agreement¹**

August 16, 1994
Washington, D. C.

Introductory Note by Thomas Robertson

On August 16, 1994, representatives of the United States and Japanese Governments exchanged letters by which they agreed to make certain modifications to their patent systems. Signed by U.S. Secretary of Commerce Ronald H. Brown and Japanese Ambassador Takakazu Kuriyama, the exchange was a result of the intellectual property discussions under the Economic Harmonization Basket of the so-called "Framework" discussions between the two countries. Initiated under the U.S.-Japan Framework for a New Economic Partnership agreement signed by President Clinton and then-Prime Minister Hosakawa on July 10, 1993, the Framework discussions began in September 1993. The intellectual property discussions presented an opportunity for each country to air grievances it has with the other's intellectual property system. While there was no restriction as to subject matter, the talks primarily focused on the patent systems of the two countries. The Japanese concerns with the U.S. system primarily deal with the differences between the U.S. system and most other patent systems, including that it is a first to invent rather than first to file system; applications are not published; interferences are necessary to determine inventorship in some cases; the practice of reexamining patents is restricted as to the grounds for invalidation and who may participate; and restriction practice is ambiguous in some respects.

The primary U.S. concerns with the Japanese patent system include the inability to make English-language filings in Japan that are followed up with Japanese translations; the long delays in the examination of patent applications in the Japanese Patent Office; the pre-grant opposition system and the practice of addressing oppositions seriatim rather than at the same time; the narrow grant of patent claims; the availability of dependent patent compulsory licenses; and the lack of a full 12-month grace period. The U.S. representatives also raised concerns about delays in court cases in Japan and the absence of a mechanism to protect confidential information in court proceedings.

The negotiations on the exchange of letters were carried out primarily by the heads of the two delegations to the intellectual property discussions, Michael Kirk, Deputy Commissioner of the U.S. Patent and Trademark Office (PTO), and Toshido Ochiai, then-Director-General of the General Administration Department of the Japanese Patent Office. In the end, three of the primary U.S. concerns and two of the primary Japanese concerns were addressed in the letters.

Under the exchange of letters, the Japanese Patent Office will, by April 1995, introduce legislation that would, after January 1, 1996, no longer allow pre-grant oppositions to the issuance of a patent and would require the consolidation of oppositions; by January 1996, establish a procedure whereby applicants can request that their applications be fully processed within 36 months; and by July 1995, greatly restrict the instances in which the grant of dependant patent compulsory licenses is possible. The effect of these changes is likely to be a more rapid examination system and an enhanced confidence on the part of patentees that their patents will not be subject to compulsory licenses.

On behalf of the U.S. Government, Secretary Brown committed to submit legislation by September 30, 1994, that would end the practice of keeping applications secret until grant by publishing them 18 months after their priority filing date. Rather than submit legislation, the U.S. PTO has instead issued draft rules which if adopted would establish the 18-month publication system. Early publication will ensure that technology is disseminated promptly to U.S. researchers and inventors in the English language, putting them on an equal footing with foreign researchers and inventors whose countries publish all pending applications 18 months after filing. Secretary Brown also committed the U.S. Government to revise its reexamination procedures by January 1, 1996, so that the grounds for requesting reexamination include compliance with all aspects of 35 U.S.C. 112 except the best mode requirement (i.e., that the application contain a written description of the invention, the manner and process of making and using

it, and claims in proper format), and third parties have an expanded opportunity to participate in reexaminations. Expanded reexamination will provide third parties with a less expensive and more rapid procedure for challenging claims than is available through litigation in Federal court. Finally, Secretary Brown stated that the U.S. PTO would not grant a dependant patent compulsory license other than in certain limited cases. This is not a significant provision in light of the fact that the U.S. PTO does not now grant such licenses.

These commitments supplement an earlier exchange of letters between U.S. and Japanese representatives in which the Japanese Patent Office agreed to accept English-language filings by July 1995, and the U.S. PTO agreed to seek the modification of U.S. patent term from 17 years from grant to 20 years from filing. The change in the way patent terms are calculated in the United States was accomplished in the Uruguay Round Agreements Act, which was enacted into law on December 8, 1994 (Pub. L. 103-465). At this time, there are no plans for the working group to resume consultations.

Letter from the Japanese Ambassador to the Secretary of Commerce

EMBASSY OF JAPAN
WASHINGTON, D. C.

August 16, 1994

Dear Secretary Brown:

I have the honor to refer to the recent discussions between the representatives of the Government of Japan and the Government of the United States of America concerning the patent systems of the two countries. I am pleased to inform you that the Government of Japan confirms that, on the basis of these discussions, the Japanese Patent Office and the United States Patent and Trademark Office are to take the actions described in the Attachment hereto. In some instances, the implementation of these measures will require approval of the Japanese Diet or the U.S. Congress.

We look forward to working with you on a regular basis on these and other matters of mutual interest in the field of intellectual property. These ongoing talks will allow the Working Group on Intellectual Property or its successor to meet

annually, or upon the request of either government, to discuss the implementation of the above actions.

I believe that the above-referenced actions and continued efforts will further promote the good relationship in the field of intellectual property between Japan and the United States of America.

Sincerely,

Takakazu Kuriyama
The Honorable Ronald H. Brown Secretary of Commerce

Attachment: Actions to be taken by the JPO:

1. (a) By April 1, 1995, in order to institute a revised opposition system by January 1, 1996, the JPO is to introduce legislation to revise the opposition system.
- (b) Under the revised system, oppositions are to take place only after the grant of a patent.
- (c) Multiple oppositions in the revised system are to be consolidated and addressed in a single proceeding to minimize the time spent during opposition.
2. (a) By January 1, 1996, the JPO is to institute a revised system of accelerated examination.
- (b) In the revised accelerated examination system:
 - (i) the JPO is to allow an applicant who has filed a patent application before a foreign national or regional industrial property office to request accelerated examination for a corresponding patent application filed in the JPO;
 - (ii) applications are to be processed to grant or abandonment within 36 months from the date of the request for accelerated examination;
 - (iii) the JPO may require the applicant to submit a copy of a search report, issued by the above mentioned national or regional industrial property office separately from or associated with its first substantive action on the merits; and
 - (iv) a fee, not to exceed the fee for filing an application, may be charged in addition to the normal fee for requesting examination but no working requirement is to be imposed.
3. Other than to remedy a practice determined after judicial or administrative process to be anti-competitive or to permit public non-commercial use, after July 1, 1995, the JPO is not to render an arbitration decision ordering a dependent patent compulsory license to be granted.

Actions to be taken by the USPTO:

1. (a) By September 30, 1994, in order to institute an “early publication” system by January 1, 1996, the USPTO is to introduce legislation to make applications publicly available 18 months after the filing date of the earliest filed application, a reference to which is made under 35 USC 119, 120, 121 or 365.

(b) The USPTO is to make publicly available all applications, filed after January 1, 1996, as soon as possible after the expiration of 18 months from the filing date or, where priority is claimed under 35 USC 119, 120, 121 or 365, from the earliest priority date. The drawing, specification, including claims, and bibliographic information of the application are to be made available to the public. Applications that are no longer pending and applications subject to secrecy orders are not to be made publicly available.

DRAFT

October 2007

III. POST GRANT PROCEEDINGS UNDER JUDICIAL CHALLENGE

While the major patent granting authorities of the world over the past two generations have moved to a post-grant system of inter partes review, the United States system has been *too* effective in weeding out bad patents: There are now clear challenges to the post grant review system.

In the more than thirty-five years since the United States in 1980 introduced a first statutory provision for administrative patent revocation procedures at the Patent Office, such proceedings are under procedural judicial challenges both at the trial level in the *Restasis* case;¹⁴ as well as in merits appeals at the Supreme Court with an oral argument on November 27, 2017, in both *Oil States Energy Services*¹⁵ and *SAS Institute v. Matal*,¹⁶ with merits decisions in the two cases expected by the end of June 2018.

¹⁴ In *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.* (E.D. Texas), the patentee Allergan sought to avoid a PTO patent validity attack by transferring formal title to the patent to the Saint Regis Mohawk Tribe (which then granted Allergan an exclusive license to the patents). The trial court determined that the clever scheme to transfer technical patent ownership to an Indian Tribe (with sovereign immunity) was *not* a successful avoidance of PTO jurisdiction to determine validity, and *also* ruled that the relevant claims of the *Restasis* patents are invalid on the basis of obviousness.

¹⁵ In *Oil States Energy Services v. Greene's Energy Group*, Supreme Court No. 16-712, the *Question Presented* asks “[w]hether *inter partes* review – an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents – violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.”

¹⁶ In *SAS Institute Inc. v. Matal*, Supreme Court No. 16-969, the *Question Presented* asks: “Does 35 U.S.C. § 318(a), which provides that the Patent Trial and Appeal Board in an inter partes review ‘shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner,’ require that Board to issue a final written decision as to every claim challenged by the petitioner, or does it allow that Board to issue a final written decision with respect to the patentability of only some of the patent claims challenged by the petitioner, as the Federal Circuit held?”

