

APPENDIX

APPENDIX A

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

**RICHARD STORER, GILLES GOSSELIN,
JEAN- PIERRE SOMMADOSSI,
PAOLA LACOLLA,**
Appellants

v.

JEREMY CLARK,
Appellee

UNITED STATES,
Intervenor

2015-1802

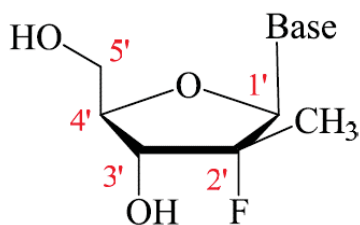
Appeal from the United States Patent and
Trademark Office, Patent Trial and Appeal Board
in No. 105,981.

Decided: June 21, 2017

Before PROST, *Chief Judge*, NEWMAN, and DYK,
Circuit Judges.

NEWMAN, *Circuit Judge*.

This patent interference contest involves methods of treating hepatitis C by administering compounds having a specific chemical and stereochemical structure, based on the following foundation formula of a five-membered ring having the fluorine substituent in the 2' (down) position:



Storer Br. at 8. The priority decision was based on enablement of this product. The interference was declared between an issued patent (Storer et al.) and a pending application (Clark), both of which were filed before the effective date of the America Invents Act, the statute that abolished the first-to-invent interference rule in favor of a first-to-file rule. By the terms of the Act, § 3(n)(2), the prior, first-to-invent, law applies to this interference.

To establish priority, Storer relied on the disclosure in the provisional specification from which priority was claimed for conception and constructive reduction to practice. In its joint decision on Clark's motion to deny Storer the benefit of the provisional application and on Clark's motion to invalidate Storer's claims on the grounds of lack of enablement and written

description,¹ the Patent Trial and Appeal Board (PTAB or “Board”) held that Storer’s provisional application was not enabling for the count of the interference, and on that ground the PTAB entered judgment granting priority to Clark.² Storer appeals that judgment and the underlying decision on Clark’s motions.

We take note that Storer initially filed in the District of Delaware, seeking review of the Board’s decision under 35 U.S.C. § 146. The district court dismissed the case, *Idenix Pharmaceuticals. LLC v. Gilead Pharmasset LLC*, 2016 WL 6804915, at *1 (D. Del. Nov. 16, 2016), based on this court’s ruling in *Biogen MA, Inc. v. Japanese Foundation for Cancer Research*, 785 F.3d 648 (Fed. Cir. 2015), that the America Invents Act eliminated the option of district court review under Section 146 for interferences declared after September 15, 2012. Although Storer says that *Biogen* was incorrectly decided, that decision is binding on this panel. Storer’s appeal of the district court’s dismissal has been stayed pending the outcome of this appeal. Order, *Idenix Pharm. LLC v. Gilead Pharmasset LLC*, No. 17-1369 (Fed. Cir. Feb. 16, 2017).

BACKGROUND

Inventors Richard Storer et al. were issued U.S. Patent No. 7,608,600 (“the ‘600 Patent”), on a final

¹ Decision on Motions – Bd.R. 125, *Clark v. Storer*, Interference No. 105,981, (P.T.A.B. Jan. 16, 2015), Doc No. 687 (“Bd. Op.”).

² *Clark v. Storer*, Interference No. 105,981, 2015 WL 1325503 (P.T.A.B. Mar. 23, 2015).

application filed on June 27, 2003. The patent is assigned to Idenix Pharmaceuticals. In the interference proceeding, Storer was initially declared the senior party based on the June 28, 2002 filing date of provisional application No. 60/392,350 (called “the S1 application” by the Board). Clark’s Application No. 11/854,218, assigned to Gilead Pharmasset, was filed September 12, 2007, with priority claimed to a provisional application filed on May 30, 2003.

Clark moved to deny Storer the priority date of the S1 application and to invalidate Storer’s claims, arguing that the S1 application did not enable compounds having the 2’F(down) substituent. Storer argued that these compounds were generically disclosed in the S1 application, and were readily obtained based on the disclosure in the S1 provisional and the prior art. The Board did not agree, and by withdrawing entitlement to the provisional’s filing date, the Board awarded priority to Clark. Storer now appeals that decision.

DISCUSSION

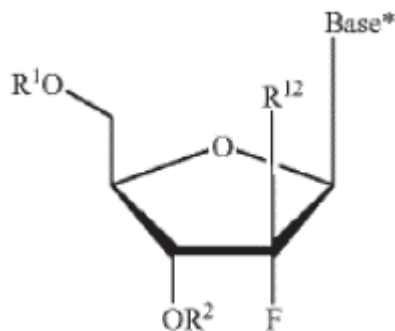
The Interfering Claims

Storer and Clark were investigating the treatment of hepatitis C using modified nucleoside compounds, including certain heterocyclic compounds having a fluorine substituent in the 2’ position. The PTAB identified the interfering subject matter, and selected claims for purposes of determining priority. From the Storer patent, the Board selected claim 1:

1. A method for the treatment of a host infected with a hepatitis C virus, comprising administering to the host infected with a

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hepatitis C virus an effective amount of a compound having the formula:



or a pharmaceutically acceptable salt thereof, wherein:

R¹ is H; mono-, di- or triphosphate; acyl; an amino acid ester; a carbohydrate; a peptide;

or a pharmaceutically acceptable leaving group which when administered in vivo provides a compound wherein R¹ is H or phosphate;

R² is H; acyl; an amino acid ester; a carbohydrate; a peptide; or a pharmaceutically acceptable leaving group which when administered in vivo provides a compound wherein R² is H;

Base* is selected from the group consisting of adenine, N⁶-alkylpurine, N⁶-acylpurine, N⁶-benzylpurine, N⁶-halopurine, N⁶-vinylpurine, N⁶-acetylenic purine, N⁶-acyl purine, N⁶-hydroxyalkylpurine, N⁶-alkylamino-purine, N⁶-thioalkyl purine, N⁶-alkylpurine, N⁶-alkyl-6-thiopurine, thymine, cytosine, 5-fluorocytosine, 5-methylcytosine, 6-azapyrimidine, 6-azacytosine, 2-and/or 4-mercaptopyrimidine,

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uracil, 5-halouracil, 5-fluorouracil, C⁵-alkylpyrimidine, C⁵-benzylpyrimidine, C⁵-halopyrimidine, C⁵-vinylpyrimidine, C⁵-acetylenic pyrimidine, C⁵-acyl pyrimidine, C⁵-hydroxyalkyl purine, C⁵-amidopyrimidine, C⁵-cyanopyrimidine, C⁵-iodopyrimidine, C⁶-iodopyrimidine, C⁵-Br-vinyl pyrimidine, C⁶-Br-vinylpyrimidine, C⁵-nitropyrimidine, C⁶-aminopyrimidine, N²-alkylpurine, N²-alkyl-6-thiopurine, 5-azacytidinyl, 5-azauracilyl, triazolopyridinyl, imidazolopyridinyl, pyrrolopyrimidinyl, pyrazolopyrimidinyl, guanine, hypoxanthine, 2,6-diaminopurine, and 6-chloropurine;

R¹² is C(Y³)₃; and

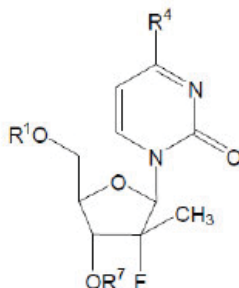
Y³ is independently H or F.

From the Clark application, the Board selected claim 164:

164. A method for the treatment of hepatitis C infection, which comprises:

administering to a mammal in need thereof an antivirally effective amount of a (2'R)-2'-deoxy-2'fluoro-2'-C-methyl nucleoside (β-D or β-L) or its pharmaceutically acceptable salt of the structure:

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wherein R¹ and R⁷ are independently H, a monophosphate, a diphosphate, a triphosphate, a H-phosphonate, an alkyl, an alkyl sulfonyl, or an arylalkyl sulfonyl; and R⁴ is NH₂ or OH.

The parties agree that the only question focuses on whether the Storer S1 provisional together with the prior art enabled compounds having a 2'F(down) substituent.

Enablement

Enablement is relevant for validity and to the issue of whether the provisional application is a constructive reduction to practice. “Constructive reduction to practice means a described and enabled anticipation under 35 U.S.C. 102(g)(1), in a patent application of the subject matter of a count.” 37 C.F.R. § 41.201. “When a party to an interference seeks the benefit of an earlier-filed United States patent application, the earlier application must meet the requirements of 35 U.S.C. § 120 and 35 U.S.C. § 112 ¶ 1 for the subject matter of the count.” *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998) (footnotes omitted). Section 112 ¶ 1 requires:

The specification shall contain a written description of the invention, and of the manner

and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, para. 1.³ Therefore, when the issue is priority based on the content of the specification, “[t]he earlier application must contain a written description of the subject matter of the interference count, and must meet the enablement requirement.” *Hyatt*, 146 F.3d at 1352.

Enablement is a matter of law, and is reviewed without deference; however, the factual underpinnings of enablement are reviewed for support by substantial evidence on the entirety of the PTO record. *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1297 (Fed. Cir. 2015). To establish enablement of a claim whereby new chemical compounds are provided for use to treat disease, the application must enable production or synthesis of the new compounds. *See In re Brebner*, 455 F.2d 1402, 1404 (C.C.P.A. 1972) (“A method of making starting materials not known in the art must be set forth in order to comply with the enablement requirement.”).

The Board held that the S1 provisional, taken together with the prior art, did not enable the specific compounds having the identified structure. Storer argued, and repeats on appeal, that a person of ordinary skill would have been able to make this class

³ This section is now § 112(a).

of compounds, having the requisite stereochemistry, based on information in the S1 provisional application and the prior art. “The enablement requirement is met where one skilled in the art, having read the specification, could practice the invention without ‘undue experimentation.’” *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (quoting *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010)).

“Whether undue experimentation is required ‘is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.’” *Id.* As summarized in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), relevant factors may “include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The Board determined that the claimed compounds having a 2′F(down) substituent were not enabled in Storer’s S1 provisional application, in that undue experimentation would be required to produce this structure. The Board analyzed the disclosure in terms of the evidentiary factors set forth in *Wands*.

Storer does not dispute the Board’s findings as to the third, fourth, fifth, sixth, and eighth *Wands* factors, but argues that these factors are not dispositive of enablement. For the third *Wands* factor—the presence or absence of working examples—Storer does not dispute that the S1

provisional contains no specific examples of synthesis of compounds having the fluoro substituent in the 2'(down) position. Bd. Op. at 24.

For the fourth *Wands* factor—the nature of the invention—the Board found that:

Count 1 is best characterized as the administration of a genus of nucleosides used in the treatment of viruses, particularly those of the family *Flaviviridae* (which includes HBV and HCV). We also find that, as of the time of filing of the S1 application, although organic fluoridation mechanisms were generally well-known in the art a 2'fluoro-2'-methyl nucleoside with the fluoro substituent in the “down” position had not yet been synthesized.

Id. at 25 (footnote omitted). Storer does not dispute this finding.

For the fifth *Wands* factor—the state of the prior art—the Board found that:

although DAST [N,N-diethylamino-sulfur trifluoride] was well-known in the prior art as fluoridating agent for nucleosides and nucleoside analogs, the prior art did not teach, or explicitly suggest, the use of DAST in the fluoridation of a tertiary alcohol to convert a tertiary alcohol at a nucleoside 2' position to a tertiary fluorine at the nucleoside 2' “down” position. We further find that, although organic fluoridation techniques were well-known in the art at the time the S1 application was filed, fluoridation of tertiary alcohols to produce a 2' “down” tertiary fluorine was not taught or suggested by the prior art.

Id. at 29. Storer does not dispute this finding.

With respect to the sixth *Wands* factor, the Board particularly relied on *Wands* factors 1, 2, 3, 4, and 7 and found that “the parties largely agree that the level of skill in the art is very high” and that

a person possessing the ordinary level of skill in this art, as of the time of the invention, would hold a doctoral degree in the field of organic, synthetic, or medicinal chemistry with at least a year’s experience in the field of nucleoside synthesis or relevant drug discovery.

Id. at 29–30. The Board also found that neither party argued the eighth *Wands* factor regarding the breadth of the claims. *Id.* at 34 n.64. These findings are not disputed.

The Board summarized the evidence and findings on which it concluded that undue experimentation would be needed to produce the designated molecule:

- (1) synthesis of a 2’-fluoro-2’-methyl nucleoside with the fluoro moiety in the “down” position required at least two years of a high-priority experimentation by persons skilled in the art, including multiple consultations with experts at the top of their fields and additional formal training;
- (2) the S1 application provides little in the way of direction or guidance as to how to synthesize such a compound;
- (3) the S1 application provides no explicit example of a 2’-fluoro-2’-methyl nucleoside, nor was an example provided by the relevant art as of the S1 application’s filing date;

(4) the invention is characterized as the administration of a genus of nucleosides used in the treatment of viruses, particularly those of the family Flaviviridae (which includes HBV and HCV) and an embodiment of the count requires a 2'-fluoro("down") 2'-methyl nucleoside;

(5) although organic fluoridation techniques were well-known in the art at the time the S1 application was filed, fluoridation of tertiary alcohols to produce a 2' "down" tertiary fluorine was not taught or suggested by the prior art;

(6) the level of skill in the art was highly sophisticated: a person possessing the ordinary level of skill in this art, as of the time of invention, would hold a doctoral degree in the field of organic, synthetic, or medicinal chemistry with at least a year's experience in the field of nucleoside synthesis or relevant drug discovery; and

(7) the art, at least with respect to fluoridation of tertiary alcohols to produce a tertiary fluorine in the 2' "down" position, was highly unpredictable.

We therefore find that *Wands* factors 1, 2, 3, 5, and 7 strongly indicate that a person skilled in the art would not arrive at the claimed invention without undue experimentation.

Id. at 34--35.

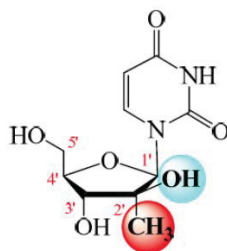
Based on these findings, the Board concluded that the interference subject matter was not enabled by Storer's S1 provisional application.

Argument on Appeal

Storer argues that the S1 provisional application “performed the substantial step of disclosing the precise chemical structure of the target compound.” Storer Br. at 47. Storer does not, however, identify any specific structure having the 2’F(down) substituent. The pages of the S1 provisional cited by Storer include generic structures, and Clark does not dispute that the “target compounds,” as the Board calls the 2’F(down) compounds, are generically included in the S1 provisional application’s generic formulas.

Storer states that the prior art contains “a well-known precursor compound that is only one step away from the target compound.” *Id.* at 8. Storer states that this precursor is “Matsuda Compound 17,” citing Akira Matsuda et al., *Alkyl Addition Reaction of Pyrimidine 2’-Ketonucleosides: Synthesis of 2’-Branched-Chain Sugar Pyrimidine Nucleosides (Nucleosides and Nucleotides LXXXI)*, 36 CHEMICAL & PHARMACEUTICAL BULL., no. 3, Mar. 1988, at 945.

Matsuda Compound 17 is presented in Storer’s brief as



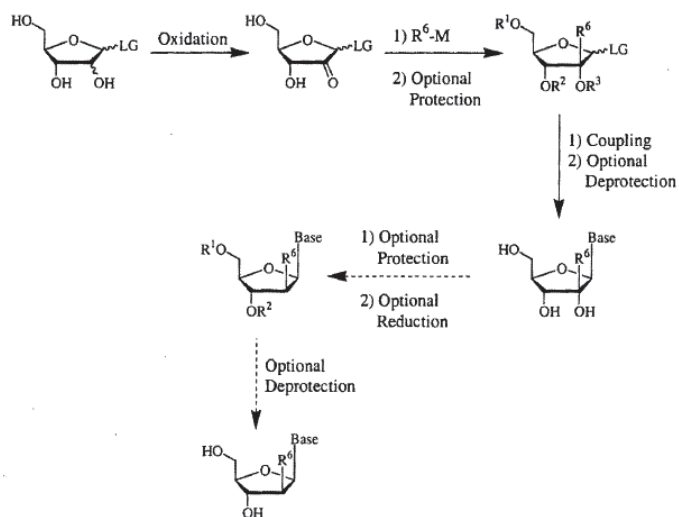
Matsuda Compound 17

Storer Br. at 12. Matsuda Compound 17 contains a methyl group in the 2'(down) position, and Storer states that Matsuda Compound 17 is readily converted into the target compound by known methods to produce the desired stereochemistry. Matsuda Compound 17 is not mentioned in the S1 provisional, but Storer argues that the precursor to Matsuda Compound 17 is in the S1 provisional, "as is that precursor's conversion to the Matsuda compound," *Id.* at 48 n.16. Storer states that the precursor "is only two steps away from the desired 2'-methyl 'up', 2'-fluoro 'down' configuration," and "each scheme discloses how to modify the 2'-keto precursor to obtain" Matsuda Compound 17. *Id.* at 9.

Thus Storer argues that the Matsuda reference, together with the information in the S1 provisional, enable synthesis of 2'F(down) compounds. Storer states that Schemes 3, 4 and 8 in the S1 provisional each describes a "2'-keto precursor, *i.e.*, a compound with '=O' at the 2' position," and that this is the path to the 2'F(down) molecule. *Id.* at 9. The three schemes from the S1 provisional are:

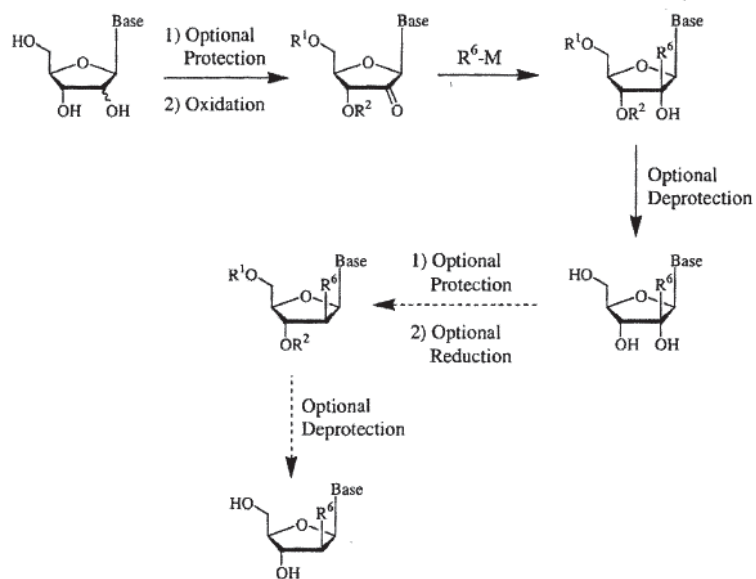
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Scheme 3

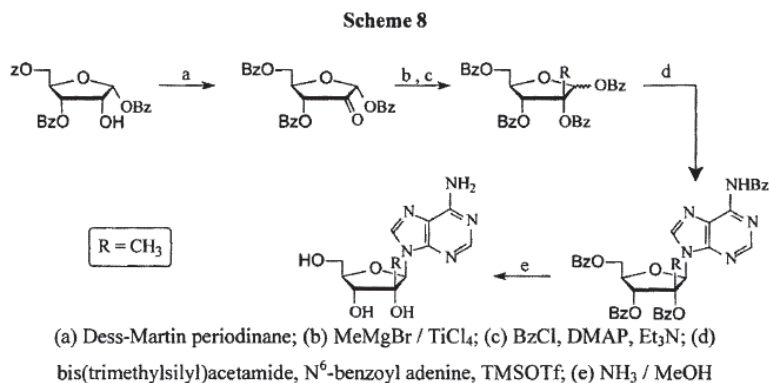


Storer Prov. Appl. at 119.

Scheme 4



Id. at 120.



Id. at 1948.

These three schemes indeed show a compound with =O at the 2' position, but none shows conversion to Matsuda Compound 17 or further conversion to the 2'F(down) analog. Clark points out that each scheme produces compounds with the opposite spatial arrangement from Matsuda Compound 17, for in Matsuda Compound 17 the 2'-OH is "up," whereas in Scheme 4 the 2'OH is "down." Clark Br. at 5.

Storer does not dispute the chemical facts, but argues that the difference between Matsuda 17 and the provisional synthesis schemes does not negate enablement because

if the alkylation reagent is methyl lithium (MeLi) or methyl Grignard (MeMgBr) for methylation as taught by the specification, one of ordinary skill in the art will obtain products with the orientation (*i.e.*, "stereochemistry") of the OH and methyl groups needed to synthesize the target compound using DAST or Deoxo-

Fluor. Furthermore, the prior art teaches how to control the stereochemistry of these groups.

Storer Br. at 9–10 n.5. Although the S1 provisional schemes show products with the opposite stereochemistry, Storer argues that a person of ordinary skill could make Matsuda Compound 17 employing these schemes. Storer argues that “a skilled artisan would have recognized that Matsuda Compound 17 was a viable precursor,” *id.* at 48, and that: “With knowledge of those structures, the hypothetical person would have known to use a common, one-step synthesis to modify the well-known precursor to obtain the target compound.” *Id.* Storer states that “simply by looking at the chemical structure of the target compound disclosed by Idenix, a person of ordinary skill would know to use a fluorination reagent,” *id.*, and “DAST and Deoxo-Fluor were the most well-known fluorinating reagents at the time for one-step fluorination reactions.” *Id.* at 49. Storer argues that Matsuda provides any necessary information not in the S1 provisional.

Clark responds that these are overstatements, for neither Matsuda Compound 17 nor any compound with the 2'F(down) structure is mentioned in the Storer S1 provisional. Clark points out that none of the several synthetic schemes in Storer's provisional application shows conversion of any precursor into Matsuda Compound 17. Clark states that Storer's synthetic schemes only disclose compounds with the “wrong stereochemistry.” Clark Br. at 37.

The Board agreed with Clark's position, and held that the S1 provisional's description of the 2'-keto precursor, in combination with the Matsuda reference,

was insufficient to enable and thereby to establish possession of the 2'F(down) methyl(up) compound of claim 1 before Clark's priority date. The Board stated, correctly, that for new chemical compounds the specification must provide sufficient guidance that undue experimentation is not required to obtain the new compounds.

ANALYSIS

The boundary between a teaching sufficient to enable a person of ordinary skill in the field, and the need for undue experimentation, varies with the complexity of the science. Knowledge of the prior art is presumed, as well as skill in the field of the invention. The specification need not recite textbook science, but it must be more than an invitation for further research. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

In *Genentech* the patentee argued that the prior art taught a method that could be used to produce a claimed human growth hormone product, compensating for lack of detail in the specification. The patentee argued that it did not need to include information in the prior art. This court agreed, but stressed the need to assure enablement of the novel aspects of the invention:

It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986). However, . . . [i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Genentech, 108 F.3d at 1366.

The Storer provisional specification does not describe synthesis of the 2'F(down) target compounds. The question devolves to the adequacy of the disclosure in the provisional of general schemes for synthesizing these general classes of modified nucleosides, taken with the knowledge of the art. The S1 provisional discloses two general approaches. Provisional schemes 3 and 8 modify the sugar portion of the target compound and then add the base portion, as the provisional application calls the "Glycosylation of the nucleobase with an appropriately modified sugar." Storer Prov. Appl. at 117.

Provisional scheme 4 shows modifying a compound with the base already attached, to achieve the desired structure. The provisional calls this "Modification of a pre-formed nucleoside." *Id.* at 119. The Board observed that none of the approaches in the provisional proceeds through a compound like Matsuda Compound 17, or suggests how Matsuda 17 may be converted into the target 2'F(down) compounds. The Board found that the Storer provisional does not exemplify such a reaction, or lead a person of ordinary skill to perform it. The Board also observed that the S1 provisional schemes produce compounds with opposite spatial arrangement from Matsuda Compound 17.

On review, we conclude that substantial evidence supports the Board's findings that the synthetic schemes in Storer's provisional application do not teach or suggest conversion of any precursor into the 2'F(down) structure, and that the Matsuda synthesis of a corresponding 2'-methyl (down), 2'-hydroxyl (up)

structure does not enable a person of ordinary skill to produce the target compounds without undue experimentation.

Wands factor 7, the predictability or unpredictability of the art, appears to be particularly relevant. Although Storer states that this is predictable chemistry, and therefore that detailed specific examples are not necessary, the Board's findings are in accord with the record. The Board found:

Having reviewed the parties' arguments, and the proffered evidence, we find that the art, with respect to fluoridation of tertiary alcohols, was highly unpredictable, as evidenced by Idenix's repeatedly unsuccessful attempts to synthesize its high-priority target nucleoside, and as further evinced by the statements of Dr. Coe and Dr. Storer.

Bd. Op. at 33–34. Regarding Dr. Coe's and Dr. Storer's statements, the Board stated:

Dr. Paul Coe, an expert in organofluorines, expressed skepticism regarding the use of DAST; and Dr. Richard Storer stated that “[a] lot of things which look simple on paper in related systems have been tried and don't work in this series. Having to make the tertiary fluoride is very different to [sic] having to make secondary.”

Id. at 31 (quoting from the record). The Board also referred to evidence presented on behalf of Clark that “attempted fluorination reactions (including those involving DAST) could fail, resulting in unfluorinated

elimination and/or rearrangement products, or products with incorrect stereochemistry.” *Id.* at 30.

Even on Storer’s position that a person skilled in this science would have started with Matsuda Compound 17, Storer has not shown that the critical stereochemical result would predictably ensue, although the reaction had never been performed. The Board received evidence of side reactions and the skepticism of experts. The Board received evidence that Storer and his team had difficulty and failures in synthesizing the target compound, as well as evidence that Clark and his team were more readily successful using apparently the same method. The Board’s finding that the chemistry was unpredictable is in accord with the evidence.

The first *Wands* factor is concerned with “undue” experimentation, and recognizes that what is “undue” of itself depends on the subject matter and skill. The Board discussed the amount of experimentation needed to produce the claimed compounds, and found that:

a high amount of experimentation is necessary to synthesize a 2'-fluoro-2'-methyl nucleoside with the fluoro moiety in the “down” position, requiring at least two years of a high priority experimentation by persons skilled in the art, including multiple consultations with experts at the top of the fields and additional formal training.

Id. at 19. The Board discussed the evidence showing Storer’s continuing research after the S1 provisional was filed, including the following findings:

- “Idenix’s research team in Montpellier, France, repeatedly attempted without success to synthesize a 2′-methyl(“up”) 2′-fluoro(“down”) nucleoside during the interval between December 2002 and September 2004.” *Id.* at 14.
- “Idenix scientists also corresponded with consultants Dr. George Fleet and Dr. Paul Coe in an attempt to effect a synthesis of the desired compound.” *Id.* at 14.
- “Idenix personnel also attended a ‘Scientific Update Course’ entitled ‘Making and Using Fluoroorganic Molecules’ in April, 2003, and submitted a report summarizing the course content.” *Id.* at 15.
- “Dr. Jean-François Griffon, leader of the Montpellier group, testified that he attempted at least seven different synthetic schemes, including several suggested by Dr. Coe, and in some cases employing DAST, without success.” *Id.* at 15.
- “[A]ttempts by the Montpellier team to use DAST in the synthesis of a 2′-fluoro-2′-methyl nucleoside produced similar failures.” *Id.* at 16.
- “With respect to the testimony of Jingyang Wang who allegedly synthesized the desired compound in a single attempt in January, 2015, at Idenix’s research facility in Cambridge, Massachusetts, we note that, prior to beginning her synthesis, Ms. Wang had received the reports from the Montpellier group as well as intermediate

compositions synthesized at Montpellier. Consequently, Ms. Wang was not, as Storer seems to suggest, attempting synthesis of a 2'-fluoro-2'-methyl nucleoside *ab initio*, but rather had the hindsight benefit of the Montpellier group's efforts." *Id.* at 17 (citations to the record omitted).

Storer argues that the Board failed to address the fact that Clark readily synthesized a target compound in a single step from Matsuda Compound 17. The Board acknowledged Storer's argument that it was "informative that Clark, a chemist without a Ph.D., was allegedly able to make a 2'-methyl (up) 2'-fluoro (down) nucleoside in just a few months using DAST." *Id.* at 13. Storer states that "Clark's experiments directly contradict the Board's reliance on the allegedly failed attempts of Griffon." Storer Br. at 55. There was evidence that Clark used a method similar to that attempted by Griffon on the Storer team, and that Clark succeeded where Griffon apparently failed. Storer stated to the Board that Griffon actually produced the target compound, but was not able to purify it from the reaction mixture.

The Board found, on consideration of the entire record, that a person of ordinary skill, with the disclosure in the provisional application and knowledge of the prior art, would not have been led to make the target compound, and could not do so without undue experimentation. The Board received evidence that successful fluorination reactions of the desired stereochemistry had not been reported for structurally similar compounds.

We conclude that substantial evidence supports the Board's finding that "a high amount of experimentation is necessary to synthesize" the target compound. The record before the Board showed sufficient variability and unpredictability to support the Board's conclusion that Storer's provisional application did not enable the interference subject matter. The Board's decision is affirmed.

AFFIRMED

APPENDIX B

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

**RICHARD STORER, GILLES GOSSELIN,
JEAN-PIERRE SOMMADOSSI,
PAOLA LACOLLA,**
Appellants

v.

JEREMY CLARK,
Appellee

UNITED STATES,
Intervenor

2015-1802

Appeal from the United States Patent
and Trademark Office, Patent Trial
and Appeal Board in No. 105,981.

**ON PETITION FOR PANEL REHEARING AND
REHEARING EN BANC**

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK,
MOORE, O'MALLEY, REYNA, WALLACH, TARANTO,
CHEN, HUGHES, and STOLL, *Circuit Judges*.

Per Curiam.

O R D E R

Appellants Richard Storer, Gilles Gosselin, Jean-Pierre Sommadossi, and Paola LaColla filed a combined petition for panel rehearing and rehearing en banc. Responses to the petition were invited by the court and filed by intervenor United States and appellee Jeremy Clark. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on November 13, 2017.