Restastis case deals with a specific, clever strategy to avoid Patent Office review procedures, and is only at the stage of an appeal to the Federal Circuit where a decision is expected at some point in 2018; whether there is any realistic possibility for a Supreme Court appeal will be better seen once a Federal Circuit decision is reached. As to *Oil States Energy Services* and *SAS Institute v. Matal*, the *Oil States Energy Services* involves a frontal attack on the Constitutionality of post grant proceedings where the PTO determines the validity of a granted patent.

In particular, *Oil States Energy Services* considers whether the PTO administrative procedure challenges to patent validity “violate[] the Constitution by extinguishing private property rights through a non-Article III forum without a jury.”¹⁷

¹⁷ *Oil States Energy Services*, supra note 2.

IV. THE NARROW FILTER OF POST GRANT REVIEW

Of the multiple post grant procedures open to patent challengers, Post Grant Review (PGR) is the most powerful tool for administrative revocation of patents. It is particularly useful to challenge a patent on a highly technical issue of patent law where the complexity of the technology adds a degree of sophistication and difficult to the legal issues.

A. Special Situation of Continuation Patent Validity

A patent application may be *refiled* over and over again as a continuing application, e.g., a continuation-in-part, where new subject matter and changing claim scope are permitted. A technologically savvy and patent-trained person will be able to sort out subtle changes in the generations of new applications, such that a later application may not be entitled to rely upon the earlier or earliest date of filing; in that case, the public work of the inventor more than a year before a later filing may constitute a statutory bar to invalidate the claims of the patent. The problem, here, is that prior to Post Grant Review it was difficult to establish such a statutory bar in the District Court. Wherefore, the Lemelson saga permitted maintenance of his patents to the great cost of the public.

Professors Lemley and Moore point out that “[i]n the most extreme cases, patent applicants add claims during the continuation process to cover ideas they never thought of themselves but instead learned from a competitor. The most egregious and notorious example of submarine patenting is Jerome Lemelson. Lemelson filed eight of the ten continuation patents with the longest delays in prosecution in our study. Those Lemelson patents spent anywhere from thirty-eight to more than forty-four years in the PTO.”¹⁸

Former Judge Seto explains:

The Federal Circuit recently decided that fourteen of Dr. Lemelson's patents relating to machine vision and bar code technologies were unenforceable under the doctrine of prosecution laches. The Federal Circuit, in affirming a decision by the District Court for Nevada, held that Lemelson's eighteen- to thirty-nine-year delay in executing his patent claims was unreasonable, and found the patents unenforceable. The Federal Circuit's decision was dated September 9, 2005, after a host of companies had already paid Dr. Lemelson and his heirs a combined \$1.5 billion in licensing fees.¹⁹

Sullivan and Loretto explain the need for post grant review in the context of the Lemelson patents:

¹⁸Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. Rev. 63, 76-77 (2004) (footnotes omitted). Since this article was written, Professor Moore has become a member of the Federal Circuit.

¹⁹Robert M. M. Seto, *A Federal Judge's View of the Most Important Changes in Patent Law in Half-a-Century*, 11 J. Tech. L. & Pol'y 141, 150 (2006) (footnotes omitted)

In particular, a renewed, and more focused, emphasis on the requirements of § 112, especially the written description, enablement, and definiteness standards, offers the opportunity for striking directly at the core problem with junk patents: that, however cunningly the inventor manipulated his specification and claim language, he himself simply did not make, or did not sufficiently disclose or claim, the technological advance from which he seeks to profit by asserting the claims against the systems of others (including those who actually made the technical innovations usable for the public). But neither these types of defenses, nor any of the other existing defenses discussed herein, will provide a rapid or broad-spectrum solution to the junk-patent problem. If these defenses were capable of such a feat, Lemelson would not have collected multiple billions of dollars to date.²⁰

Sullivan and Loretto explain the complexity of the Lemelson patents:

“Lemelson's patents contain broadly-worded claims that have been asserted to read on common ‘high-tech’ products – such as the bar code scanners sold by Symbol Technologies, Inc. – even though many of the patents claim priority, through an extraordinary series of continuation applications, to applications filed as early as the mid-1950s. For example, U.S. Patent No. 4,979,029, issued Dec. 18, 1990, upon an application filed on March 27, 1990, claims priority from Application No. 477,467, which was filed on December 24, 1954. Claim 1 of this patent is directed to ‘[a] method for inspecting an image field to determine if an [sic] select image phenomenon is present in said image field’, and comprises steps such as ‘scanning an image field containing at least one optically contrasting image field portion which is detectable with an electro-optical scanning means’ and ‘generating first electrical signals which vary in accordance with variations in the optical characteristics of the optical field scanned.’”²¹

Wysocki, Jr., explains how Lemelson made his money through patents:

²⁰ Jeffrey D. Sullivan and David Loretto, *Symbol Technologies v. Lemelson, Prosecution Laches, and the Still-Unmet Challenges of Junking ‘Junk Patents’*, 33 AIPLA Q.J. 285, 317 (2005).

²¹ *Id.*, 33 AIPLA Q.J. at 286 n.3.

Few people paid much attention to Jerome H. Lemelson until he figured out a way to make \$500 million.

For decades, Mr. Lemelson has been a soft-spoken, somewhat-nerdy engineer who doesn't manufacture products and rarely even makes prototypes but who turns out a steady stream of blueprints and drawings and has filed huge applications at the U.S. Patent and Trademark Office. He files and amends and divides his applications. Eventually, sometimes 20 years later, he usually gets a patent. Over the years, the 73-year-old Mr. Lemelson has accumulated nearly 500 U.S. patents, more than anybody alive today. They cut through a wide swath of industry, from automated warehousing to camcorder parts to robotic-vision systems.

But he hasn't just hung the patents on a wall, like vanity plates. Seeking royalties, he has turned the strongest ones into patent-infringement claims-and a fortune.

* * *

In 1992 alone, [Lemelson] collected a total of \$100 million from 12 Japanese automotive companies, which decided to settle with him rather than fight him in court over a portfolio of some of his innovations: "machine vision" and image-processing patents. The claims cover various factory uses ranging from welding robots to vehicle-inspection equipment.

"This is what made him rich," says Frederick Michaud, an Alexandria, Va., attorney who represented the Japan Automobile manufacturers Association. "But he's still current, let me tell you."

These days, Mr. Lemelson is casting a longer shadow than ever. True, he makes huge donations, including funding the annual \$500,000 Lemelson-MIT Prize for innovation that will be presented tomorrow night at a gala in Washington.

MUCH CONTROVERSY

But behind the pomp lies controversy. Critics say Mr. Lemelson not only exploits the patent system but manipulates it.

* * *

[Mr. Lemelson] is currently embroiled in a brutal legal battle with Ford Motor Co. Unlike more than 20 other automotive companies, Ford has refused to get a license from him on the machine-vision and image-processing patents. In a filing in federal court in Reno, Nev., it charged that Mr. Lemelson, in an abuse of the system, "manipulated" the U.S. Patent Office. Ford contended in its suit that Mr. Lemelson "unreasonably and inexcusably delayed" the processing of his applications to make the patents more valuable and more up-to-date. A Ford lawyer, in testimony before a congressional committee, once compared his patents to "submarines," sometimes surfacing decades after they were filed, with claims covering new technology.

In 1995, U.S. Magistrate Judge Phyllis Atkins in Nevada sided with Ford, stating that "Lemelson's use of continuing applications has been abusive and he should be barred from enforcing his asserted patent rights." In her report, she also stated that Mr. Lemelson "designs his claims on top of existing inventions for the purpose of creating infringements." Mr. Lemelson has appealed, blaming the Patent Office for his delays in filing claims. A federal district judge is expected to rule soon.

* * *

Another battle on the horizon will pit Mr. Lemelson against Ford and more than a dozen secret allies. In dispute are some of his pending patent applications that cover "flexible manufacturing" techniques. Ford is trying to prevent them from being issued; if the patents are issued, Mr. Lemelson plans to enforce them. Discussing the litigation-Mr. Lemelson estimates the two sides have spent well over \$10 million, with no end in sight-he says, "It's almost, in my opinion, madness."

Meanwhile, Mr. Lemelson is inspiring a horde of imitators. Firms are springing up whose main business is obtaining patents and, like him, enforcing them by first offering a license and then, if refused, suing. Working with them are individual inventors who have decided that patented ideas, legally enforced, can be more lucrative than manufacturing and marketing.

"I'm not interested in building a company and getting into manufacturing. I focus on new inventions, on new things," say Charles Freeny Jr., a 65-year-old inventor in Irving, Texas, with a patent covering transmission of digital information over a network. Today, enforcement of Mr. Freeny's rights is in the hands of E-data Corp., a tiny Secaucus, N.J., company with three employees. Its main business is to try to extract royalty payments from alleged infringers.