FOR THE COURT

November 3, 2017

Date

/s/ Peter R. Marksteiner

Peter R. Marksteiner

Clerk of Court

APPENDIX C

UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND
APPEAL BOARD

JEREMY CLARK
Junior Party
(Application No. 11/854,218)

v.

RICHARD STORER, GILLES GOSSELIN,
JEAN-PIERRE SOMMADOSSI,
and PAOLA LACOLLA
Senior Party
(US 7,608,600 B2)

Interference No. 105,981 (JGN)
Technology Center 1600

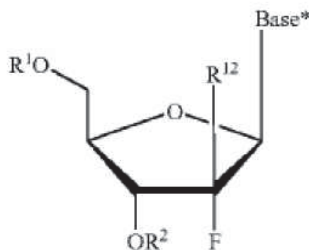
Decision on Motions - Bd.R. 125

Before RICHARD E. SCHAFER, DEBORAH KATZ,
and JOHN G. NEW, *Administrative Patent Judges*.
NEW, *Administrative Patent Judge*.

I. INTRODUCTION

This interference is before a merits panel for a decision on non-priority motions. The interference involves Junior Party Jeremy Clark's ("Clark") US Appl. No. 11/854,218 (the "218 application") and Senior Party Richard Storer, Gilles Gosselin, Jean-Pierre Sommadossi, and Paola LaColla's ("Storer") US Patent 7,608,600 B2 (the "600 patent"). Declaration at 1.¹ The subject matter of the interference is generally related to a method of using a class of 2'-fluoro, 2'-methyl (or halomethyl) nucleosides with a uracil or cytosine base for the treatment of a host infected with the hepatitis C virus ("HCV"). An important aspect of the nucleosides is the position of the fluorine moiety (F) in the "down" position as shown in the image below. Count 1 of the interference is Storer claim 1 or Clark claim 164 and recites:

1. A method for the treatment of a host infected with a hepatitis C virus, comprising administering to the host infected with a hepatitis C virus an effective amount of a compound having the formula:



¹ Paper No. 1

or a pharmaceutically acceptable salt thereof, wherein:

R¹ is H; mono-, di- or triphosphate; acyl; an amino acid ester; a carbohydrate; a peptide;

or a pharmaceutically acceptable leaving group which when administered *in vivo* provides a compound wherein R¹ is H or phosphate;

R² is H; acyl; an amino acid ester; a carbohydrate; a peptide; or a pharmaceutically acceptable leaving group which when administered *in vivo* provides a compound wherein R² is H;

Base* is selected from the group consisting of adenine, N⁶-alkylpurine, N⁶-acylpurine, N⁶-benzylpurine, N⁶-halopurine, N⁶-vinylpurine, N⁶-acetylenic purine, N⁶-acyl purine, N⁶-hydroxyalkyl purine, N⁶-alkylaminopurine, N⁶-thioalkyl purine, N²-alkylpurine, N²-alkyl-6-thiopurine, thymine, cytosine, 5-fluorocytosine, 5-methylcytosine, 6-azapyrimidine, 6-azacytosine, 2- and/or 4-mercaptopyrimidine, uracil, 5-halouracil, 5-fluorouracil, C⁵-alkylpyrimidine, C⁵-benzylpyrimidine, C⁵-halopyrimidine, C⁵-vinylpyrimidine, C⁵-acetylenic pyrimidine, C⁵-acyl pyrimidine, C⁵-hydroxyalkyl purine, C⁵-amidopyrimidine, C⁵-cyanopyrimidine, C⁵-iodopyrimidine, C⁶-iodo-pyrimidine, C⁵-Br-vinyl pyrimidine, C⁶-Br-vinyl pyrimidine, C⁵-nitropyrimidine, C⁶-amino-pyrimidine, N²-alkylpurine, N²-alkyl-6-thiopurine, 5-azacytidinyl, 5-azauracilyl, triazolopyridinyl, imidazolopyridinyl, pyrrolopyrimidinyl,

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pyrazolopyrimidinyl, guanine, hypoxanthine, 2,6-diaminopurine, and 6-chloropurine;

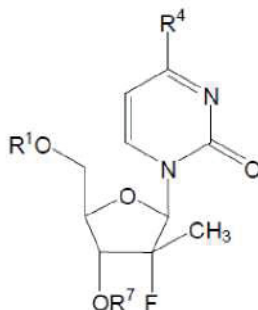
R^{12} is $C(Y^3)_3$; and

Y^3 is independently H or F.

or

164. A method for the treatment of hepatitis C infection, which comprises:

administering to a mammal in need thereof an antivirally effective amount of a (2'R)-2'-deoxy-2'-fluoro-2'-C-methyl nucleoside (β -D or β -L) or its pharmaceutically acceptable salt of the structure:



wherein R^1 and R^7 are independently H, a monophosphate, a diphosphate, a triphosphate, a H-phosphonate, an alkyl, an alkyl sulfonyl, or an arylalkyl sulfonyl; and

R^4 is NH_2 or OH .

Declaration at 3.

Before us are the following motions:

1. Clark Substantive Motion 1² to deprive Storer of the benefit of its US Appl. No. 60/392,350.
2. Clark Substantive Motion 2³ to deprive Storer of the benefit accorded with respect to Count 1 of its U.S. Appl. No. 60/466,194.
3. Clark Substantive Motion 3⁴ to deprive Storer of the benefit accorded with respect to Count 1 of its U.S. Appl. No. 60/470,949.
4. Clark Substantive Motion 10⁵ to deprive Storer of the benefit accorded with respect to Count 1 of US Appl. No. 10/6018,907.
5. Clark Substantive Motion 7⁶ for judgment against Storer's US Patent No. 7,608,600 B2 on the grounds of unpatentability under 35 U.S.C. § 112, 1st paragraph, for lack of enablement and written description.
6. Clark Substantive Motion 5⁷ to substitute Clark's proposed count 2 or, alternatively, Clark's proposed count 3, for Count 1.
7. Clark Substantive Motion 8⁸ for judgment against Storer's US Patent No. 7,608,600 B2 on the ground of unpatentability under

² Paper No. 389

³ Paper No. 390

⁴ Paper No. 391

⁵ Paper No. 392

⁶ Paper No. 154

⁷ Paper No. 162

⁸ Paper No. 155

35 U.S.C. § 101, for lack of utility and, accordingly, under 35 U.S.C. § 112, 1st paragraph, for lack of enablement.

8. Clark Substantive Motion 9⁹ for judgment against Storer's US Patent No. 7,608,600 B2 on the ground of unpatentability under 35 U.S.C. §§ 102(e) or 103 as being either anticipated by, or obvious over, Clark's US Appl. No. 10/828,753.
9. Clark Miscellaneous Motion 18¹⁰ to exclude evidence.
10. Storer Substantive Motion 5¹¹ to substitute proposed count B for Count 1.
11. Storer Substantive Motion 11¹² for judgment against Clark on the grounds of unpatentability of all of Clark's involved claims as anticipated under 35 U.S.C. § 102(e) and/or 103.
12. Storer Contingent Motion 14¹³ to add a new claim to the interference.
13. Storer Contingent Motion 15¹⁴ to add an application to the interference.

⁹ Paper No. 156

¹⁰ Paper No. 427

¹¹ Paper No. 157

¹² Paper No. 158

¹³ Paper No. 327

¹⁴ Paper No. 328

14. Storer Miscellaneous Motion 16¹⁵ to
exclude evidence.

We address these motions in the order presented
above.

¹⁵ Paper No. 425

II. CLARK MOTIONS

A. Clark Substantive Motion 1¹⁶

Clark Substantive Motion 1 seeks to deny Storer benefit for Count 1 of its US Appl. No. 60/392,350, filed June 28, 2002 (the “S1” application) pursuant to 37 C.F.R. § 41.208(3). Clark Subs. Motion 1, Paper 389 at 1. As challenger of Storer’s accorded benefit, Clark must demonstrate that the S1 application does not constitute a constructive reduction to practice of Count 1. Bd.R. 42.201; SO ¶ 208.4.2. Clark argues that the S1 application does not describe, enable or provide a credible utility of any of the 2'-fluoro-2'-methyl nucleosides that constitute the subject matter of Count 1.

1. Enablement of the compounds of Count 1

The first paragraph of 35 U.S.C. § 112 requires that the specification of a patent must enable a person skilled in the art to make and use the claimed invention. *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988). However, a patent need not disclose what is already well known in the art at the time of invention.

¹⁶ In addition to Clark’s arguments set forth in the main body of this decision, Clark continues to argue that, despite the panel’s prior decision (*see* Paper No. 350), interference estoppel should apply in this interference and that the Board should therefore reject Storer’s attempts to argue issues that Storer raised, or could have raised, in the ’871 interference. Motion at 8–9. Clark’s attention is directed to the Federal Circuit’s recent decision in *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1296–97 (Fed. Cir. 2014), holding that, because an interference action under 35 U.S.C. § 146 was pending in the district court, the Board’s decision lacked requisite finality for purposes of estoppel. We therefore decline to address this argument further.

See Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463 (Fed. Cir. 1984).

Clark seeks relief on the basis that Storer's S1 application does not constitute a constructive reduction to practice of the subject matter of Count 1, i.e., it does not include a described and enabled anticipatory embodiment that falls within Count 1. Count 1 is recited *supra*, and relates to methods of treating HCV infections with members of a genus of nucleosides, all of which possess a fluorine atom at the "down" position of the 2' carbon atom on the ribose ring. Both parties agree that the S1 application provides no explicit disclosure or example of how such an embodiment of Count 1 can be synthesized. *See* Clark Subs. Motion 1, Paper 389 at 12; Storer Opp. 1, Paper 402 at 12; *see also* Ex. 1194, pp. 97–99, 101, 110, 121–122, 130. Failure to synthesize a single embodiment of the compounds recited in Count 1 would effectively prevent practice of the methods recited in the S1 application.

The question therefore devolves onto whether Clark, as challenger, can show, by a preponderance of the evidence, that a person skilled in the art, upon reading the Specification of the S1 application, and being knowledgeable concerning the prior art in the field of nucleoside synthesis, would not have been able to synthesize the 2'-fluoro ("down") nucleosides of Count 1 without undue experimentation. *See Wands*, 858 F.2d at 736–37; *see also Alcon Research Ltd. v. Barr Laboratories, Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014).

Whether synthesis would require undue experimentation is a “conclusion reached by weighing many factual considerations.... includ[ing] (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims”). *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988).

With respect to the first *Wands* factor, the quantity of experimentation necessary for a skilled artisan to arrive at the invention, Clark argues that an artisan attempting to synthesize a compound recited in Count 1 would have been required to engage in an extensive and undue amount of experimentation. Clark Subs. Motion 1, Paper 389 at 15 (citing Ex. 2001, ¶¶ 167–176, 186, 202, 214, 229–231, 235, 248–250; Ex. 2044, p. 1; Ex. 2145, ¶¶ 85–101).

Clark points to the findings of the panel in the related 105,871 interference, which found that the Idenix team members had diligently attempted to make a 2'-fluoro-2'-methyl nucleoside as a high priority target for several years. Clark Subs. Motion 1, Paper 389 at 11. Clark observes that, during this interval, the Idenix team members were employed as chemists, several of whom hold doctoral degrees, but were nevertheless uniformly unsuccessful in synthesizing the target nucleoside. *Id.* Furthermore, argues Clark, Idenix also consulted outside experts, including individuals to whom Dr. Richard Storer, one of the Senior Party, referred to as an “expert in organofluorine chemistry” and a

“world expert in carbohydrate chemistry” for advice on how to make a 2'-fluoro-2'-methyl nucleoside. However, argues Clark, Storer alleged it was successful only after Clark's C2 application was published and Idenix scientists followed a procedure described therein. Clark Subs. Motion 1, Paper 389 at 15–16. Furthermore, argues Clark, documents produced by Storer show that Idenix chemists and/or consultants tried or considered trying numerous different fluorinating reagents when unsuccessfully attempting to synthesize a 2'-fluoro-2'-methyl nucleoside during the interval 2002–2005. Clark Subs. Motion 1, Paper 389 at 11.

Clark rejects the argument of Storer, and its technical expert Dr. Masad J. Damha,¹⁷ that one skilled in the art as of June 28, 2002 would “immediately see,” based on the prior art, that the fluorinating reagent N, N-Diethylaminosulfur trifluoride (Et₂NSF₃ or “DAST”) could be readily used to make a 2'-fluoro-2'-methyl nucleoside from a nucleoside substituted at the 2' position with a tertiary

¹⁷ Storer's expert witness is Dr. Masad J. Damha. Dr. Damha is currently James McGill Professor of Chemistry at McGill University, Montreal, Canada, where he has been a faculty member since 1992. Ex. 1132, ¶ 2. He has also received a number of distinguished awards and is the author of approximately 150 papers and book chapters in peer-reviewed journals, many of which address the synthesis of nucleoside analogs. *Id.*, ¶ 7. Dr. Damha has also consulted for pharmaceutical companies in the United States and Canada and has presented lectures and conference presentations at academia and industry on synthesis and applications of nucleosides, oligonucleotides and their analogs. *Id.*, ¶ 9. Upon review of his curriculum vitae, we find that Dr. Damha is therefore qualified to opine as an expert on the subject matter of this interference.

alcohol (OH) because DAST was a well-known and predictable reagent for fluorinating nucleosides, including those with tertiary alcohols at the 2' position. Clark Subs. Motion 1, Paper 389 at 10 (citing Storer Substantive Motion 5, pp. 18–20, ll. 11–3; Storer Contingent Responsive Motion 14, p. 18–19, ll. 6–16; Ex. 1132,¹⁸ ¶¶ 64, 69–76). Clark points out that Dr. Damha admitted, on cross-examination, that none of the references on which he relied for this contention actually show fluorination of a tertiary alcohol at a nucleoside's 2' position using DAST. *Id.* (citing Ex. 1194, p. 125, ll. 4–18; Ex. 2145,¹⁹ ¶ 96; Ex. 1148,²⁰ pp. 10761–10770; Ex. 1160,²¹ pp. 65–96; Ex. 1161,²² pp. 574–578).

Storer argues that the S1 application provides precursor molecules and guidance that would have enabled one skilled in the art to synthesize a 2'-methyl (“up”) 2'-fluoro (“down”) nucleoside without undue experimentation. Storer Opp. 1, Paper 402 at 4–5. Storer points to compound 17 of Exhibit 1140, Akira Matsuda et al., *Alkyl addition reaction of pyrimidine 2'-Ketonucleosides: Synthesis of 2'-Branched-Chain Sugar Pyrimidine Nucleosides (Nucleosides and Nucleotides. LXXXI)*, 36(3) CHEM. PHARM. BULL. 945–953 (1988) (“Matsuda”). Storer contends that a skilled artisan would have recognized that compound 17 of Exhibit 1140 was a precursor to the claimed

¹⁸ Paper No. 679

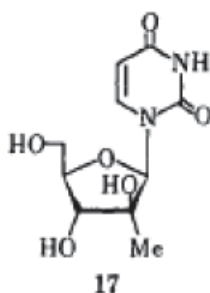
¹⁹ Paper No. 400

²⁰ Paper No. 345

²¹ Paper No. 309

²² Paper No. 310

compound. *Id.* at 4–5 (citing Ex. 1200, ¶ 91; Ex. 2139, at 110–112, ll. 25–7; Ex. 1144, p 949; Ex. 2001, ¶ 323). Compound 17 of Matsuda is reproduced below:



Compound 17 of Matsuda depicts 2'-hydroxy-2'-methyl cytidine

Storer argues that a skilled artisan, when looking at the structure of the claimed compound, would necessarily have recognized the need for a fluorinating reagent for synthesis and that replacement of a hydroxyl (OH) group with fluorine (deoxyfluorination) was a well-known organic transformation, as cited in such reference texts such as Richard C. Larock, *COMPREHENSIVE ORGANIC TRANSFORMATIONS: A GUIDE TO FUNCTIONAL GROUP PREPARATIONS* (2nd ed.) (1999) (“Larock 1999”) (Ex. 1199). Storer Opp. 1, Paper 402 at 5 (citing Ex. 1200, ¶ 89; Ex. 2139, p. 100–101, ll. 22–15; Ex. 1248,²³ p. 90, ll. 13–19, p. 91, ll. 14–21, Ex. 1200, ¶ 79; Ex. 2139, p. 127, ll. 4–7; Ex. 1199, at 689 to 690 (Chapter 8, “Halogenation of Alcohols”)).

Storer also points out that Larock teaches the use of DAST in the deoxyfluorination of a “variety of chemical compounds with success” and argues that, by 2002, DAST was known as “the most convenient and

²³ Paper No. 549

powerful reagent for deoxyfluorination” reactions.²⁴ Storer Opp. 1, Paper 402 at 5–6 (citing Ex. 2014, p. 259; Ex. 1200, ¶ 82; Ex. 1223,²⁵ p. 2357; Ex. 2139, pp. 126–127, ll. 17–3). Therefore, argues Storer, a skilled artisan would have appreciated that DAST could have been used to transform the hydroxyl group of known nucleosides, such as Matsuda Compound 17, into the 2’ (“down”) fluorinated nucleosides recited in Count 1. *Id.* at 6 (citing Ex. 1200, ¶ 85). Accordingly, contends Storer, the prior art disclosed information that would have enabled a skilled artisan to synthesize a 2’-methyl (“up”) 2’-fluoro (“down”) nucleoside within the scope of Count 1. *Id.* (citing Ex. 1200, ¶¶ 74–99).

By way of example, Storer points out that an Idenix scientist, Jingyang Wang, synthesized the compound, using DAST, on her first attempt without the benefit of Clark’s publication. Storer Opp. 1, Paper 402 at 6 (citing Ex 1232,²⁶ ¶¶ 17–20; Ex. 1233,²⁷ p. 70, ll. 5–11; *see also* Ex. 1231²⁸). Storer argues that is also informative that Clark, a chemist without a Ph.D., was allegedly able to make a 2’-methyl (up)-2’-fluoro (down) nucleoside in just a few months using DAST.

²⁴ DAST is a nucleophilic fluorinating agent and acts by displacing the hydroxyl group and inverting the position of the methyl group. Thus, a 2’-hydroxy (“up”)–2’ methyl (“down”) cyclic sugar may become a 2’-methyl (“up”) -2’-fluoro (“down”) cyclic sugar. *See, e.g.*, Ex. 2014.

²⁵ Paper No. 527

²⁶ Paper No. 535

²⁷ Paper No. 536

²⁸ Paper No. 534

Id. (citing Ex. 1246,²⁹ p. 40, ll. 2–3; Ex. 1247,³⁰ ¶¶ 32, 39, 41).

Consequently, argues Storer, the synthesis of a 2'-fluoro-2'-methyl nucleoside would not have required undue experimentation by one skilled in the art.

We find it informative that Idenix's research team in Montpellier, France, repeatedly attempted without success to synthesize a 2'-methyl ("up") 2'-fluoro ("down") nucleoside during the interval between December, 2002 and September, 2004. *See, generally*, Ex. 2128; 2129. Regular progress reports and correspondence of the Montpellier team during this interval demonstrate that synthesis of a 2'-fluoro-2'-methyl nucleoside during this interval was considered to be a high-priority result. Exs. 2026–2044; *see, e.g.*, Ex. 2037, p. 3 (report dated July, 31, 2003: stating that synthesis of a 2'-fluoro-2'-methyl nucleoside with the fluoro substituent in the "down" position "still a high priority").

During this interval, Idenix scientists also corresponded with consultants Dr. George Fleet and Dr. Paul Coe in an attempt to effect a synthesis of the desired compound. *See, e.g.*, Ex. 2034³¹ ("Prioritized Summary of Idenix Meeting with G.W.J. Fleet held on 10th May 2004"); Ex. 2038 (communication from Dr. Coe to Dr. Storer entitled "Thoughts on your synthesis problems"). Dr. Richard Storer, one of the inventors of the S1 application, describes Dr. Fleet as "an expert in carbohydrate chemistry" and "one of the

²⁹ Paper No. 547

³⁰ Paper No. 548

³¹ Paper No. 74

best in the world” and describes Dr. Coe as “an expert in organofluorine chemistry.” Ex. 2131³², pp. 35, 74. Both consultants suggested possible schemes for the synthesis of a 2'-fluoro-2'-methyl nucleoside with the fluorine substituent in the “down” position. Ex. 2034; Ex. 2038. In the latter communication, Dr. Coe related that:

[I]n our experience and indeed in that of manner [sic] other[,] particularly the de Clerc group[,] the most viable routes to fluoro nucleosides are by sugar/base condensation methods the anomer problem notwithstanding, for the very reasons you have discovered, in that leaving groups generated in situ[,] e.g.[,] in DAST reactions are readily attacked by the pyrimidine ring nucleophiles or elimination and/or participation of the blocking groups. Further migrations of groups can readily occur.

Ex. 2038, p. 1.

Idenix personnel also attended a “Scientific Update Course” entitled “Making and Using Fluoroorganic Molecules” in April, 2003, and submitted a report summarizing the course content. Ex. 2039.

Nevertheless, despite these consultations, the Montpellier team was never able to successfully synthesize a 2'-fluoro-2'-methyl nucleoside with the fluorine substituent in the “down” position. Dr. Jean-François Griffon,³³ leader of the Montpellier

³² Paper No. 625

³³ By the standard we determined *infra*, we find that Dr. Griffon qualifies as a person skilled in the art. See Ex. 2152 (Paper No. 542).

group, testified that he attempted at least seven different synthetic schemes, including several suggested by Dr. Coe, and in some cases employing DAST, without success. Ex. 2128, ¶¶ 8–64; Ex. 2132, p. 57. As Dr. Griffon reported in an email to Dr. Storer on March 4, 2003: “As I told you last week at the end of the Summary Meeting, the compound I obtained after treatment with DeoxoFluor³⁴ and deprotection was not the (very!) expected Fluoro derivative but the 2'-methylene derivative.” Ex. 2029, p. 1. A diagram in the accompanying report documents the failure of this synthetic scheme, the end product having a 2'-methylene group rather than the desired 2'-methyl-2'-fluoro groups:

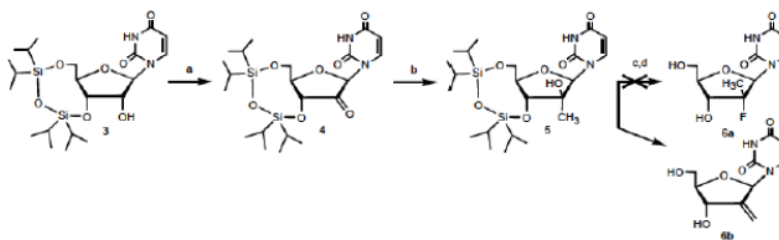


Illustration from Ex. 2029 indicating synthesis of an undesired 2'-methylene nucleoside (6b) rather than a 2' (down) fluorination (6a).

Id., p. 3

Furthermore, attempts by the Montpellier team to use DAST in the synthesis of a 2'-fluoro-2'-methyl

³⁴ Deoxo-Fluor® is, like DAST, a nucleophilic organic fluorinating agent. See, e.g., R.P. Singh and M.S. Jean'ne, *Recent advances in nucleophilic fluorination reactions of organic compounds using deoxofluor and DAST*, 17 SYNTHESIS 2561–2578 (2002).

nucleoside produced similar failures, as this diagram from an Idenix summary of results indicates:

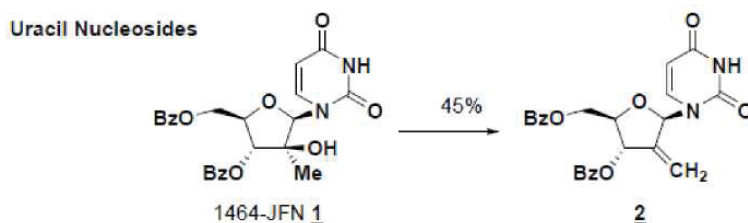


Illustration from Ex. 2041 indicating synthesis of an undesired 2'-methylene nucleoside via DAST reaction.

Ex. 2041, p. 2. The difficulties experienced by Idenix in synthesizing a 2'-fluoro-2'-methyl nucleoside are expressed in a November 11, 2014 email from Dr. Storer stating:

When we get this information together we'll decide what, if anything, we will do in house and how it it [sic] fits with what anyone else knows. *A lot of things which look simple on paper in related systems have been tried and don't work in this series. Having to make the tertiary fluoride is very different to having to make a secondary.*

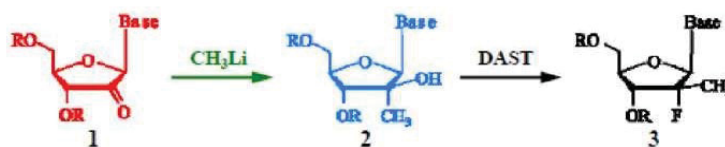
Ex. 2044, p. 1 (emphasis added).

With respect to the testimony of Jingyang Wang who allegedly synthesized the desired compound in a single attempt in January, 2015, at Idenix's research facility in Cambridge, Massachusetts, we note that, prior to beginning her synthesis, Ms. Wang had received the reports from the Montpellier group as well as intermediate compositions synthesized at Montpellier. Ex. 1233, pp. 99–101. Consequently, Ms. Wang was not, as Storer seems to suggest,

attempting synthesis of a 2'-fluoro-2'-methyl nucleoside *ab initio*, but rather had the hindsight benefit of the Montpellier group's efforts. *Id.*

Similarly, Storer's expert, Dr. Damha, points in his Declaration to what he terms Scheme A, of which the first step is disclosed by the S1 application. Ex. 1132, ¶ 67; *see also* Ex. 1003, p. 120. Scheme A of Dr. Damha's declaration is reproduced below:

Scheme A



Scheme A shows a sequence of two steps by which a 2'-keto group is replaced by a 2'-hydroxyl (up) - 2'-methyl (down) nucleoside which is in turn replaced by DAST with a 2'-methyl (up)-2'-fluoro (down) nucleoside.

Ex. 1132, ¶ 67. The intermediate form 2 in Scheme A also corresponds to Matsuda compound 17. *Id.*, ¶ 69, fn. 5. According to Dr. Damha:

A person skilled in the art as of June 28, 2002 could therefore simply look at the 2'-F-2'-methyl-ribonucleoside species disclosed in the '350 Application, and synthesize it without undue experimentation using: (i) the starting materials and reagents disclosed in the '350 Application and known in the art [i.e., Matsuda compound 17], and (ii) the then-existing routine DAST chemistry. It is well known that all organic reactions produce by-product(s). As of June 28, 2002, it would not have been a

surprise to a person skilled in the art that DAST fluorination might lead to elimination, rearrangement, or other by-products. However, just like all other organic reactions, the DAST fluorination does not need to be perfect to be useful in organic synthesis, as separation and purification techniques were well-known as a [sic] of June 2002.

Id., ¶ 76. However, Dr. Damha's opinion is not borne out by the fact that this very reaction was attempted by the Montpellier group and was not successful: attempts to fluorinate compound 17 with DAST yielded a 2'-methylene nucleoside. *See* Ex. 2041, p. 2. Such a result is supported by Dr. Coe's suggestion that "leaving groups generated in ... DAST reactions are readily attacked by the pyrimidine ring nucleophiles or elimination and/or participation of the blocking groups." Ex. 2038, p. 1. The use of other fluorinating agents yielded similarly unsuccessful results. *See, e.g.*, Ex. 2029, p. 3 (using DeoxoFluor® as the fluorinating agent).

We therefore find, based upon the proffered evidence, that a high amount of experimentation is necessary to synthesize a 2'-fluoro-2'-methyl nucleoside with the fluoro moiety in the "down" position requiring at least two years of a high priority experimentation by persons skilled in the art, including multiple consultations with experts at the top of their fields and additional formal training.

With respect to the second *Wands* factor, the amount of direction or guidance presented, Clark argues, and Storer does not contest, that the S1 application provides no explicit explanation or

example describing synthesis of a 2'-fluoro "down" nucleoside as embodied in Count 1. *See* Clark Subs. Motion 1, Paper 389 12; Storer Opp. 1, Paper 402 at 12. Clark also argues that no synthesis of a 2'-fluoro-2'-C(H/F)³ nucleoside, including any 2'-fluoro-2'-methyl nucleoside, had been reported in the available art as of the S1 application's June 28, 2002 filing date. Clark Subs. Motion 1, Paper 389 at 9 (citing Ex. 2001, ¶¶ 137, 231; Ex. 2005, p. 22, ll. 4–8; Ex. 1194,³⁵ p. 91, ll. 12–16). Rather, argues Clark, its own US Appl. Pub. No. 2005/0009737 A1 (the "C2 application"), published on January 13, 2005 (subsequent to the S1 application's June 28, 2002 filing date), was the first reported synthesis of a 2'-fluoro-2'-methyl nucleoside, an embodiment of Count 1. *Id.* at 9–10 (citing Ex. 2001, ¶¶ 137, 162; Ex. 2003, ¶¶ 221, 222; Ex. 2005, p. 22, ll. 4–8; Ex. 2013,³⁶ cover page (item 43), ¶ [0294]–[0035]).

Furthermore, argues Clark, the S1 application's failure to disclose any specific starting materials or conditions under which such a compound could be made cannot be rectified by reliance on the prior art for all of the required teachings. *Id.* (citing *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997); also citing Ex 2005, pp. 24–25, ll. 13–10, 26, ll. 2–5). Clark contends that Storer and its expert, Dr. Damha, argue that the S1 application discloses "starting materials" and reagents (e.g., methyl lithium) for making 2'-fluoro-2'-methyl nucleosides, and that an artisan purportedly would have

³⁵ Paper No. 498

³⁶ Paper No. 56

“immediately identified” operative methods for making such compounds by reacting DAST with a 2'-methyl-2'-hydroxy nucleoside. Clark Subs. Motion 1, Paper 389 at 13.