* * *

A new breed of intellectual-property lawyer has emerged, too. Many seem to be inspired by Mr. Hosier, who pioneered the use of contingency fees in patent cases and whose work for Mr. Lemelson alone has brought him more than \$150 million in fees. The lawyer's success – he lives in a 15,000-square-foot house near Aspen, Colo. – has made the field "a very hot area. It's going crazy," says Joseph Potenza, a patent attorney in Washington. Between 1991 and 1996, the American Bar Association says, the number of intellectual-property lawyers soared to 14,000 from 9,400.

One Houston company, Litigation Risk Management Inc., is even helping finance inventors' intellectual-property efforts by bringing in Lloyd's of London to finance 80% of the cost of the litigation. Joby Hughes, Litigation Risk's president, says that if the licensing or litigation effort succeeds, the London insurance exchange will get a 25% profit on the money it puts up. Mr. Hughes's company gets a fee for arranging the deal.

A BOOMING FIELD

Companies long active in intellectual-property enforcement say business is strong. One is Refac Technology Development Corp. The New York company buys the rights to patents and licenses them to manufacturers, which pay royalties to both Refac and the inventors. Last year, Refac's net income more than doubled to \$4.7 million on revenue of \$9.2 million.

The purpose of the U.S. patent system comes into question, however. A patent doesn't require the inventor to go into manufacturing; technically, a patent is a right to exclude somebody else from using your ideas in commercial products, for 20 years from the date of filing. (Before June 1995, patents were valid for 17 years from date of issue. These and other patent revisions remain a hot topic in Congress.)

U.S. Commissioner of Patents and Trademarks Bruce Lehman says he is outraged by "these people who file patent applications and never, ever, ever go to market with an invention, based on their application. I thought what the patent system was all about was coming here and getting a patent and going to some banker or venture capitalist or something and get money, and then you go out and start a

company and put products out on the marketplace. And you go sue the people that infringe on you.”

But to the new intellectual-property players, it is the patent itself that has the economic value. And that has long been Mr. Lemelson's notion.

A native New Yorker, Mr. Lemelson worked for big companies and tried his hand at toy manufacturing. By his own testimony, that venture didn't succeed. Over time, he turned to crafting patents and then to seeking licenses. He often got involved in legal battles. His biggest one in toyland was a 15-year fight with Mattel Inc. over the flexible track in its Hot Wheels toys. In 1989, he won a \$71 million patent-infringement judgment, but it was overturned on appeal.

BIG DEAL WITH IBM

In electronics, Mr. Lemelson's big break came in 1980, when International Business Machines Corp. agreed to take a license on a portfolio of his computer patents. "After the IBM deal, I became a multimillionaire," he says. "It didn't put me on easy street because I had so many balls in the air at one time. But it certainly helped a lot."

An even bigger break came in the mid-1980s, when Mr. Lemelson met Mr. Hosier. In 1989, the already successful patent lawyer put together the "machine vision" licensing campaign. Mr. Hosier focused his negotiations on 12 Japanese automotive companies, and the talks dragged on through mid-1992. That July, Mr. Lemelson sued four of the companies, Toyota Motor Corp., Nissan Motor Co., Mazda Motor Corp. and Honda Motor Co. Within a month, the Japanese agreed to settle; the 12 companies paid him the \$100 million.

At a post-settlement celebration of sorts, in the Brown Palace Hotel in Denver, the Japanese insisted on taking photographs, which show eight grim-looking Japanese surrounding a beaming Mr. Lemelson. He contends that it was a heroic victory, a patriotic act. "My federal government has made <in taxes> probably over a quarter of a billion dollars on my patents over the years," he says. "A good part of it has been foreign money."

Similar infringement suits followed, against Mitsubishi Electric Corp., against Motorola Inc., against the Big Three Detroit auto makers. Initially, both Mitsubishi and Motorola decided to fight; later, they settled. The suits against General Motors Corp. and Chrysler Corp. were "dismissed without prejudice." In effect, any

further action against GM or Chrysler is in abeyance until the Ford outcome is known.

WHY THEY SETTLED

By all accounts, the strategy was well-planned and well-executed. Mr. Hosier says the Japanese were more inclined to settle than the Americans. Commissioner Lehman says the Japanese are "particularly freaked by litigation. And so you start out with them. . . . And, of course, they all pay up, and that establishes a precedent." After the Japanese settlement, several European auto makers also agreed to take licenses on Mr. Lemelson's patents.

Some who settled say they concluded that Mr. Lemelson had a good case. Others call it an uphill battle to try to persuade a judge or jury that the government had repeatedly made mistakes in issuing him all those patents. With a legal presumption that patents are valid, his opponents say they had the burden of proving the Patent Office had goofed 11 times in a row.

In any event, by 1994, Mr. Lemelson had amassed about \$500 million in royalties from his patents. But Ford has held out.

Even as the lawyers haggled over the law, many of the facts in the case were undisputed. In 1954 and 1956, both sides agree, Mr. Lemelson made massive patent filings, which included, for example, many drawings and descriptions of an electronic scanning device. As an object moved down a conveyor belt, a camera would snap a picture of it. Then that image could be compared with a previously stored one. If they matched, a computer controlling the assembly line would let the object pass. If the two images didn't match up, it might be tossed on a reject pile. But because Mr. Lemelson's filings were so extensive and complex, the Patent Office divided up his claims into multiple inventions and initially dealt with only some of them. Thus, for whatever reason, his applications kept dividing and subdividing, amended from time to time with new claims and with new patents. It was as if the 1954 and 1956 filings were the roots of a vast tree. One branch "surfaced" in 1963, another in 1969, and more in the late 1970s, the mid-1980s and the early 1990s. All direct descendants of the mid-1950s filings, they have up-to-date claims covering more recent technology, such as that for bar-coding scanning. The lineage was presented to the court in a color-coded chart produced by Ford. It shows how the mid-1950s applications spawned further applications all through the 1970s and 1980s. One result: a group of four bar-code patents issued in 1990

and 1992, with a total of 182 patent claims, all new and forming the basis of 14 infringement claims against Ford. But because of their 1950s roots, these patents claim the ancient heritage of Mr. Lemelson's old applications and establish precedence over any inventor with a later date.

The entire battle has become numbingly complex, a battle over whether the long stretch between the mid-1950s and the new claims in the 1990s constituted undue delay. Ford says yes. Mr. Lemelson says no. The magistrate judge found for Ford. Another question is whether Mr. Lemelson's original filings-his scanner and camera and picture of images on a conveyer belt-should be considered the concepts of bar-code scanning, and thus Ford's use of bar coding in its factories make it an infringer of his patents. Mr. Lemelson says yes. Ford says no, arguing Mr. Lemelson depicted a fixed scanner (bar-code scanners can be hand-held). "As we said in our lawsuit, if you walk into the Grand Union and show up for work with a 'Lemelson' bar-code scanner, it won't work," quips Jesse Jenner, a lawyer for Ford.

It's impossible to say which side will ultimately prevail. Or whether there will be a settlement. But the clear winners so far are the lawyers. Mr. Lemelson alone employs a small army of them. And Mr. Hosier pretty much thanks himself for that, noting an old joke: "One lawyer in town, you're broke. Two lawyers in town, you're rich."²²

B. One Decision for Every 600 Patents Per Year

More than 99 percent of all granted patents each year *avoid* a post grant challenge. Thus, what is not as widely understood outside the patent community is that the Patent Office has scientific and patent legal experts who determine

²² H.R. 400, *The 21st Century Patent Improvement Act of 1997*, 143 Cong. Rec. H1585-01, 1997 WL 182364 (April 16, 1997)(quoting Bernard Wysocki, Jr., *How Patent Lawsuits Make a Quiet Engineer Rich and Controversial*, Wall Street Journal (Apr. 9, 1997)).

whether to sustain a patent in post grant proceedings; in contrast, the same task in a District Court normally falls to a jury of peers. Thus, a patent challenger at the Patent Office who risks a post grant patent validity challenge on anything but a “sure” thing is essentially signing a death warrant for any chance to succeed in a District Court defense based on patent validity: Any patent challenge that has survived a proceeding at the Patent Office makes it more difficult to reach the opposite conclusion in a subsequent District Court action. Therefore, patent challenges are rare in post grant proceedings unless the patent challenger has an extremely solid position – or is otherwise desperate, without, for example, sufficient funding to undergo a full blown patent litigation.