However, Clark relates, Dr. Damha, on cross-examination, admitted that: (1) no such methods are found in the S1 application; (2) the S1 application does not discuss any fluorinating reagents, including DAST; (3) the S1 application does not disclose intermediate Compound 2 and final Compound 3 shown in Dr. Damha's "Scheme A"; (4) nothing in Scheme 4 of the S1 application suggests isolating the intermediate Compound 2 needed for the Damha "Scheme A" route, which has a methyl group "down" and a hydroxyl group "up" at the 2' position (the opposite 2' stereochemistry from the compounds in Scheme 4); and (5) contrary to his declaration, the S1 application does not "explicitly disclose" the reagent methyl lithium. Clark Subs. Motion 1, Paper 389 at 14 (citing Ex. 1194, pp. 97, ll. 5–8, 98, ll. 11–17, 98–99, ll. 22–17, 101, ll. 15–16, 110, ll. 14–24, 121–122, ll. 19–11, 130, ll. 7–16).

Clark also argues that Dr. Damha's opinion relies on references not mentioned in the S1 application, and he did not consider whether the S1 application would have guided an artisan to such literature. Clark Subs. Motion 1, Paper 389 at 14 (citing Ex. 1194, pp. 102, ll. 12–17, 133–135, ll. 24–2).

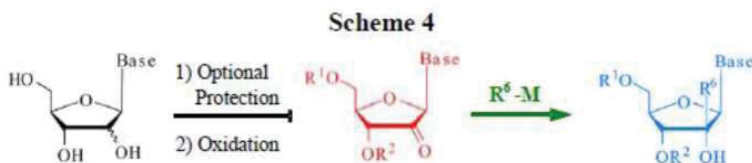
Storer responds that the S1 application provides adequate guidance for synthesizing compounds within Count 1. Storer Opp. 1, Paper 402 at 9–10. Storer argues that the fluorination reagent DAST was known to the skilled artisan for substituting fluorine for a

hydroxyl group with inversion. *Id.* at 10. Therefore, argues Storer, recognizing that inversion will occur, a skilled artisan would have known to start with a nucleoside having a similar structure to that defined by Count 1, but with a 2'-OH (up) group, in order to obtain the desired 2'-F (down) structure of the compounds within Count 1. *Id.* at 12. (citing Ex. 1200, ¶ 90).

Storer points out that Clark's expert, Dr. Stanislaus Wnuk³⁷ agreed that a skilled artisan would have recognized Matsuda Compound 17 as a potential precursor to the subject matter of count 1, which is depicted at paragraph 323 of his Declaration. Storer Opp. 1, Paper 402 at 12 (citing Ex. 2001). Storer points out that Matsuda Compound 17 differs from the claimed compound in that the configuration at the 2'-position is inverted with a 2'-OH (up) instead of a 2'-fluoro (down). *Id.* at 12–13 (citing Ex. 1200, ¶ 92; Ex. 2139, pp. 107–108, ll. 18–6). Further, alleges Storer, both parties' experts agree that the synthesis of the compound of Count 1 would have been essentially a one-step reaction of Matsuda Compound 17 with DAST. *Id.* at 13 (citing Ex. 1200,

³⁷ Clark's expert witness, Dr. Stanislaus F. Wnuk received his Ph.D. in organic chemistry from Adam Mickiewicz University in Poznan, Poland in 1983 and is currently Professor of Chemistry at Florida International University, a position he has held since 1997. Ex. 2001, ¶¶ 8–9. He is the author of over 120 publications, more than 80 of which pertain to nucleosides or nucleotides, with approximately 30 of those relating to fluorinated nucleosides or nucleotides. *Id.*, ¶ 12. He has also received a number of research and teaching awards. *Id.*, ¶ 11. Upon review of his curriculum vitae, we find that Dr. Wnuk is sufficiently qualified as an expert to opine on the synthesis of fluorinated nucleosides.

¶ 94; Ex. 2139, p. 156, ll. 2–12). Store contends that the synthesis of Matsuda Compound 17 is the same as the product of the first steps of Scheme 4 of the S1 application which is reproduced, in part, below:



The initial reaction steps of Scheme 4 depicts synthesis of Compound 17 of Matsuda, where R⁶ is methyl, R¹ and R² are protective groups, and the base is uracil

Id. (citing Ex 1132, ¶¶ 65, 66; Ex. 1003, p. 120). Storer points out that the intermediate compound (2'-keto) of Scheme 4 is the starting material of Matsuda Compound 17, wherein R¹ and R² form protecting groups and the Base is uracil. *Id.* (citing Ex. 1132, ¶¶ 65–66; Ex. 1003, p. 120; Ex 1144, pp. 945–953).

As such, contends Storer, the specification of the S1 application teaches the starting materials and methods for making Matsuda Compound 17, which is a precursor to the claimed compound. Storer Opp. 1, Paper 402 at 13. Storer concludes that the S1 application therefore provides a skilled artisan with the starting materials and guidance for making the compounds within Count 1 without undue experimentation. *Id.* (citing Ex. 1200, ¶ 97).

We agree with Clark that the S1 application provides no explicit explanation or guidance as to how to synthesize a 2'-fluoro “down” nucleoside as embodied in Count 1. Moreover, we have related *supra* how the Idenix team identified such a molecule

as a high-priority target, but failed to synthesize such a compound for approximately two years subsequent to the submission of the S1 application. Moreover, we have related how the Idenix team attempted the very syntheses that Storer's expert Dr. Damha states would be suggested by the disclosures of the S1 document, but were unable to successfully synthesize the target molecule. We therefore find that the S1 application provides little in the way of direction or guidance as to how to synthesize a 2'-fluoro-2'-methyl nucleoside with the fluoro moiety in the "down" position.

The third *Wands* factor enquires into the presence or absence of working examples of the invention. It is uncontested by the parties that there were no examples of such a molecule reported in the art prior to submission of the S1 application. Clark Subs. Motion 1, Paper 389 at 9. Clark contends, and Storer does not contest, that the S1 application lacks a single, specific example teaching how to synthesize any nucleoside having a fluorine atom substituent on the ribose ring. Clark Subs. Motion 1, Paper 389 at 12–13 (citing Ex. 2001, ¶¶ 138, 186, 202, 214, 230, 249; Ex. 2049, pp. 1–5297, ll. 1–21, Figs. 1–4). Additionally, argues Clark, the S1 application lacks any working example that an artisan could have modified, without extensive experimentation, to make a compound falling within either of Count 1's chemical formulae. *Id.* at 13 (Ex. 2001, ¶¶ 138–141, 186, 202, 214, 229, 230, 235, 248, 249; Ex. 2049, pp. 1, ll. 1–5297, Figs. 1–4; Ex. 2005, pp. 23–24, ll. 18–3).

With respect to the fourth *Wands* factor, the nature of the invention, Clark contends that Count 1 is directed to methods for treating HCV infection using

certain 2'-fluoro-2'-C(H/F)³ nucleosides, including certain 2'-fluoro-2'-methyl nucleosides. Clark Subs. Motion 1, Paper 389 at 9 (citing Ex. 2001, ¶¶ 45–50; Ex. 2003,³⁸ ¶¶ 26, 28, 31–33, 40–42; Ex 2012,³⁹ p. 2:8–17; Ex. 2098,⁴⁰ col. 2221, ll. 9–52). According to Clark, because such compounds were not commercially available as of June 28, 2002, it would have been necessary for an artisan to make a compound falling within one of Count 1's chemical formulae. *Id.* (citing Ex. 2001, ¶ 136; Ex. 2005, p. 20, ll. 23–26).

Storer does not contest Clark's characterization of the nature of the invention, but responds that the nature of the invention is such as to require a high level of skill in the art, so much so that a skilled artisan would have been familiar with the methods for synthesizing nucleosides of the type within Count 1.

We find that the nature of the invention, as recite in Count 1 is best characterized as the administration of a genus of nucleosides used in the treatment of viruses, particularly those of the family *Flaviviridae* (which includes HBV and HCV⁴¹). We also find that, as of the time of filing of the S1 application, although organic fluoridation mechanisms were generally well-known in the art a 2'-fluoro- 2'-methyl nucleoside with the fluoro substituent in the “down” position had not yet been synthesized.

³⁸ Paper No. 47

³⁹ Paper No. 55

⁴⁰ Paper No. 137

⁴¹ See, e.g., Clark Subs. Motion 1, Paper 398 at 2

With respect to the fifth *Wands* factor, the state of the prior art, Clark argues that no synthesis of a 2'-fluoro-2'-C(H/F)₃ nucleoside, including any 2'-fluoro-2'-methyl nucleoside, had been reported in the available art as of S1's June 28, 2002 filing date. Clark Subs. Motion 1, Paper 389 at 9 (Ex. 2001, ¶¶ 137, 231; Ex. 2005, p. 22, ll. 4–8; Ex. 1194,⁴² p. 91, ll. 12–16). Rather, argues Clark, its US Appl. Pub. No. 2005/0009737 A1 (the “C2 application”), published on January 13, 2005 (subsequent to the S1 application's June 28, 2002 filing date), was the first reported synthesis of a 2'-fluoro-2'-methyl nucleoside. *Id.* at 9–10 (citing Ex. 2001, ¶¶ 137, 162; Ex. 2003, ¶¶ 221, 222; Ex. 2005, p. 22, ll. 4–8; Ex. 2013,⁴³ cover page (item 43), ¶ [0294]–[0035]).

Storer argues that the specification of the S1 application, when viewed in light of the prior art, discloses sufficient information to enable a skilled artisan to synthesize a 2'-methyl (up)-2'-F (down) nucleoside without undue experimentation. Storer Opp. 1, Paper 402 at 4. According to Storer, and as argued *supra*, a skilled artisan would have readily recognized that a well-known precursor to the nucleoside, such as Matsuda Compound 17, could have been transformed in a single step to a nucleoside within the scope of the count. *Id.* (citing Ex. 1132, ¶25; Ex. 1144,⁴⁴ p. 949; Ex 1115,⁴⁵ pp. 40–45). Storer argues that compounds that were one reaction step

⁴² Paper No. 498

⁴³ Paper No. 56

⁴⁴ Paper No. 293

⁴⁵ Paper No. 269

away from the compounds of Count 1, such as 2'-methyl (down)-2'-OH (up) nucleosides, were well known by June 2002. *Id.* (citing Ex. 1132, ¶ 25; Ex. 1144, p. 949; Ex. 1115, pp. 40–45).

Reviewing the evidence before us, we find, with respect to the prior art, that certain methods of organic fluoridation were well-known at the time of invention, but that synthesis of a 2'-fluoro-2'-methyl nucleoside had not yet been reported in the prior art. See Ex. 1132, ¶ 33. The fluorinating agent DAST was well-known in the prior art to be useful in the fluorination of nucleosides and nucleoside analogs. For example, Johanna Wachtmeister et al., *Synthesis of 4-substituted carbocyclic 2,3-dideoxy-3-C-hydroxymethyl nucleoside analogues as potential anti-viral agents*, 55 TETRAHEDRON 10761 (1999) (“Wachtmeister”) teaches the use of DAST in the fluoridation of certain carbocyclic nucleoside analogs in which the oxygen in the five-member ribose ring is replaced with a carbon atom and fluoridation takes place at the C-4 position. Ex. 1148, p. 10763. Similarly, P. Herdewijn et al., *Synthesis of nucleosides fluorinated in the sugar moiety. The application of diethylaminosulfur trifluoride to the synthesis of fluorinated nucleosides*, 8(1) NUCLEOSIDES AND NUCLEOTIDES 65 (1989) (“Herdewijn”) teaches using DAST for, *inter alia*, fluoridation of nucleosides at the 2' position. Ex. 1160, pp. 65–96. A. Van Aerschot et al., *2',3'-difluoro- and 3'-azido-2'-fluoro substituted dideoxypyrimidines as potential anti-HIV agents*, 98(12) BULL. SOC. CHIM. BELG. 937 (1989) (“Van Aerschot”) teaches the use of DAST to produce various

2'-fluoro-nucleoside analogs. Ex. 1151,⁴⁶ pp. 938–941. Hiroyuki Hayakawa et al., *Diethylaminosulfur trifluoride (DAST) as a fluorinating agent of pyrimidine nucleosides having a 2',3'-vicinal diol system*, 38(5) CHEM. PHARM. BULL. 1136 (1990) (“Hayakawa”) teaches that although “participation of the base moiety often thwarts the desired introduction of a fluorine atom ... appropriate modification of the base and/or sugar moieties allowed the desired fluorodehydroxylation to occur, giving 5'-, 3'- β and 2'- α -fluorinated uracilnucleosides in good yields.” Ex. 1152, p. 1136. Consequently, we find that it was well-known in the prior art that DAST could be employed in the 2' fluoridation of nucleosides and nucleoside analogs.

Dr. Damha cites these prior art references, among others, as demonstrating that:

The fluorinating reagent, DAST, may be used to prepare a 2'-F-ribonucleoside in a single step from an “arabinonucleoside” (compound 2 of Scheme A, above). As of June 28, 2002, DAST had routinely been used in the nucleoside field to install a fluoro group at the 2'-position of nucleosides, often with an unprotected nucleobase, in a single step under very mild conditions.

Ex. 1132, ¶ 71. However, Dr. Damha admits that none of these references teaches using DAST to convert a tertiary alcohol at a nucleoside 2' position to a tertiary fluoride at the nucleoside 2' position:

⁴⁶ Paper No. 300

Q. [Ms. Austin] I just want to make sure the record is clear. So just maybe a yes or a no, did any of these references describe using DAST to convert a tertiary alcohol at a nucleoside 2' position to a tertiary fluoride at the nucleoside 2' position?

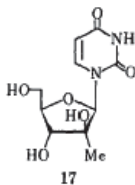
[...]

A. [Dr. Damha] No.

Ex. 1194, p. 125. And Dr. Wnuk opined in response that "I believe it is an oversimplification to assert that, because DAST had been used to fluorinate certain secondary and tertiary alcohols⁴⁷ with inversion of stereochemistry, it was therefore well-known that it would react similarly with significantly different substrates." Ex. 2145, ¶ 96.

We consequently find, with respect to the fifth *Wands* factor, that although DAST was well-known in the prior art as fluoridating agent for nucleosides and

⁴⁷ In a secondary alcohol, the carbon atom binding the hydroxyl group is attached directly to two alkyl groups, which may be the same or different. In a tertiary alcohol, the carbon atom binding the hydroxyl group is attached directly to three alkyl groups, any combination of same or different. By way of example, Matsuda compound 17:



is a tertiary alcohol because the 2' carbon binding the hydroxyl group is bound to three carbons: the 1' and 3' ring carbons and the carbon of the methyl (Me) group.

nucleoside analogs, the prior art did not teach, or explicitly suggest, the use of DAST in the fluoridation of a tertiary alcohol to convert a tertiary alcohol at a nucleoside 2' position to a tertiary fluorine at the nucleoside 2' "down" position. We further find that, although organic fluoridation techniques were well-known in the art at the time the S1 application was filed, fluoridation of tertiary alcohols to produce a 2' "down" tertiary fluorine was not taught or suggested by the prior art.