The small number of post grant Patent Office challenges is manifested by the fact that there are only roughly 500 written decisions for *all* the post grant proceedings per year (out of an also small average of 1000 total post grant procedures that have commenced but are settled), including inter partes review, covered business method review, and post-grant review.²³

²³ Jason D. Eisenberg and Robert Greene Sterne, eds., 1 Patent Office Litigation § 15:26, *Statistics* (Jan. 2017 Update)(“Based on statistics ... updated in August of 2016, the number of petitions filed seeking inter partes review, covered business method review, and post-grant review currently averages 1,000 annually. Of those 1,000 petitions, roughly 50% proceed to a final written decision on the merits. While the appeal rate varies substantially from period to period, one or both parties appeal a final written decision between 50-60 % of the time. This accounts for roughly 250 appeals per year that never existed before the AIA. Of those, the vast majority are appeals pursued by patent owners, approximately 80%. Only about 10% are appeals taken by petitioners alone, and another 10% are cross-appeals. Like the underlying composition of the Board's docket, roughly 72% of the appeals involve electrical, communications, computer, and software technology, 16% involve chemical or biotechnology, and 12% involve mechanical or design technology.

“Post-grant proceedings on appeal are faring roughly as one would expect, based on the historically high affirmance rate of Office decisions. For example, based on all appeals from reexaminations decided between 2011 and 2016, 70% of inter partes reexamination decisions were affirmed by the Federal Circuit (with 53% of those being Rule 36 affirmances) and 94% of ex parte reexamination appeals were affirmed by the Federal Circuit (with 68% of those being Rule 36 affirmances). As of August 15, 2016, the Federal Circuit had decided 134 appeals from AIA post-grant proceedings, affirming 84% of them (with 63% of

To put this number in perspective a total of nearly 300,000 patents were granted in 2015, slightly more than half of which were of foreign origin.²⁴

Thus, there are roughly 500 decisions per year in post grant procedures compared to a base issuance of roughly 300,000 patents per year, or 1 decision in a post grant proceeding per every 600 patents granted. (If one used as the base the patents open to one form or another of post grant challenge, the number would be closer to about 1 per 6,000 patents in force, counting the seventeen years that some post grant challenges can be instituted.)

One of the leading patent academics in the country, Professor Rochelle Cooper Dreyfuss of New York University Law School, helps put the statistics in perspective:

While ... statistics speak loudly about the public's eagerness and ability to use these [PTO] procedures to “weed out” bad patents, it is more difficult to interpret what the numbers mean from a normative standpoint. To some, they suggest that the Board is out of control. As Randall Rader, once chief judge of the Federal Circuit, put it, the judges of the PTAB are “acting as death squads, killing property rights.”^[109] Or in the words of two bloggers, the PTAB is “where patent claims go

those being Rule 36 affirmances). The reversal rate was at 8%, as was the remand rate. The Federal Circuit had also decided 13 petitions for writ of mandamus taken from post-grant proceedings and denied all of them.”).

²⁴ The total is 298,407, of which 52.8 % were of foreign origin. See United States Patent and Trademark Office, *U.S. Patent Statistics Chart, Calendar Years 1963 – 2015*, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm, last visited October 21, 2017.

^[109] Tony Dutra, *Rader Regrets CLS Bank Impasse, Comments on Latest Patent Reform Bill*, BNA Pat. Trademark & Copyright L. Daily, Oct. 29, 2013.

to die.”^[110] More temperately, after comparing cancellation rates in IPRs to invalidation rates in court and considering the number of claims cancelled in IPRs that had previously survived ex parte reexamination,^[111] Gregory Dolin concluded that it is “too easy to invalidate a duly issued patent” in an IPR. He called the CBM statistics “even more staggering.”^[112]

But the numbers can be understood in a very different way. Before the PTAB can issue a final written decision cancelling claims, it must decide whether to institute a proceeding. The standard for determining whether to institute, although slightly different for the three procedures, is essentially whether it is more probable than not that at least one challenged claim is unpatentable. Since the preponderance of the evidence standard for determining whether a claim *should* be cancelled is also, essentially, whether it is more probable than not invalid, the high invalidation rate is basically a reflection of the PTAB's ability to forecast correctly how it will decide on at least one claim. Because the panel that decides whether to institute also decides the case on the merits, a strong correlation is to be expected.^[113]

^[110] Michelle Carniaux & Michael E. Sander, *Claims Can Survive Inter Partes and Covered Business Method Review (But Few Do)*, IPR Blog (Apr. 7, 2014), <http://interpartesreviewblog.com/claims-can-survive-inter-partes-covered-business-method-review/>.

^[111] See Gregory Dolin, *Dubious Patent Reform*, 56 B.C. L. Rev. 881, 926-27 (2015) (citing John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-06 (1998)); Shawn P. Miller, *Where's the Innovation: An Analysis of the Quantity and Qualities of Anticipated and Obvious Patents*, 18 Va. J.L. & Tech. 1, 6-7 (2013).

^[112] Dolin, *supra* note 111, at 926, 930.

^[113] The PTO is considering a pilot program in which institution decisions would be made by only one judge; if that judge decides to institute, two new judges would be added to decide the case. See Lee, *supra* note 37. [Note 37: 37 C.F.R. § 42.108(a) (2014) ; *id.* § 42.208 (permitting the Board to institute on only some claims and to refuse to consider all asserted grounds for invalidation); *id.* § 42.300; see also *Bank of Am., N.A. v. Intellectual Ventures II LLC*, No. CBM2014-00031 (P.T.A.B. Aug. 18, 2014) (institution decision) (instituting on nine of eighteen claims challenged). The PTAB then granted the patent holder's motion for adverse judgment on all challenged claims.]

This is especially so because the institution decisions are far from pro forma: they are often as long as the merits decision, cover the same issues (claim construction is often central), and are as thoughtful and probing of the arguments as the decisions on the merits.^[114] Admittedly, once the PTAB decides one claim may be invalid, it can entertain challenges to other claims as well. But it need not hear *every* claim the petitioner seeks to cancel. Partial institutions are possible, and in practice, the PTAB screens out claims that appear to be valid at the institution stage. That is, in deciding whether to institute, the PTAB often considers every claim and every ground to determine whether each claim is more likely than not unpatentable on each alleged ground.^[115]²⁵

October 24, 2017

^[114] To take two examples, arbitrarily chosen, the institution decision in *SAP America, Inc. v. Versata Development Group, Inc.* was forty-four pages long. No. CBM2012-00001 (P.T.A.B. Jan. 9, 2013) (institution decision). In the same case, the final written decision was thirty-five pages. *Id.* (P.T.A.B. June 11, 2013). The institution decision in *U.S. Bancorp v. Retirement Capital Access Mgmt. Co.* was fifteen pages. No. CBM2013-00014 (P.T.A.B. Sept. 20, 2013) (institution decision). There, the final written decision was twenty-one pages. *Id.* (P.T.A.B. Aug. 22, 2014).

^[115] 37 C.F.R. § 42.108(a) (2014) ; *id.* § 42.208 (permitting the Board to institute on only some claims and to refuse to consider all asserted grounds for invalidation); *id.* § 42.300; *see also Bank of Am., N.A. v. Intellectual Ventures II LLC*, No. CBM2014-00031 (P.T.A.B. Aug. 18, 2014) (institution decision) (instituting on nine of eighteen claims challenged). The PTAB then granted the patent holder's motion for adverse judgment on all challenged claims.

²⁵ Rochelle Cooper Dreyfuss, *Giving the Federal Circuit a Run for its Money: Challenging Patents in the PTAB*, 91 Notre Dame L. Rev. 235, 251-52 (2015)(original footnotes included in brackets)(original emphasis).

Professor La Belle summarizes the Rader-inspired “death squad” hysteria:

Early studies indicate that patent challengers are enjoying high rates of success with the new [PTO patent challenge] proceedings.^[170] In IPRs, petitioners have won complete victories almost two-thirds of the time when pursuing their petitions to a final decision.^[171] And even when not securing a total win, petitioners have managed to persuade the PTAB to institute IPR on at least one challenged claim in eighty-four percent of proceedings.^[172]

Based on these high rates of invalidation, critics have referred to the PTAB alternatively as a ‘death squad’^[173] and a ‘killing field.’^[174] Former Chief Judge Rader stated at an intellectual property conference that the PTO ‘was in tension with itself, with thousand[s] of examiners ‘giving birth’ to patents and hundreds of judges on the PTAB ‘acting as death squads, kind of killing property rights.’^[175]

^[170] See Brian J. Love & Shawn Ambwani, *Inter Partes Review: An Early Look at the Numbers*, 81 U. Chi. L. Rev. Dialogue 93, 101 (2014) (finding that the PTAB invalidated all instituted IPR claims almost 78% of the time).

^[171] *Id.*

^[172] *Id.* at 100. A more recent study finds that the rate at which the PTAB is instituting IPRs has been slowly and consistently declining since 2012. See Saurabh Vishnubhakat, Arti K. Rai & Jay P. Kesan, *Strategic Decision Making in Dual PTAB and District Court Proceedings*, 31 Berkeley Tech. L.J. 45, 78, 107 (2016).

^[173] Rob Sterne & Gene Quinn, *PTAB Death Squads: Are All Commercially Viable Patents Invalid?*, IPWatchdog.com (Mar. 24, 2014), <http://www.ipwatchdog.com/2014/03/24/ptabdeathsquads-are-all-commercially-viable-patents-invalid/id=48642/> (quoting former Fed. Cir. Chief Judge Randall Rader, Comments at the 2013 American Intellectual Property Law Association Annual Meeting (Oct. 25, 2013)).

^[174] Erich Spangenberg, *Patent Predictions for 2015*, IPNav: Blog (Dec. 31, 2014), <http://www.ipnav.com/blog/erich-spangenbergs-patent-predictions-for-2015/> [<https://perma.cc/XsN4-XQRG>].

^[175] Ryan Davis, *PTAB's “Death Squad” Label Not Totally Off-Base, Chief Says*, Law360 (Aug. 14, 2014, 5:47 PM), <http://www.law360.com/articles/567550/ptab-s-death-squadlabelnot-totally-off-base-chief-says> [<https://perma.cc/7FXK-DCJ6>].

A former high-level PTO official similarly criticized the agency for ‘creating’ and then ‘destroying’ patents, wondered how long such a ‘business model’ can last, and warned that ‘if the PTAB continues on this path, the raison d’etre of the Patent Office and the entire patent system will be called into question.’^[176] ²⁶

C. Maturation of the Patent Bar

As pointed out by Dilger and Lord, “[t]here is evidence ... that patent owners are becoming more successful in combating IPR petitions.”²⁷ The early high rate of invalidation in post grant procedures has been attributed by Judge Smith to the selection of weak patents by patent challengers for such proceedings.²⁸

^[176] Sterne & Quinn, *supra* note 173. While Rob Sterne and Gene Quinn do not identify the “former top USPTO official,” I heard John Whealan (former Deputy General Counsel for Intellectual Property Law and Solicitor at the PTO) make these same observations at the Center for American and International Law’s 52nd Annual Conference on Intellectual Property Law on November 10, 2014 in Plano, Texas.

²⁶ Megan M. La Belle, *Public Enforcement Of Patent Law*, 96 B.U. L. Rev. 1865, 1891-92 (2016)(original footnotes integrated into text in brackets).

²⁷ Nate Dilger & John Lord, *Evaluating the Effectiveness of the Inter Partes Review Process*, 39-AUG L.A. Law. 16 (July/August 2016).

²⁸ *Id.* (quoting Sarah Tran, *Policy Tailors and the Patent Office*, 46 U.C. Davis L Rev. 487, 498-99 (2012)) (“The decrease in granted petitions may also be tied to the type of patents now being challenged, in particular, the overall strength of those patents. The early IPR petitions appeared to focus on the weakest patents, a point that Judge Smith noted during a 2014 meeting of the U.S. Patent and Trademark Office’s Patent Public Advisory Committee. Indeed the stated goal of the AIA was to give the Patent Office a ‘toolbox’ of new proceedings to ‘weed out low quality patents ... includ[ing] post-grant review, IPR, supplemental examination, and derivation proceedings, as well as a transitional post-grant review program for certain business methods patents.’”).

“The goal of minimizing uncertainty regarding claim scope applies * * * to post-grant reviews * * *.”²⁹

D. Need for Validity “Police” at the PTO

That the need for greater validity “police” remains despite the Rader “death squad” hysteria is manifested by Professor La Belle’s conclusion that “[i]nvalid patents, even if unenforced, are problematic. They dampen innovation, hamper competition, and harm consumers. Yet no public agency polices patents after they are issued. We rely instead on private parties, despite the fact that incentives for private validity challenges are seriously lacking. Even with the passage of the AIA and the creation of new and improved administrative proceedings, it is not clear that substantially more patents--or the right type of patents--are being challenged.”³⁰

²⁹ Manzo, *Patent Claim Construction in the Federal Circuit* § 1:5, *Additional considerations that complicate patent claim construction* (2017 ed.)(citing *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989)] (“The issued claims are the measure of the protected right.”)(citing, *inter alia*, *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 232 (1942), and *General Electric Co. v. Wabash Appliance Corporation*, 304 U.S. 364, 369 (1938)).

³⁰ La Belle, *supra*, 96 B.U. L. Rev. at 1928.

V. CASE STUDIES

A. The *Restasis* Case

Under the *Leahy Smith America Invents Act* of 2011, the procedures have been tightened up to make it easier for patent challengers to establish the invalidity of patents under Post Grant Review (PGR) and Inter Partes Review (IPR). Literally billions of dollars have been saved by consumers through the effective use of the PGR and IPR review proceedings. Indeed, a former member of the Federal Circuit before his resignation from the bench had dubbed these post grant proceedings as “death squads” for patents.

As an added feature to the *Restasis* case, the patentee has employed a clever (but unsuccessful) trick to block a Patent Office challenge to validity by transferring patent title to the Saint Regis Mohawk Tribe (which then granted Allergan an exclusive license under the patents).

The *Restasis* scheme is explained by Hiltzik.

[T]he drug maker sold its *Restasis* patents to the St. Regis Mohawk Tribe, which promptly granted the company an exclusive license to those same patents and obligingly filed a motion to dismiss the Inter Partes Review. In return, the tribe was paid \$13.75 million up front and the promise of \$15 million a year in royalties. One wonders if the tribe could have held out for more, since *Restasis* sales come to \$1.5 billion a year, according to Allergan.

In announcing the deal, Allergan executives exuded all the sincerity of made men singing the praises of their *capo di tutti capi*. Allergan claimed it was approached by the tribe with “a sophisticated opportunity to strengthen the defense of our *Restasis* intellectual property,” and praised the “thoughtful and enterprising approach” of the native Americans, whose home base is in the rural hinterlands a few miles south of the St. Lawrence River and Canadian border, “to achieve their

goals of self-reliance and help them address the most urgent needs in their community.”

To [Circuit Judge] Bryson, the deal smelled more as if the deal’s real motivation was to “attempt to avoid the IPR proceedings” currently before the patent office “by invoking the Tribe’s sovereign immunity.”

What Allergan is after, he found, is “the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits.” If successful, he said, “Allergan’s tactic ... could spell the end” of the IPR program, which was an important component of patent reform in 2011.³¹

Hiltzik explains the extreme nature of the Allergan gambit:

In the annals of cynical corporate subterfuges, it would be hard to top the effort by the drugmaker Allergan to fend off a patent challenge by selling its drug rights to a rural New York Indian tribe.

That’s saying a lot, given the creativity of corporate lawyers searching for ways to subvert the law. But a federal judge in Texas this week called foul on Allergan’s stunt. “In reality,” observed Judge William Bryson of Marshall, Texas, Allergan tried to “purchase — or perhaps more precisely, to rent — the Tribe’s sovereign immunity” purely in order to defeat the patent challenge.³²

Hiltzik further explains that “[t]he St. Regis Mohawk Tribe, which acted as Allergan’s patent front, isn’t showing any regrets thus far. As recently as

³¹ Michael Hiltzik, *A judge calls foul on Allergan's attempt to hide its drug patents behind an Indian tribe's sovereignty*, Los Angeles Times (October 19, 2017), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-allergan-tribe-20171019-story.html>.

³² Michael Hiltzik, *A judge calls foul on Allergan's attempt to hide its drug patents behind an Indian tribe's sovereignty*, Los Angeles Times (October 19, 2017), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-allergan-tribe-20171019-story.html>.

Wednesday, the tribe sued Microsoft and Amazon on behalf of a small technology company called SRC Labs, which claims that the big companies are infringing its patents on data processing technologies. SRC's goal in assigning its patents to the tribe was to head off a counter-challenge from Microsoft and Amazon."³³

B. *Oil States Energy Services Case*

In the *Oil States Energy Services* case, *certiorari* has been granted to the patent challenger, so the case is now before the Supreme Court on the merits. The petitioner argues that a patent validity challenge through an administrative proceeding is unconstitutional.

C. *SAS Institute v. Matal Case*

In *SAS Institute Inc. v. Matal*, in an Inter Partes Review proceeding, the PTO examined only *some* of the claims; here, petitioner questions whether “th[e] Board [must] issue a final written decision as to every claim challenged by the petitioner, or does [the statute] allow that Board to issue a final written decision with respect to the patentability of only some of the patent claims challenged by the petitioner, as the Federal Circuit held?”

³³ Michael Hiltzik, *A judge calls foul on Allergan's attempt to hide its drug patents behind an Indian tribe's sovereignty*, Los Angeles Times (October 19, 2017), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-allergan-tribe-20171019-story.html>.

Both *Oil States Energy Services* and *SAS Institute Inc. v. Matal* will be argued before the Supreme Court on Monday November 27, 2017. Merits decisions in both cases are expected before the Court completes its present Term at the end of June 2018.