The sixth *Wands* factor is the relative level of skill of those in the art. The parties largely agree that the level of skill in the art is very high and on the qualifications of a person of ordinary skill. See Ex. 1132, ¶ 14; Ex. 2001, ¶¶ 60–61. We therefore find that a person possessing the ordinary level of skill in this art, as of the time of invention, would hold a doctoral degree in the field of organic, synthetic, or medicinal chemistry with at least a year's experience in the field of nucleoside synthesis or relevant drug discovery. Alternatively, that artisan could hold a master's degree in one of those same fields with at least three years of practical experience in the field of nucleoside synthesis or relevant drug discovery.

With respect to the seventh *Wands* factor, the predictability or unpredictability of the art, Clark argues that the fluorination chemistry involved in attempting to synthesize 2'-fluoro ("down") 2'-C(H/F)₃ ("up") nucleosides was unpredictable at the time of Idenix's attempts to do so, because there was no precedent in the literature for making such a substitution on tertiary carbons of the ribose ring. Clark Subs. Motion 1, Paper 389 at 12 (citing Ex. 2001, ¶¶ 154–159, 231; Ex. 2005, p. 22, ll. 12–17,

Ex. 2007, pp. 19, ll. 4–12, 22, ll. 5–18; Ex. 2022,⁴⁸ pp. 65–96; Ex. 2023,⁴⁹ pp. 574–78; Ex. 2024,⁵⁰ pp. 2315–16; Ex. 2025,⁵¹ pp. 251–54; Ex. 1194, pp. 91, ll. 12–16, 92, ll. 3–93:18, 125, ll. 4–18). Clark maintains that the prior art demonstrated that attempted fluorination reactions (including those involving DAST) could fail, resulting in unfluorinated elimination and/or rearrangement products, or products with incorrect stereochemistry. *Id.* (citing Ex. 2001, ¶¶ 156, 231; Ex. 2014,⁵² p. 259, ll. 15–20; Ex. 2015,⁵³ pp. 7570–7571, ll. 18–4; Ex. 2016,⁵⁴ pp. 2563 (left col, ll. 11–14, Scheme 5), 2564 (Scheme 9); Ex. 2017,⁵⁵ pp. 1090–91; Ex. 2018,⁵⁶ pp. 554–55; Ex. 2139,⁵⁷ pp. 156–157, ll. 15–3).

Clark argues further that the documents that produced by Storer in the related 105,871 Interference demonstrate that DAST treatment of tertiary and secondary alcohols failed to produce fluorinated products. Clark points out that Dr. Paul Coe, an expert in organofluorines expressed skepticism

⁴⁸ Paper No. 62

⁴⁹ Paper No. 63

⁵⁰ Paper No. 64

⁵¹ Paper No. 65

⁵² Paper No. 57

⁵³ Paper No. 58

⁵⁴ Paper No. 59

⁵⁵ Paper No. 60

⁵⁶ Paper No. 61

⁵⁷ Paper No. 368

regarding the use of DAST; and Dr. Richard Storer stated that “[a] lot of things which look simple on paper in related systems have been tried and don’t work in this series. Having to make the tertiary fluoride is very different to [sic] having to make secondary.” *Id.* (citing Ex. 2001, ¶¶ 157, 158, 174; Ex. 2007, pp. 15–17, ll. 15–2; 20, ll. 3–8; Ex. 2029, p. 2 (numbered p. 1); Ex. 2035, p. 3 (numbered p. 2); Ex. 2038, pp. 1–3, 5–10; Ex. 2041,⁵⁸ p. 1; Ex. 2042,⁵⁹ p. 1; Ex. 2043,⁶⁰ pp. 38, 40; Ex. 2044,⁶¹ p. 1; Ex 2139, pp. 146, ll. 9–22, 147, ll. 14–23).

Storer responds that deoxyfluorination with DAST was highly predictable. Storer Opp. 1, Paper 402 at 7 (citing Ex. 1200, ¶¶ 100–131). According to Storer, the references that Clark and its expert, Dr. Wnuk, rely on in support of their argument that fluorination with DAST was unpredictable are Exhibit 2018, Krzysztof W. Pankiewicz et al., *A synthesis of 9-(2-deoxy-2-fluoro-β-D-arabinofuranosyl) adenine and hypoxanthine. An effect of C3'-endo to C2'-endo conformational shift on the reaction course of 2'-hydroxyl group with DAST*, 57 J. ORG. CHEM. 553–59 (1992)⁶² (“Pankiewicz”) and Exhibit 1152, Hiroyuki Hyakawa et al., *Diethylaminosulfur trifluoride (DAST) as a fluoridating agent of pyrimidine nucleosides having a 2',3'-vicinal diol system*, (38(5)

⁵⁸ Paper No. 81

⁵⁹ Paper No. 82

⁶⁰ Paper No. 83

⁶¹ Paper No. 84

⁶² Paper No. 61

CHEM. PHARM BULL. 1136–39 (1990) (“Hayakawa”)⁶³. Storer argues that Clark relies upon these references to demonstrate that using DAST in the preparation of fluoridated nucleosides may result in a “rearrangement product” and an “unfluorinated 2'-cyclo derivative.” *Id.* (citing Storer Motion 1, p. 12, ll. 6–11; Ex. 2001, ¶ 156; Ex. 2145, ¶ 98). However, argues Storer, both Pankiewicz and Hayakawa teach that DAST deoxyfluorination of a nucleoside with a 2'-OH (up) proceeded with inversion to form a nucleoside with a 2'-F (down) in over 80% yields without any alleged rearrangement or unfluorinated products reported. *Id.* (citing Ex. 1152, p. 1139; Ex. 2018, p. 559; Ex. 2139, p. 149–150, ll. 10–11. Ex. 1248, p. 87, ll. 2–11).

Storer also disputes that Exhibit 2015 teaches that fluorination with DAST may proceed with double inversion resulting in a “product with unexpected stereochemistry” as Clark and its expert suggest. Storer Opp. 1, Paper 402 at 8 (citing Clark Motion 1, p. 12, ll. 6–11; Ex. 2001, ¶ 156). Exhibit 2015 is Lak S. Jeong et al., *Unanticipated retention of configuration in the DAST fluorination of Deoxy-4'-thiopyrimidine nucleosides with “up” hydroxyl groups*, 35(41) TETRAHEDRON LETTERS, 7569–72 (1994) (“Jeong”). According to Storer, the title of the article explains that the double inversion was not the norm. *Id.* According to Storer, Jeong teaches that the double inversion was a result of the sulfur atom in the thiofuranose ring, which is not present in the

⁶³ Paper No. 301

compounds of Count 1. *Id.* (citing Ex. 2139, p. 136, ll. 8–12).

Storer also points to Exhibits 2014, 2016, and 2017, which Clark and its expert rely upon to argue that deoxyfluorination with DAST may result in an “unfluorinated dehydration product,” a “rearrangement product,” or an “elimination product.” Storer Opp. 1, Paper 402 at 9 (citing Storer Motion 1, p. 12, ll. 6–11; Ex. 2001, ¶ 156). According to Storer, none of the DAST reactions relied upon by Clark was performed on a nucleoside. *Id.* Nevertheless, argues Storer, Exhibit 2014 teaches that “diethylaminosulfur trifluoride (DAST) appears to be the most convenient and powerful reagent for deoxyfluorination,” and Exhibit 2016 teaches that “Deoxo-Fluor ... and DAST ... are widely used in one-step reactions for the introduction of fluorine into organic compounds.” *Id.* (quoting Ex. 2014, p. 259; Ex. 2016, p. 2561). Moreover, argues Storer, Dr. Wnuk agreed that the latter statement describes the state of the art for fluorination in 2002. *Id.* (citing Ex. 2139, p. 139, ll. 13–21).

Having reviewed the parties’ arguments, and the proffered evidence, we find that the art, with respect to fluoridation of tertiary alcohols, was highly unpredictable, as evidenced by Idenix’s repeatedly unsuccessful attempts to synthesize its high-priority target nucleoside, and as further evinced by the statements of Dr. Coe and Dr. Storer. *See* Ex. 2038, p. 1; Ex. 2044, p. 1.

In summary, having reviewed the *Wands* factors argued by the parties,⁶⁴ we find that (1) synthesis of a 2'-fluoro-2'-methyl nucleoside with the fluoro moiety in the “down” position required at least two years of a high-priority experimentation by persons skilled in the art, including multiple consultations with experts at the top of their fields and additional formal training; (2) the S1 application provides little in the way of direction or guidance as to how to synthesize such a compound; (3) the S1 application provides no explicit example of a 2'-fluoro-2'-methyl nucleoside, nor was an example provided by the relevant art as of the S1 application's filing date; (4) the invention is characterized as the administration of a genus of nucleosides used in the treatment of viruses, particularly those of the family *Flaviviridae* (which includes HBV and HCV) and an embodiment of the count requires a 2'-fluoro (“down”) 2'-methyl nucleoside; (5) although organic fluoridation techniques were well-known in the art at the time the S1 application was filed, fluoridation of tertiary alcohols to produce a 2' “down” tertiary fluorine was not taught or suggested by the prior art; (6) the level of skill in the art was highly sophisticated: a person possessing the ordinary level of skill in this art, as of the time of invention, would hold a doctoral degree in the field of organic, synthetic, or medicinal chemistry with at least a year's experience in the field of nucleoside synthesis or relevant drug discovery; and (7) the art, at least with respect to fluoridation of tertiary alcohols to produce a tertiary fluorine in the 2'

⁶⁴ Neither party argued the eighth *Wands* factor, the breadth of the claims.

“down” position, was highly unpredictable. We therefore find that *Wands* factors 1, 2, 3, 5, and 7 strongly indicate that a person skilled in the art would not arrive at the claimed invention without undue experimentation. We therefore conclude that the S1 application does not enable any species of Count 1, all of which require a fluorine atom in the 2’ “down” position.

A party is accorded benefit of the date of an earlier application if its earlier application constitutes a constructive reduction to practice of the count. Bd.R. 41.201. Clark, as the party challenging Storer’s accorded benefit of the S1 application, must therefore demonstrate that the S1 application does not provide a constructive reduction to practice of Count 1. SO ¶ 208.4.2. Constructive reduction to practice means a described and enabled anticipation under 35 U.S.C. 102(g)(1) in a patent application of the subject matter of Count 1. Bd.R. 41.201. Thus, even if the S1 application does not describe and enable the full scope of Count 1, Storer cannot be deprived of the filing date of the S1 application if the S1 application describes a single embodiment or species that meets all of Count 1’s limitations.

Neither party disputes that all of the species of the genus contemplated within the scope of Count 1 require a fluorine atom in the “down” position and a C(H/F)₃ moiety in the “up” position at the 2’ carbon of the sugar ring. We have found that the analysis of the factors set forth in *Wands* compel the conclusion that, at the time the S1 application was filed, a person skilled in the art would not have been able to synthesize any of the 2’-fluoro (“down”) nucleosides of Count 1 without undue experimentation. We

therefore conclude that the S1 application does not enable a single species of Count 1 and, consequently, the S1 application is not a constructive reduction to practice of Count 1. Because we find this issue to be dispositive of the motion, we do not reach Clark's other arguments. Clark Substantive Motion 1 to deny Storer the accorded benefit of its S1 application is granted.

B. Clark Substantive Motions 2 and 3

Clark Substantive Motion 2 seeks to deprive Storer of the benefit accorded with respect to Count 1 of its U.S. Appl. No. 60/466,194 (the "S2 application") filed April 28, 2003. Clark Subs. Motion 2, Paper 390 at 1. Clark Substantive Motion 3 seeks to deprive Storer of the benefit accorded with respect to Count 1 of its US Appl. No. 60/470,949 (the "S3 application") filed May 14, 2003. Clark Subs. Motion 3, Paper 391 at 1.

Clark argues that although Storer was accorded benefit of the S2 and S3 applications when the present interference was declared, Storer has not relied upon either in any of its motions in the present interference. Clark Subs. Motion 2, Paper 390 at 9; Clark Substantive Motion 3, Paper 391 at 9. According to Clark, that constitutes an admission by Storer that the S2 and S3 applications are unrelated to the subject matter in dispute between the parties. Clark Subs. Motion 2, Paper 390 at 9; Clark Substantive Motion 3, Paper 391 at 9.

Clark argues that Count 1 of the interference pertains to a method for treating HCV infection. Clark Subs. Motion 2, Paper 390 at 10; Clark Subs. Motion 3

Paper 391 at 10 (citing Declaration,⁶⁵ p. 3, ll. 16–17; Ex. 2001, ¶¶ 45–50; Ex 2003, ¶¶ 26, 28, 29, 31–33; 40–42; Ex. 2012,⁶⁶ p. 2:8–17; Ex. 2098, col. 2221, ll. 9–52). However, argues Clark, the S2 and S3 applications are deficient because it fails to mention HCV or methods for treating HCV infection, as required by Count 1. *Id.* (citing Ex. 2001, ¶¶ 256–261; Ex. 2003, ¶¶ 140–141, 145–147; Ex. 2050,⁶⁷ pp. 1–36, Figs. 1–3). According to Clark, the S2 and S3 applications disclose processes for chemically synthesizing certain prodrugs of antiviral nucleosides. *Id.* (citing Ex. 2001, ¶¶ 58, 59; Ex. 2003, ¶¶ 49, 136–137; Ex. 2050, pp. 1, ll. 3–6, 6–9, ll. 24–9).

Clark also argues that Count 1 requires certain compounds, specifically, certain 2'-fluoro-2'-C(H/F)₃ nucleosides, which the S2 and S3 applications fail to disclose. Clark Subs. Motion 2, Paper 390 at 10; Clark Subs. Motion 3, Paper 391 at 10 (citing Ex. 2001, ¶ 256–261; Ex. 2050, pp. 1–36, Fig. 1–3). Therefore, argues Clark, as of the filing dates of the S2 and S3 applications, an artisan would not have believed that S2 and S3's applicants were in possession of any compound(s) falling within either of Count 1's chemical formulae, or any method(s) for treating HCV infection involving such compound(s). Clark Subs. Motion 2, Paper 390 at 11; Clark Subs. Motion 3, Paper 391 at 13 (citing Ex. 2001, ¶¶ 256–261).

Clark also argues that the S2 and S3 applications fail to provide an enabling anticipation of Count 1

⁶⁵ Paper No. 1

⁶⁶ Paper No. 55

⁶⁷ Paper No. 112

because it does not teach an artisan as how to make any nucleoside falling within the scope of Count 1, or teach how to treat HCV infection using any such nucleoside, without undue experimentation. Clark Subs. Motion 2, Paper 390 at 11; Clark Subs. Motion 3, Paper 391 at 13 (citing Ex. 2001, ¶¶ 256–261; Ex. 2003, ¶¶ 136–147; Ex. 2050, pp. 1–36, Fig. 1–3).

Storer argues only that Clark has failed to establish that it is entitled to the relief requested. Storer Opp. 2, Paper 403 at 2; Storer Opp. 3, Paper 403 at 2. Storer does not provide substantive argument and does not direct us to evidence to contradict Clark’s arguments.

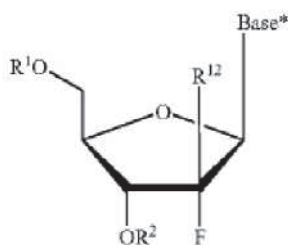
We have reviewed the disclosures of the S2 and S3 applications. For the reasons stated with respect of the S1 application, we agree with Clark that the S2 and S3 applications do not describe either the genus of Count 1 or an embodiment that meets all the limitations of that count. Clark Substantive Motions 2 and 3 to deprive Storer of the benefit accorded with respect to Count 1 of its S2 and S3 applications are granted.