D. The *Prozac* Case

1. A \$ 34 Billion Stock Price Fall

It is not just the patent challengers who should benefit from PTO proceedings to determine patent validity. Perhaps the most notorious determination of patent invalidity in a trial court is the *Prozac* case. *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 222 F.3d 973, 988 (Fed. Cir. 2000)(Gajarsa, J.), which Professors Burk and Lemley point out was, in their understated fashion, “quite controversial”.³⁴ The Prozac invalidity ruling triggered a one day drop in the value of patentee Eli Lilly’s stock to the tune of \$ 34 billion dollars.³⁵ It is

³⁴ Dan L. Burk and Mark A. Lemley, *Inherency*, 47 Wm. & Mary L. Rev. 371, 385 (2005)(“*Eli Lilly & Co. v. Barr Laboratories, Inc.*, [251 F.3d 955 (Fed. Cir. 2001),] held that Lilly's own prior patent on a method of treating anxiety with Prozac inherently anticipated its later patent on a method of blocking serotonin uptake, since Prozac operates by inhibiting serotonin uptake. [*Id.* at 969-70. *** [T]he panel's conclusion that the first Lilly patent was prior art, even though it was filed after the second patent, was quite controversial. See *id.* at 975(Newman, J., dissenting).]”)(footnotes integrated into text in brackets).

³⁵ John R. Allison, Mark A. Lemley, Kimberly A. Moore and R. Derek Trunkey, *Valuable Patents*, 92 Geo. L.J. 435, 474 (2004)(citing M. Patricia Thayer, *Double Patenting Sounds Death Knell for Prozac Patent: Eli Lilly and Co. v. Barr Laboratories, Inc.*, at [http:// www.hewm.com/use/articles/elilly.pdf](http://www.hewm.com/use/articles/elilly.pdf) (last visited May 18, 2004).) (“Eli Lilly's stock fell almost 30% (and over \$34 billion) on the day its Prozac patent was held invalid, even though this holding occurred only one year before the patent would otherwise have expired. See M. Patricia Thayer, *Double Patenting Sounds Death Knell for Prozac Patent: Eli Lilly and*

difficult, at best, to rely upon an appellate court to overturn a District Court ruling such as in the *Prozac* case.³⁶

In her dissent in the *Prozac* case, Judge Newman summarized the holding as follows: “The panel has reached the truly anomalous result of holding invalid for obviousness [the *Prozac* patent], on a theory of obviousness-type double patenting, an invention that was made and applied for nine years before the asserted ‘prior art’ was filed.”³⁷ Her opinion more completely explains *why* the court was wrong in creating a new ground of double patenting to invalidate the *Prozac* patent:

The Federal Circuit, sitting en banc, vacated the panel's prior opinion [invalidating the *Prozac* patent on the ground of double patenting, 222 F.3d 9735 (Fed. Cir. Aug. 9, 2000) (Gajarsa, J.),] and returned the case to the panel for further consideration. The panel now again holds claim 7 of the '549 (Molloy) patent [for Prozac, assigned to Eli Lilly] invalid for double patenting, but this time it bases that determination on a different patent, the '213 patent (Stark). The panel now grants summary judgment invalidating claim 7 of the '549 patent for double patenting with the Stark patent. However, this shift has led the panel into factual

Co. v. Barr Laboratories, Inc., at <http://www.hewm.com/use/articles/elilly.pdf> (last visited May 18, 2004).

³⁶ *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 222 F.3d 973, 988 (Fed. Cir. 2000)(Gajarsa, J.) (“[T]he circumstances giving rise to the present case support our conclusion that claim 7 [covering Prozac] is invalid for obviousness-type double patenting. This case arose when [generic manufacturer and patent challenger] Barr filed an ANDA application seeking FDA approval for marketing fluoxetine hydrochloride as an antidepressant, and Lilly responded by suing for infringement of, *inter alia*, claim 7 of the '549 patent. Under the '895 patent, which issued in 1977 and expired in 1994, Lilly possessed the right to exclude others from administering any compound, including fluoxetine hydrochloride, within the class of claimed compounds to treat depression. In effect, under the '895 patent, Lilly had the right to exclude others from engaging in the very conduct for which Barr currently seeks FDA approval. Now, by asserting claim 7 of the '549 patent, Lilly attempts to extend the term of exclusivity it enjoyed under the '895 patent for an additional nine years beyond the statutorily prescribed term. “Effectively extending the patent term, however, is precisely the result that the doctrine of obviousness-type double patenting was created to prevent.” [*In re Berg*, 140 F.3d 1428, 1435 (Fed.Cir.1998).]”)

³⁷ As explained by Circuit Judge Newman in *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 972-76 (Fed. Cir. 2001)(dissenting from the refusal to reconsider the case en banc).

and legal areas that were not developed at trial, and into misapplication and misstatement of the law of double patenting. I must, respectfully, dissent.

Obviousness–Type Double Patenting

The judge made law of obviousness-type double patenting was developed to cover the situation where patents are not citable as a reference against each other and therefore can not be examined for compliance with the rule that only one patent is available per invention. Double patenting thus is applied when neither patent is prior art against the other, usually because they have a common priority date. See *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278–81 (Fed.Cir.1992) (summarizing the criteria for obviousness-type double patenting). As the court explained in *In re Boylan*, 392 F.2d 1017, 1018 n. 1 (CCPA 1968), “it must always be carefully observed that the appellant's patent is not ‘prior art’ under either section 102 or section 103 of the 1952 Patent Act.”

These fundamental requirements for application of the law of double patenting are not met by the '549 and Stark patents. The Stark patent was filed nine years after the effective filing date of the '549 patent; there is no formal relationship between them; the '549 disclosure was a cited reference against Stark; and they have different inventorships. The panel ignores these routine criteria and the effect they have on a double patenting analysis. Whatever effect the '549 and Stark patents may have on each other, it is not “double patenting.”

The district court had rejected Barr's double patenting arguments after summary judgment proceedings, ruling that:

“Barr's primary contention is that claim 7 of the '549 patent is invalid for double patenting because it merely sets forth the “scientific explanation” for the subject matter of certain of Lilly's other patents. Barr's summary judgment briefing on this issue is a confusing amalgamation of broad patent law principles that are not clearly applicable to the issues before the Court. In fact, the only case law cited in support of its theory is a dissenting opinion, never adopted thereafter by any court as best we could determine. Even disregarding any limitation on the application of this legal theory to the issues at hand, we observe that Barr's briefs focus extensively on the formulation and restatement of its legal theory to the exclusion of any evidence sufficient to explain or support it. Most notably, Barr has failed to provide any authoritative, reliable scientific opinion to establish that claim 7 of the

'549 patent constitutes merely the later scientific explanation of what has already been claimed in the patents that came before.”

*** [T]he panel now *** sua sponte finds double patenting between claim 7 of the '549 patent and claim 1 of the Stark patent. The '549 disclosure, in the form of three issued divisional patents, was prior art cited against the Stark patent. Patentability of the Stark claims over this prior art was successfully argued in the PTO. The panel reaches the anomalous conclusion that the earlier filed '549 patent (effective filing date January 10, 1974) is invalid for obviousness-type double patenting with the Stark patent that was filed nine years later (April 8, 1983). Such a result is not available under the laws of 35 U.S.C. § 102 and § 103; neither can it be achieved under the rubric of double patenting.

* * *

Claim 7 of the '549 Molloy patent:

“The method of * * * [blocking the uptake of monoamines by brain neurons in animals] comprising administering to said animal a monoamine blocking amount of N methyl 3-p-trifluoromethylphenoxy-3-phenylpropylamine [fluoxetine] or a pharmaceutically-acceptable acid addition salt thereof.”

Claim 1 of the '213 Stark patent:

“A method for treating anxiety in a human subject in need of such treatment which comprises the administration to said human of an effective amount of fluoxetine or norfluoxetine or pharmaceutically-acceptable salts thereof.”

The panel holds that the later-discovered and later-filed anxiety-treatment use of fluoxetine invalidates the patent on the earlier discovery of monoamine (serotonin) blocking use because the earlier discovery is “inherent” in the later one. That is not a correct statement of either the law of double patenting or the law of inherency. The 1974 invention can not be invalidated based on what was filed and claimed in the 1983 application, even on the panel's incorrect view of the law of inherency as applied to biological inventions.

The district court remarked on the absence of reliable evidence as well as legal precedent to support Barr's proffered theories. The panel, however, finds that “Barr has offered a panoply of evidence to support the recognition of this inherent biological function.” Panel op. at 23. I take note that the panel cites only references

dated after the '549 application was filed. These references are not prior art to the '549 claims. Later discoveries and scientific advances may well elucidate the earlier ones, but that does not retrospectively erase the patentability of the earlier work.

The complex factual issues that have been raised in the record, in connection with the relationship between serotonin uptake and the various pharmaceutical uses of fluoxetine, can not be resolved in favor of Barr and adversely to Lilly on the summary judgment record, for the material facts have been placed squarely at issue. Indeed, the scientific evidence in the record weighs heavily against the panel's findings.