C. Clark Substantive Motion 7

Clark’s Substantive Motion 7 seeks judgment against Storer on the grounds that involved claims 1–12, 17, 18, 20, 33, 34, 36, 38, 49–57, 62, 64, and 76–85 of Storer’s involved US Patent No. 7,608,600 B2 (the “600 Patent”) are unpatentable under 35 U.S.C. § 112, 1st paragraph for lack of enablement and written description. Clark Subs. Motion 7, Paper 154 at 1. To prevail, Clark must demonstrate that the

Specification of the '600 patent does not support the full scope of the claimed subject matter.

Claim 1 of the '600 patent has been recited *supra* as part of Count 1 and we do not repeat it here. As we have related, Clark argues that the salient limitation of Storer claim 1, for purposes of enablement, is the fluorine atom in the 2' "down" position, thus:



Ex. 1001-2, col. 2221, ll. 14-24. Storer's involved dependent claims 2-12, 17, 18, 20, 33, 34, 36, 38, and 49 all depend from claim 1 and all claim a fluorine atom in the 2' "down" position. Ex. 1001-2. Storer's involved claims 51-57, 62, 64, and 76-85 all depend from independent claim 50, which also claims a fluorine atom in the 2' "down" position, as do all of the involved claims depending from it. *Id.*

Storer's '600 patent issued from Storer's S4 application, which claims priority benefit of the S1 application. See Ex. 1001, p. 1. Clark argues that, as of June 27, 2003, the filing date of the S4 application, there was no available prior art reporting synthesis of a 2'-fluoro-2'-C(H/F)₃. Clark Motion 7, paper 154, at 9, citing Wnuk Decl., Ex. 2001, ¶¶ 136, 137. Clark argues further that the prior art as of 27 June 2003 would not have taught an ordinarily skilled artisan how to make the recited nucleoside without undue experimentation. *Id.* at 10.

Storer does not argue or direct us to evidence of art available prior to the June 27, 2003 filing of the S4 application that reporting or describing synthesis of the recited nucleosides. Accordingly, because we have found *supra* that the S1 application does not enable a nucleoside as recited in Count 1, we find that the specification of the '600 patent does not enable Storer's involved claims. We therefore conclude that the involved claims 1–12, 17, 18, 20, 33, 34, 36, 38, 49–57, 62, 64, and 76–85 of '600 patent are unpatentable under 35 U.S.C. § 112, 1st paragraph, for lack of enablement.⁶⁸ Clark Substantive Motion 7 for judgment against the involved claims of Storer's '600 patent is granted.

D. Clark Substantive Motion 10

Clark next moves to deprive Storer of the benefit accorded with respect to Count 1 of US Appl. No. 10/608,907, filed June 27, 2003 (the "S4" application). Motion at 1. Clark contends that the S4 application lacks enablement, written description, and utility for subject matter anticipating Count 1. Clark Subs. Motion 10, Paper 392 at 1. Storer has opposed. Storer Opp. 10, Paper 405. Clark has replied. Clark Reply 10, Paper 422.

Because we have determined *supra* that Storer's involved claims 12, 17, 18, 20, 33, 34, 36, 38, 49–57, 62, 64, and 76–85 are unpatentable under 35 U.S.C.

⁶⁸ We note that all of the remaining claims of the '600 patent similarly recite a fluorine atom in the 2' "down" position and may likewise be unpatentable under 35 U.S.C. § 112, first paragraph, for the same reasons. Storer may wish to seek re-examination of these claims.

§ 112, first paragraph, for lack of enablement, we need not reach this motion.

E. Clark Substantive Motion 5

Clark next moves to substitute its proposed count 2 or, alternatively, its proposed count 3, for Count 1. Clark Subs. Motion 5, Paper 192 at 1. Clark's Proposed Count 2 is simply its Count 164 of its '218 application. *Id.*

However, because we have already determined that Storer's involved claims are unpatentable, we *sua sponte* remove Storer's unpatentable claim 1 from the count and reformulate Count 1 as Clark's claim 164.

We therefore need not reach Clark's Substantive Motion 5.

F. Clark's Substantive Motion 8

Clark's Substantive Motion 8 seeks judgment against Storer on the ground that all of Storer's involved claims, claims 1–12, 17, 18, 20, 33, 34, 36, 38, 49–57, 62, 64, and 76–85 of Storer's '600 patent are unpatentable under 35 U.S.C. § 101, for lack of utility and, accordingly under 35 U.S.C. § 112, 1st paragraph, for lack of enablement. Clark Subs. Motion 8, Paper 155 at 1.

Our decision on Clark's Substantive Motion 7 that Storer's involved claims are unpatentable under 35 U.S.C. § 112, 1st paragraph, for lack of enablement is dispositive of the patentability of Storer's claims. Therefore, it is unnecessary for us to reach this motion. Clark's Substantive Motion 8 is consequently dismissed.

G. Clark Substantive Motion 9

Clark Substantive Motion 9 seeks judgment against Storer on the ground that all of Storer's involved claims, claims 1–12, 17, 18, 20, 33, 34, 36, 38, 49–57, 62, 64, and 76–85 of Storer's '600 patent are unpatentable under 35 U.S.C. §§ 102(e) or 103 as being either anticipated by, or obvious over, Clark's US Appl. No. 10/828,753 (the "C2 application"), filed April 21, 2004. Clark Subs. Motion 9, Paper 156 at 1.

Our decision on Clark's Substantive Motion 7 that Storer's involved claims are unpatentable under 35 U.S.C. § 112, 1st paragraph, for lack of enablement is dispositive of the patentability of Storer's claims. Therefore, it is unnecessary for us to reach Clark Substantive Motion 9.

H. Clark Miscellaneous Motion 18

Clark has moved to exclude the following Storer Exhibits: 1132, 1175–76, 1177, 1200, 1201, 1228, 1229, 1231, 1232, and 1233. Clark Misc. Motion 18, Paper 427 at 1.

1. Storer Exhibit 1132

Clark argues that Storer Exhibit 1132, the Declaration of Masad J. Damha, Ph.D., (the "Damha Declaration") is inadmissible under SO ¶ 105.6 because it is an affidavit without an original signature. Clark Misc. Motion 18, Paper 427 at 1. According to Clark, Dr. Damha, Storer's declarant, testified at his deposition that he did not sign a paper copy of Exhibit 1132 in ink, but instead inserted a digital image of his signature. *Id.* (citing Ex. 1194 , p. 26, ll. 14–24). Furthermore, argues Clark, there is no original copy of Exhibit 1132 with a handwritten original signature that could have been retained or

made available on demand, which is also in violation of SO ¶ 105.6. *Id.* (citing Ex. 1194, pp. 26–27, ll. 25–4).

Alternatively, argues Clark, paragraphs 61–81 of the Damha Declaration should be excluded under Federal Rule of Evidence 702 because Dr. Damha’s opinions expressed in these paragraphs are not based on sufficient facts or data. Clark Misc. Motion 18, Paper 427 at 2. According to Clark, when opining that it would have been trivial for an artisan to make 2'-fluoro-2'-methyl nucleosides, Dr. Damha did not take into account Storer’s own documents from the prior '871 interference (e.g., Ex. 2029, Ex. 2035, Ex. 2041, Ex. 2042, and Ex. 2043).

Storer responds that Dr. Damha verified during his deposition that he personally inserted his digital signature into his Declaration. Storer Opp. 18, Paper 29 at 1 (citing Ex. 1194, p. 26, ll. 19–24. Therefore, argues Storer, although Dr. Damha did not handwrite his signature on a paper copy of his declaration, he did verify that he personally electronically signed the declaration. *Id.* Storer submits that the Board should accept this as sufficient. *Id.*

Storer also argues that Clark did not timely object to Exhibit 1132 at the deposition and also failed to request a conference call with the Administrative Patent Judge managing the interference to seek authorization to belatedly object to Exhibit 1132. Storer Opp. 18, Paper 29 at 1 (citing 37 C.F.R. § 41.155(a)).

Dr. Damha has affirmed that the digital signature is a reproduction of his own signature and that the

declaration was his own. We therefore decline to exclude the Exhibit on this ground.

More substantially, we agree with Storer that whether Dr. Damha examined the '871 interference documents prior to forming his opinion on whether a person of ordinary skill could have synthesized 2'-fluoro-2'-methyl nucleoside compounds is a question of the probative weight of the opinion testimony and not one of admissibility. We held, *supra*, that Dr. Damha was qualified as an expert. He may express his opinions on matters relevant to this interference. Federal Rule of Evidence 702 states that a "witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if ... the testimony is based on sufficient facts or data." Fed. R. Evid. 702(b).

We therefore decline to exclude Exhibit 1132.

2. Storer Exhibits 1175 and 1176

Clark next argues that Storer Exhibits 1175⁶⁹ and 1176⁷⁰, which comprise two emails to the Patent Trial and Appeal Board concerning the '871 interference, with copies to Administrative Patent Judge New, discuss Storer's allegations of inequitable conduct and request authorization to move for additional discovery in the present interference, are inadmissible in their entirety because they are irrelevant under Rule 402, as well as confusing and a waste of time under Rule 403. Clark Misc. Motion 18, Paper 427 at 3.

⁶⁹ Paper No. 458

⁷⁰ Paper No. 459

Storer was not authorized to file a motion asserting inequitable conduct and has not raised the issue in any of its substantive or contingent motions considered herein. Because this evidence is unrelated to any of the matters before us we decline to address the admissibility of Exhibits 1175 and 1176 as an evidentiary matter. However, because the exhibits are extraneous to this proceeding we order that they be expunged from the record. Bd.R. 7(a) & 122(c)(1)(iii).

3. Storer Exhibit 1177

Storer Exhibit 1177⁷¹ is a copy of an order (Docket No. T-1156-12) from Federal Court of Canada, regarding the litigation with respect to the Canadian versions of Storer's involved patent and Clark's involved application in that venue. Clark seeks exclusion of Exhibit 1177 on substantially the same grounds that it seeks exclusion of Exhibits 1175 and 1176. Clark Misc. Motion 18, Paper 427 at 4.

Storer has not raised, in any of its substantive or contingent motions, any argument that relies upon this Exhibit and, having reviewed the Exhibit, we can discern no purpose for it to be included in this proceeding. Because the exhibit appears to be extraneous to this proceeding, we decline to consider it as an evidentiary matter and order that it be expunged from the record of this proceeding. Bd.R. 7(a) & 122(c)(1)(iii).

4. Storer Exhibit 1200

Clark next seeks exclusion of Exhibit 1200, the Second Declaration of Dr. Damha. Clark Misc. Motion 18, Paper 427 at 5. According to Clark,

⁷¹ Paper No. 460

Dr. Damha failed to consider relevant information. Clark argues that Dr. Damha did not take into account the Storer Documents when forming his view that it would have been trivial for an artisan to make 2'-fluoro-2'-methyl nucleosides as of June 28, 2002. *Id.* (citing Ex. 1244, pp. 26–40, ll. 19–15). Clark argues further that Dr. Damha testified that such evidence was not important and that there was not “any chance” that it could have affected his opinions, despite the Board having previously found it significant. *Id.* (citing Ex. 1244, pp. 31–40, ll. 15–15).

We have related *supra*, with respect to Storer’s Exhibit 1132, why the credibility of Dr. Damha’s opinion testimony is a probative question on the merits of Storer’s substantive motions. The issue is one of the weight of the testimony rather than one of admissibility. We employ the same reasoning here. Clark’s motion to exclude Exhibit 1200 is denied.

5. Storer Exhibit 1201

Storer Exhibit 1201 is the Second Declaration of Raffaele De Francesco, Ph.D. According to Clark, Dr. De Francesco opines on an artisan’s ability to perform high throughput testing of compounds for activity against hepatitis C virus (“HCV”) using an HCV replicon assay during the 2000–2003 timeframe. Clark Misc. Motion 18, Paper 427 at 5 (citing Ex. 1201, ¶¶ 82, 95–101). Clark argues that Dr. De Francesco’s opinions are based on unpublished techniques allegedly used in his own labs. Because the reaction conditions and experimental processes for these screening experiments were not published, argues Clark, they were not available to the artisan to utilize, test or publicly critique. Clark Misc.

Motion 18, Paper 427 at 5–6 (citing Ex. 2171, ¶ 128). Therefore, contends Clark, De Francesco’s testimony regarding his non-public activities within his laboratory does not provide any insight whatsoever into any issue pending in this. Motion at 6.

Storer did not oppose Clark’s motion to exclude Exhibit 1201. Nevertheless, we are not persuaded by Clark’s arguments. As we have related *supra*, with respect to Storer’s Exhibits 1132 and 1200, the credibility of Dr. De Francesco’s opinion testimony is a probative question on the merits of Storer’s motions. The issue is one of weight and not one of admissibility. We employ the same reasoning here. Clark’s motion to exclude Exhibit 1201 is denied.

6. Storer Exhibit 1228 and 1229

Storer Exhibit 1228⁷² is the transcript of the deposition of Stanley Moncrief Lemon and Storer Exhibit 1229⁷³ is the transcript of the deposition of Jeffrey Scott Glenn, both taken on Tuesday, July 31, 2012. Clark Misc. Motion 18, Paper 427 at 7. Clark argues that both transcripts are inadmissible as hearsay under Rule 802, and under SO ¶¶ 157.1 and 157.3, because they are transcripts of depositions taken in the prior 105,871 interference. *Id.* Clark contends that if Storer wanted to rely on the testimonies of Drs. Lemon and Glenn, it should have submitted a new declaration from both individuals in the present case, thereby making them subject to cross-examination in this interference. *Id.*

⁷² Paper No. 531

⁷³ Paper No. 532

Storer points out that Clark has failed to demonstrate that Storer relies on Exhibits 1228 and 1229 to prove the truth of any statements therein. Storer Opp. 18, Paper 429 at 7, 8. Storer points out that Clark has not directed the Board to any statements in either Exhibit that Storer relies on to prove the truth of an asserted matter. *Id.* Finally, Storer argues that that Clark was a party to the prior 105,871 interference and that Clark cross-examined both deponents during their respective depositions. *Id.* (citing Exs. 1228; 1229). Moreover, contends Storer, Clark submitted the Declarations of Drs. Lemon and Glenn, which was the basis for the deposition as Exhibit 2167. *Id.* Therefore, argues Storer, Clark is not prejudiced by the introduction of Exhibits 1228 into evidence. *Id.*

We agree that Storer has not relied upon Exhibits 1228 and 1229 in support of any of its arguments in its substantive or contingent motions. Accordingly, we can discern no purpose for it to be included in this proceeding. We decline to consider it as an evidentiary matter and order that it be expunged from the record of this proceeding. Bd.R. 7(a) & 122(c)(1)(iii).