It is highly relevant that the Stark application was examined in light of prior art that included the '549 Molloy disclosure. While Barr cites cases that established rules with respect to the subsequent patentability of a genus when a species is known, this has no relevance to the question at bar. Further, these rules relate to whether a subsequent invention is patentable, not a prior one. Here, however, it is the first-filed (Molloy) invention that the panel invalidates in view of the later-filed Stark invention. Although the Stark patent issued seven months before the '549 patent, the panel incorrectly holds that the later-filed but earlier-issued Stark claim renders obvious the '549 claim of nine years earlier priority. Neither *In re Berg*, 140 F.3d 1428 (Fed.Cir.1998), relied on by the panel, nor any other case, supports such an inverted holding.

When two patents issue with claims that are not patentably distinct, the principle served by the judge made law of double patenting is that because patent protection started with the first patent to issue, it should not extend to the expiration of the second patent to issue. Thus the law of double patenting does not consider the patents as prior art; the law simply requires elimination of the extension of exclusivity by truncating the term of the second patent to issue, to coincide with the term of the first patent to issue.

When the second patent to issue is (as here) the first patent that was filed, an anomaly may arise when there is a valid charge of obviousness-type double patenting. I repeat, that charge is not here available because the first patent that was filed was in fact a reference against the second patent. The panel, ignoring this immutable fact, undertakes an obviousness-type double patenting analysis. When two patents are appropriately considered for obviousness-type double patenting, an anomaly arises, for example, when the claims of patent B are "obvious" in light of

the claims of patent A, but the claims of patent A are not obvious in light of the claims of patent B. An illustration is shown in *In re Berg*, where one patent was directed to a species, and the other to a genus that included the species. A genus is usually not patentable over a species, but a species may, depending on the facts, be patentable over the genus. Judge made law has developed a special and simple test for double patenting in such a situation: the requirement of “cross-reading.” By applying the rules of cross-reading, double patenting will not lie, for cases in which the first patent to issue is the second patent that was filed, unless the claims cross read; that is, unless the claims of each patent would have been obvious in view of the claims of the other patent. This simple expedient avoids the analytical trap into which the panel fell.

The panel has reached the truly anomalous result of holding invalid for obviousness, on a theory of obviousness-type double patenting, an invention that was made and applied for nine years before the asserted “prior art” was filed.

The panel states that *In re Berg* requires that unless the PTO is solely and exclusively responsible for all delays in issuing the first-filed patent, the patentee can not rely on the fact of its earlier filing. That is not the *Berg* holding. In *Berg* the same inventors filed, on the same day, patent applications whose claims stood in the relationship of genus and species of the same method for preparing an abrasive particle suitable for use in an abrasive composition. When the species application was about to issue, the examiner rejected the genus application on the grounds of obviousness-type double patenting. *Berg* argued that each application should be evaluated as to whether it represented a patentable advance over the other, a two-way test of cross-reading applied in particular circumstances. This court stated that the purpose of the two-way test, as it had been developed in our precedent, was “to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing.” The Federal Circuit then held that *Berg* was not entitled to the benefits of the two-way test because he could have included all of the claims in a single application. Neither the facts of *Berg* nor the law as developed therein applies to the patents here under consideration.

The panel also holds that because Lilly disclaimed the Stark patent before trial, this bars Lilly from disclaiming that portion of the '549 patent that would have extended beyond the Stark patent's original life. No precedent so holds, and I

discern no basis for such a new rule. A terminal disclaimer is a standard response to a charge of double patenting; this remedy need not be withheld, at least in the absence of fraud or bad faith. To deny a patentee the opportunity of simplifying the issues or improving its litigation position is an unnecessary if not a punitive action, unwarranted on this record.

The New Rules of Patentability of Biological Inventions

The panel states that “the natural result of fluoxetine hydrochloride is the inhibition of serotonin uptake,” and holds that a discovery of a new and unobvious biological property is unpatentable because it is inherent in the chemical compound. As authority the panel cites a dissenting opinion in *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1233 (Fed.Cir.1994) (Lourie, J. dissenting in part), the dissent suggesting that a patent to a method which “is an inherent, inevitable result of the practice” of another method patent constitutes same-invention double patenting. Thus the panel holds the '549 claim to serotonin inhibition to be invalid as the natural and inherent result of the Stark treatment for relief of anxiety. However, every biological property is a natural and inherent result of the chemical structure from which it arises, whether or not it has been discovered. To negate the patentability of a discovery of biological activity because it is “the natural result” of the chemical compound can have powerful consequences for the patentability of biological inventions. The narrow facts of *Burroughs Wellcome* and the dissenting view therein do not warrant the new rule now adopted.

The panel also states that “there is not sufficient evidence on which a jury could base a finding that fluoxetine hydrochloride does not inhibit the uptake of serotonin.” Indeed, it is far from clear what could be proved, as well as what must be proved, on the panel's theory of double patenting, for the many scientific articles cited in the record show the complexity of the mechanism of action of fluoxetine. However, the panel's ruling that Lilly would have to prove that serotonin inhibition does not occur on treatment with fluoxetine, in order to avoid double patenting invalidity of its claim for serotonin inhibition on treatment with fluoxetine, will surely add confusion and uncertainty to patent practice.

In this period of unprecedented development of patent-supported biological advance, the nation needs a stable and comprehensible patent law, lest this court falter in its leading role in implementing the law's fundamental purposes.³⁸

2. Unpredictability in the Judicial System

As seen from the *Prozac* case, it is not just the patent challengers who should benefit from PTO proceedings to determine patent validity. Perhaps the most notorious determination of patent invalidity in a trial court is the *Prozac* case which Professors Burk and Lemley point out was, in their understated fashion, “quite controversial”.³⁹ The Prozac invalidity ruling triggered a one day drop in the value of patentee Eli Lilly’s stock to the tune of \$ 34 billion dollars.⁴⁰ It is difficult, at best, to rely upon an appellate court to overturn a District Court ruling such as in the *Prozac* case.⁴¹

³⁸ *Eli Lilly & Co. v. Barr Laboratories*, 251 F.3d at 972-76 (Newman, J., dissenting from the refusal to reconsider the case en banc)(bold emphasis added)(footnote omitted).

³⁹ Dan L. Burk and Mark A. Lemley, *Inherency*, 47 Wm. & Mary L. Rev. 371, 385 (2005)(“*Eli Lilly & Co. v. Barr Laboratories, Inc.*, [251 F.3d 955 (Fed. Cir. 2001),] held that Lilly's own prior patent on a method of treating anxiety with Prozac inherently anticipated its later patent on a method of blocking serotonin uptake, since Prozac operates by inhibiting serotonin uptake. [*Id.* at 969-70. *** [T]he panel's conclusion that the first Lilly patent was prior art, even though it was filed after the second patent, was quite controversial. See *id.* at 975(Newman, J., dissenting).]”)(footnotes integrated into text in brackets).

⁴⁰ John R. Allison, Mark A. Lemley, Kimberly A. Moore and R. Derek Trunkey, *Valuable Patents*, 92 Geo. L.J. 435, 474 (2004)(citing M. Patricia Thayer, *Double Patenting Sounds Death Knell for Prozac Patent: Eli Lilly and Co. v. Barr Laboratories, Inc.*, at [http:// www.hewm.com/use/articles/elilly.pdf](http://www.hewm.com/use/articles/elilly.pdf) (last visited May 18, 2004).) (“Eli Lilly's stock fell almost 30% (and over \$34 billion) on the day its Prozac patent was held invalid, even though this holding occurred only one year before the patent would otherwise have expired. See M. Patricia Thayer, *Double Patenting Sounds Death Knell for Prozac Patent: Eli Lilly and Co. v. Barr Laboratories, Inc.*, at [http:// www.hewm.com/use/articles/elilly.pdf](http://www.hewm.com/use/articles/elilly.pdf) (last visited May 18, 2004).

⁴¹ *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 222 F.3d 973, 988 (Fed. Cir. 2000)(Gajarsa, J.)(“[T]he circumstances giving rise to the present case support our conclusion that claim 7 [covering Prozac] is invalid for obviousness-type double patenting. This case arose when [generic manufacturer and patent challenger] Barr filed an ANDA application seeking FDA approval for marketing fluoxetine

3. Broad PTO Interpretation of *Lilly v. Barr*

The Patent Office in its *Manual of Patent Examining Procedure* cites *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001), as basis for the proposition that when “any invention claimed in [a commonly owned] application [is] *** an obvious variation of[] an invention claimed in the patent” then “a nonstatutory double patenting rejection may be appropriate *** when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent.”⁴²

hydrochloride as an antidepressant, and Lilly responded by suing for infringement of, *inter alia*, claim 7 of the '549 patent. Under the '895 patent, which issued in 1977 and expired in 1994, Lilly possessed the right to exclude others from administering any compound, including fluoxetine hydrochloride, within the class of claimed compounds to treat depression. In effect, under the '895 patent, Lilly had the right to exclude others from engaging in the very conduct for which Barr currently seeks FDA approval. Now, by asserting claim 7 of the '549 patent, Lilly attempts to extend the term of exclusivity it enjoyed under the '895 patent for an additional nine years beyond the statutorily prescribed term. “Effectively extending the patent term, however, is precisely the result that the doctrine of obviousness-type double patenting was created to prevent.” [*In re Berg*, 140 F.3d 1428, 1435 (Fed.Cir.1998).]”

⁴² MPEP § 804, *Definition of Double Patenting* [R-07](October 2015) (“A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985). In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is: is any invention claimed in the application anticipated by, or an obvious variation of, an invention claimed in the patent? If the answer is yes, then a nonstatutory double patenting rejection may be appropriate. Nonstatutory double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent, or a non-commonly owned patent but subject to a joint research agreement as set forth in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3), when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).”).

The *Manual* interpretation of *Lilly v. Barr Labs.* is followed *sub silentio* in a series of cases from the Patent Trial and Appeals Board:

In the *Hong-Zhu* case, Judge D.Z. Newman quotes with approval from *Eli Lilly v. Barr Labs.*: “‘A later claim that is not patentably distinct from,’ i.e., ‘is obvious over[] or anticipated by,’ an earlier claim is invalid for obviousness-type double patenting.”⁴³ The opinion of Judge R.J. Smith in the *Hyde* case emphasizes the focus of the Board not on the date of the reference patent cited for double patenting but instead deals with double patenting keyed to “an earlier patent claim”. Thus, as stated by Judge R.J. Smith in the *Hyde* case,⁴⁴ “[o]bviousness-type double patenting prohibits the issuance of claims in a second patent that are ‘not patentably distinct from the claims of the first patent.’ *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985). ‘A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.’ *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).”

More recently, Judge Smith in the *Deluca* case focused once again on the patentable distinctness of claims: “Obviousness-type double patenting prohibits the issuance of claims in a second patent that are ‘not patentably distinct from the claims of the first patent.’ *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985) (citations omitted). An obviousness-type double patenting analysis is generally analogous to an obviousness analysis under 35 U.S.C. § 103. *See, e.g., Abbvie Inc.*

⁴³ *Ex Parte Hong Zhu*, 2016 WL 3357335, slip op. at 6 (Patent Tr. & App. Bd. 2016)(D.Z. Newman, APJ)(quoting *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1385 (Fed. Cir. 2010)(alteration in original),(quoting *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001)).

⁴⁴ *Ex parte Hyde*, 2016 WL 5234733, slip op. at 3 (Patent Tr. & App. Bd. 2016)(R.J. Smith, APJ)(citations omitted in the original opinion).

v. Mathilda and Terence Kennedy Institute of Rheumatology Trust, 764 F.3d 1366, 1378-79 (Fed. Cir. 2014) (citing cases). However, resolution of a double patenting analysis is based on the claims at issue and the claims of the reference patent. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) ('A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.')⁴⁵

In the *Cooper* case, Judge Wilson followed *Eli Lilly v. Barr Labs.* by focusing upon extension of term for a double patenting rejection, as opposed to whether a reference patent is prior art:

The judicial doctrine of obviousness-type double patenting precludes an applicant from extending the term of protection for a patented invention by claiming an obvious variant of the patented invention in a subsequent patent application. *See In re Longi*, 759 F.2d 889, 892 (Fed. Cir. 1985). Generally, an obviousness-type double patenting analysis entails two steps. First, the claim in the earlier patent and the claim in the pending application are construed to determine the differences between them. Second, a determination is made whether the differences in subject matter between the two claims render the claims patentably distinct. *See, e.g., Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent or copending application, the disclosure of the patent or copending application may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279 (Fed. Cir. 1992).⁴⁶

⁴⁵ *Ex parte Deluca*, 2017 WL 2061608, slip op. a 4 (Patent Tr. & App. Bd. 2017)(R.J. Smith, APJ).

⁴⁶ *Ex parte Cooper*, 2017 WL 2061524, slip op. at 2 (Patent Tr. & App. Bd. 2017)(Wilson, APJ)(emphasis added).

Judge Flax in the *Cao* case focuses upon a determination “whether the claims are patentably distinct”:

“Obviousness-type double patenting entails a two-step analysis. First, the allegedly conflicting claims are construed and, second, the difference(s) between the claims are considered to determine whether the claims are patentably distinct. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). “A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.” *Id.* Here, as we noted above, Appellants' claims recite subject matter not recited in Chou's claims, thus, the scope of the respective claims is not the same. We find the aforementioned elements of Appellants' claims not recited by Chou's claims would not have been obvious in view of the claims of Chou.”⁴⁷

4. PTO Invalidity Decisions Keyed to Technical Issues

As pointed out in *Herschler*, citing *Ruscetta* and *Lukach*, “[i]t is now well settled law that disclosure of a species is insufficient to provide descriptive support for a generic or sub-generic claim[.]”⁴⁸ That a highly technical issue is more likely to succeed at the PTO versus in the court to deny patentability or validity is manifested by the *Ruscetta* line of cases, as prominently featured in the *Lukach* case.

It is important to understand that technically-focused case law plays better at the PTAB than it does in the courts. For example, a search of case law beginning with January 1, 2010, showed two (2) Federal Circuit cases citing *Lukach* but in

⁴⁷ *Ex parte Cao*, 2017 WL 1177254, slip op. at 7 (Patent Tr. & App. Bd. 2017)(Flax, APJ).

⁴⁸ *In re Herschler*, 591 F.2d 693, 696 (CCPA 1979)(citing *In re Ruscetta*, 255 F.2d 687 (CCPA 1958), *In re Lukach*, 442 F.2d 967 (CCPA 1971); *In re Smith*, 458 F.2d 1389 (CCPA 1972)).

the same period of time there were ninety-seven (97) PTAB cases citing the same case. The same search without any date restrictions showed eight (8) Federal Circuit cases but one hundred ninety two (192) Board decisions.⁴⁹

It is important at the Board to cite *recent* case law, particularly where a leading case is relatively old. Thus, for example, the underlying principle of *Lukach* may be traced to the 1958 *Ruscetta* case where a search without date restrictions shows thirteen (13) PTO decisions citing *Ruscetta*, while a total of fourteen (14) Federal Circuit and CCPA opinions cite to *Ruscetta*.

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⁴⁹ The search was conducted on October 24, 2017 on Westlaw, for decisions of the PTAB for ["re lukach" and DA(aft 1/1/2010)], for *all* Federal Cases: There were only two (2) cases citing *Lukach* but ninety-seven (97) Board decisions (including *ex parte* appeals). A search without date restrictions shows a total of eight (8) published Federal Circuit opinions citing *Lukach*, while a search for Board opinions citing *Lukach* yields one hundred ninety two (192) decisions.

VI. PREISSUANCE SUBMISSIONS BEFORE EXAMINATION

It makes sense to simplify proceedings which is best accomplished by encouraging a third party challenger presenting evidence of unpatentability early in proceedings, often *prior* to an examination on the merits by the Examiner. To facilitate earlier action on an application, it is proposed that a simple rule 35 USC § 122(f) be implemented as follows:

35 U.S.C. 122 Confidential status of applications; publication of patent applications.

* * *

(f)(1) Notwithstanding the provisions of paragraph (e)^[*] any third party within four months of publication of the patent application may submit a request for inter partes preissuance participation upon payment of a fee of \$ 1000 and thereupon participate in a preissuance proceeding under section (e)(2), provided the requirements of section (e)(2) are met within four months thereafter. A total of no more than forty pages of double spaced text shall be permitted (exclusive of references cited in the preissuance proceeding).

^[*]**35 U.S.C. 122 Confidential status of applications; publication of patent applications.**

• * * *

(e) PREISSUANCE SUBMISSIONS BY THIRD PARTIES.—

(1) IN GENERAL.—Any third party may submit for consideration and inclusion in the record of a patent application, any patent, published patent application, or other printed publication of potential relevance to the examination of the application, if such submission is made in writing before the earlier of—

(A) the date a notice of allowance under section 151 is given or mailed in the application for patent; or

(B) the later of—

(i) 6 months after the date on which the application for patent is first published under section 122 by the Office, or

(ii) the date of the first rejection under section 132 of any claim by the examiner during the examination of the application for patent.

(2) OTHER REQUIREMENTS.—Any submission under paragraph (1) shall—

(A) set forth a concise description of the asserted relevance of each submitted document;

(B) be accompanied by such fee as the Director may prescribe; and

(C) include a statement by the person making such submission affirming that the submission was made in compliance with this section.

(2) A patentee shall have the right to file a response days of no more than forty pages within ninety from the filing of a preissuance submission, whereupon the patent challenger under the foregoing paragraph shall have sixty days to file a response of no more than thirty pages.

VII.. CONCLUSION

At some point before the end of June 2018 the Supreme Court will in the *Oil States Energy* case will determine whether or not the current post-grant system to challenge patents at the Patent Office is constitutional. At that point, the patent community must decide whether to move forward with various reforms to strengthen the patent system.

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