7. Storer Exhibits 1231, 1232, and 1233

Storer Exhibit 1231 is the laboratory notebook by Jingyang Wang, an employee of Idenix Pharmaceuticals, Inc., one of the Storer real parties-in-interest. Clark contends that Exhibit 1231 is inadmissible under Rules 402, 403, 802, and 901(a), and SO ¶¶ 152.2.2 and 157.1. Clark Misc. Motion 18, Paper 427 at 7.

We considered Exhibits 1232 and 1233 with respect to our conclusion that the S1 application did not enable the embodiments of a 2' fluoro "down" nucleoside within the scope of Count 1. Clark prevailed upon that issue notwithstanding the consideration of these exhibits. Exclusion of the exhibits would not influence the outcome of our review. It is therefore unnecessary for us to consider the admissibility of the exhibits.

8. Summary

For the reasons set forth above, Clark's Miscellaneous Motion 18 is denied.

III. STORER MOTIONS

A. Storer Substantive Motion 5

Storer moves to substitute proposed Count B for Count 1 and to be accorded benefit of the S1 application. Motion at 1. All of the species encompassed by Storer's proposed Count B and disclosed in the Genus Disclosure of Storer's involved application have a fluorine atom in the 2' "down" position. *See* Storer Subs. Motion 5, Paper 157 at App'x 8-2 ("R⁷ is F"; "[F is shown in the 2' "down" position of the above formula]"). We have related *supra* that the claims of Storer's involved application fail to provide an enabling disclosure for any of the embodiments of the nucleosides within the scope of its involved claims. All of those claims are characterized by a fluorine in the 2' "down" position. As a result of our determination we removed Storer's claim 1 as an alternative of the count. Storer's proposed Count B broadens the species substituents at other positions of the nucleotide but includes the fluorine in the 2' "down" position. Thus, Storer's proposed Count B is

unsuitable as a vehicle for determining priority in this interference for the same reasons that Storer's Claim 1 was unsuitable. We therefore deny Storer's Substantive Motion 5.

B. Storer Substantive Motion 11

Storer next argues that Clark's involved claims are unpatentable under 35 U.S.C. § 102(e)(2) and/or 35 U.S.C. §§ 102(e)(2)/103(a) over Storer's '600 patent. Storer Subs. Motion 11, Paper 158 at 1. Storer does not challenge that the Clark '218 application has an effective filing date of May 30, 2003, the date Clark's '368 provisional application was filed. *Id.*

Storer argues that its '600 patent, which it cites as prior art under 35 U.S.C. § 102(e), has an effective filing date of June 28, 2002, the filing date of its S1 application, which precedes the May 30, 2003, filing date of Clark's '368 application. Storer Subs. Motion 5, Paper 157 at 2. Therefore, argues Storer, the '600 patent is prior art to the Clark claims. *Id.*

We have related *supra* why Storer's involved claims are not supported by an enabling disclosure of an embodiment having a 2'-fluoro "down" nucleoside. For the same reason, the earlier S1 application fails to provide an enabling disclosure for nucleoside with the fluorine in the down position. Storer is not entitled to the benefit of the June 28, 2002, filing date of the S1 application. Storer's '600 patent is not prior art for Clark's '638 application. We therefore deny Storer's Substantive Motion 11.

C. Storer Contingent Responsive Motion 14

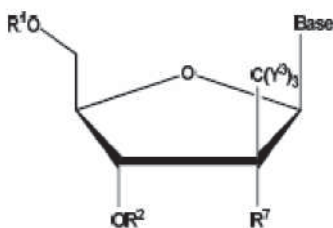
Storer Contingent Responsive Motion 14 seeks to add a new claim, claim 14 to the interference if any of

Clark Substantive Motions 7, 8, or 9 are granted.
 Storer Cont. Motion 14, Paper No. 327 at 1.

Because we have granted Clark Substantive Motion 8, we now address Storer Contingent Motion 14.

Storer Claim 14 recites:

14.A method for the treatment of a host infected with a hepatitis C virus, comprising administering to the host infected with a hepatitis C virus an effective amount of a compound of the formula:



or a pharmaceutically acceptable salt thereof,
 wherein:

Base is selected from the group consisting of thymine, cytosine, 5-fluorocytosine, 5-methylcytosine, 6-azapyrimidine, 6-azacytosine, 2- and/or 4 mercaptopyrimidine, uracil, 5-halouracil, 5-fluorouracil, C⁵-alkylpyrimidine, C⁵-benzylpyrimidine, C⁵-halopyrimidine, C⁵-vinylpyrimidine, C⁵-acetylenic pyrimidine, C⁵-acyl pyrimidine, C⁵-amidopyrimidine, C⁵-cyanopyrimidine, C⁵-iodopyrimidine, C⁶-iodo-pyrimidine, C⁵-Br-vinyl pyrimidine, C⁶-Br-vinyl pyrimidine, C⁵-nitropyrimidine, C⁵-aminopyrimidine, 5-azacytidinyl, 5-azauracilyl;

R⁷ is F;

R¹ is H; phosphate; monophosphate, diphosphate; triphosphate; a stabilized phosphate prodrug; acyl; lower acyl; alkyl; lower alkyl; sulfonate ester; alkyl or arylalkyl sulfonyl; methanesulfonyl; benzylsulfonyl; a lipid; a phospholipid; an amino acid; a carbohydrate; a peptide; a cholesterol; or other pharmaceutically acceptable leaving group which when administered in vivo provides a compound wherein R¹ is H or phosphate;

R² is phosphate; monophosphate; diphosphate; triphosphate; a stabilized phosphate prodrug; acyl; lower acyl; alkyl; lower alkyl; sulfonate ester; alkyl or arylalkyl sulfonyl; methanesulfonyl; benzylsulfonyl; a lipid; a phospholipid; an amino acid; a carbohydrate; a peptide; a cholesterol; or other pharmaceutically acceptable leaving group which when administered in vivo provides a compound wherein R² is H or phosphate; and wherein each Y³ is H.

Motion App'x at 2-1-2. We note that all of the embodiments of Storer's proposed claim 14 possess a fluorine atom in the 2' "down" position.

Responsive motions may be filed to cure a claim defect raised on a notice of requested relief or a substantive motion. Bd.R. 41.121(a)(2). However, we have related *supra* why the S1 application fails to enable a fluorine atom in the 2' "down" position of any of the embodiments of the nucleoside species within the scope of count 1. Storer's proposed claim 14 fails to cure this defect of the Storer claims corresponding

to Count 1. We therefore deny Storer's Contingent Responsive Motion 14.

D. Storer Contingent Miscellaneous Motion 15

Storer Contingent Motion 15 seeks the addition to this interference of Storer US Appl. No. 14/220,534, (the "'534 application") filed March 20, 2014. Storer Cont. Motion 15, Paper 328 at 1. Storer's proposed Claim 14 is the sole claim pending in the '534 application. *Id.* The '534 application claims the benefit accorded the S1 and S4 applications. *Id.* at 2.

When Storer was authorized to file the contingent responsive motion to add Storer's new claim 14, Storer was also required to file a contingent miscellaneous motion to add the new continuation application with the new claim to the interference. *See* Order Responsive Motion Bd.R. 41.121(a)(2), Paper 326, at 3:1–3. Storer Contingent Miscellaneous Motion 15 serves that purpose. Storer Cont. Motion 15, Paper 328 at 1.

Because we have denied Storer's Contingent Responsive Motion 14 to add its new claim 14, we do not reach Storer's Contingent Motion 15 to add the '534 application to the instant interference.

E. Storer Miscellaneous Motion 16

Storer seeks to exclude the following Exhibits, in full or in part: Storer Exhibits 1194, 1243, 1244, and exclusion of Clark Exhibits 2088, and 2100. Storer Misc. Motion 16, Paper 425 at 1–5.

1. Storer Exhibit 1194

Storer Exhibit 1194 is the deposition of Dr. Damha, taken on April 15, 2014. Storer argues that the questions posed by Clark's counsel at page 81, lines 9

to 19 page 85, lines 14 were beyond the scope of Dr. Damha's direct testimony given in Exhibit 1132 and/or were irrelevant as to whether one of ordinary skill in the art as of June 28, 2002 would have been able to synthesize a 2'-fluoro-2'-methyl-nucleoside at issue. Storer Misc. Motion 16, Paper 427 at 1. Specifically, Storer argues that Dr. Damha did not, in his Declaration, address Idenix's post-June 28, 2002 efforts to synthesize a 2'-fluoro-2'-methyl-nucleoside, which was the subject of the questions posed by Clark's counsel in the disputed pages. *Id.* at 1–2.

Clark responds that, first, impeachment evidence is always relevant and within the scope of permissible cross-examination. Clark Opp. 16, Paper 430 at 1 (citing Fed. R. Evid. 611(b); 702).

Second, Clark denies that, in the disputed questions in Exhibit 1194, the questions exceeded the scope of Dr. Damha's direct testimony. Clark Opp. 16, Paper 430 at 3. Clark contends that the questions went to the bases for the opinions proffered in Exhibit 1132 and, specifically, whether those opinions took into account Idenix's synthesis efforts. *Id.*

Third, Clark points out that Storer's counsel did not object to the questions posed by Clark's counsel pp. 82, ll.11–13; 82, ll. 15–18; 82, ll. 20–21; 82, l. 23; 82, l. 25; 83, ll. 3–4; 83, ll. 6–7; and 85, ll. 10–13 of Exhibit 1194, and to which Dr. Damha at pp. 82, l. 14; 82; l. 19, 82, l. 22; 82, l. 24; 83, l. 2; 83, l. 5; 83, l. 8; and 85, l. 14, respectively, responded. Clark Opp. 16, Paper 430 at 3 (citing Ex. 1194). Therefore, argues Clark, these questions and answers should not be excluded. *Id.*

We are not persuaded by Storer's arguments. In the disputed passages of Exhibit 1132, Dr. Damha is

questioned repeatedly whether, in arriving at his opinion that one of ordinary skill in the art would be aware of “a method for preparing a 2'-F-2'-methyl-ribonucleoside of the '350 Application and within the scope of Claim 38 of the Storer Patent,” he had been made aware of, or considered, any of Idenix's efforts to synthesize the compound during the interval between 2002 and 2005. For example, during the Dr. Damha's deposition, he responded to the questions as below:

Q. So you're not aware that in the prior interference Idenix put forth its story about how its chemists tried to make 2'-fluoro-2'-methyl nucleosides during the 2002 to 2005 time period?

MR. KINTON: Same objection. Beyond the scope.

A. No.

Q. So then you couldn't have considered any of Idenix's story about its attempt to make those compounds in forming your opinions?

A. None whatsoever.

Q. And did you consider any Idenix documents about trying to make 2'-fluoro-2'-methyl nucleosides when you formed your opinion?

A. No.

Q. Did you consider any Idenix lab notebooks when forming your opinion?

A. On how to make these compounds, no.

Q. What about Idenix's meeting minutes?

A. No.

...

Q. Did you ever ask to see such information when forming your opinions?

A. No.

Q. Why not?

MR. KINTON: Objection. Irrelevant.

Ex. 1194, p. 82, ll. 3–24; p. 83, ll. 6–10. These, and the other disputed passages, all inquire whether Dr. Damha had reviewed, or had knowledge of, any documents concerning Idenix's research efforts between 2002 and 2005. Dr. Damha responded in the negative to this entire line of questioning:

Q. Do you think what Idenix actually tried in terms of attempting to make a 2'-fluoro-2'-methyl nucleoside might be important when forming your opinion?

MR. KINTON: Objection. Irrelevant. Assumes facts.

A. No, not at all. I formed my opinion on literature and knowledge that I have gained as a nucleoside nucleic acid chemist. And in fact, having used procedures that are directly applied to the synthesis of the 2'-methyl-2'-fluoro compounds.

Ex. 1194, pp. 84–85, ll. 22–9. Thus, this line of questioning by Clark inquires as to the materials that formed the basis for Dr. Damha's opinion expressed in his Declaration. As such, it is neither beyond the scope of Dr. Damha's declaration, nor is it irrelevant. Moreover, Clark is entitled to attempt to impeach the credibility of Storer's expert on cross-examination. FRE 611(b). Storer's motion to exclude the cited

passages of Storer's Exhibit 1194 is consequently denied.

2. Storer Exhibit 1243

Storer Exhibit 1243⁷⁴ is the transcript of the deposition of Dr. De Francesco. Storer moves to exclude certain passages in the Exhibit, *viz.*, page 81, lines 12–13 and 21–22 and page 82, lines 6–8 as exceeding the scope of Dr. De Francesco's direct testimony in his Declaration (Ex 1201). Storer Misc. Motion 16, Paper 427 at 3. According to Storer, Dr. De Francesco did not address in his declaration the disclosure in Exhibit 1003 of the bases for particular compounds, including Formula (IV), which was the subject of the questions posed by Clark's counsel.

Clark responds that, first, Dr. De Francesco's testimony in the contested passages is admissible because Clark's counsel's questions were within the scope of Dr. De Francesco's direct testimony in his Declaration or, alternatively, went to a matter affecting Dr. De Francesco's credibility. Clark Opp. 16, Paper 430 at 4 (citing FRE 611(b), 702).

We are not persuaded by Storer's arguments. In his Declaration, Dr. De Francesco opined:

The '350 and '907 applications state that the compounds of the invention exhibit antiviral activity against *Flaviviridae* viruses such as HCV, and can be used to treat infections by those viruses. Ex 1003, at 44:3–4, 57:15–19; Ex 1002, at 46:3–4, 58:4–9. As of June 28, 2002 and June 27, 2003, persons skilled in the art would have believed that the Relevant

⁷⁴ Paper No. 544

Compounds could have anti-HCV activity because: (i) the Relevant Compounds are nucleoside analogs, and it was known at the time that certain nucleoside analogs exhibit antiviral activity due to interference with viral polymerases required for replication of viral genetic material (referred to herein as “genome replication”), as described in ¶¶ 39–40;

(ii) it had been shown experimentally at the time that certain 2'- modified nucleosides exhibit anti-*Flaviviridae* activity, in particular against BVDV and YFV, as described in ¶¶ 41–46;

(iii) persons skilled in the art would have believed that nucleoside analogs that exhibit activity against BVDV are likely to also exhibit activity against HCV, and that nucleoside analogs that exhibit activity against BVDV and YFV are highly likely to also exhibit activity against HCV, as described in ¶¶ 47–67;

(iv) as of June 27, 2003, it had been experimentally shown that certain 2'- modified nucleosides exhibit anti-HCV activity, as described in ¶ 68–70; and

(v) there were no specific reasons to doubt anti-HCV activity of the Relevant Compounds, as described in ¶ 71.

Ex. 1201, 21. In the contested passages of Exhibit 1243, Dr. De Francesco states:

Q. Would you turn back to page 57 of the '350 application, which is Exhibit 1003?

...

A. Uh-huh.

Q. And could you identify for me what the base is for that formula?

MR. FRIEBEL: Objection, beyond the scope of his declaration.

...

A. (Perusing.) No. Sorry. This is — I think this is beyond my — it would require a better understanding of chemistry than I have.

Q. So you have no idea what the base would be?

MR. FRIEBEL: Same objection.

A. (Perusing.) I didn't review these as part of my opinion because I don't think this was requested to me. Tentatively, I would say it's one of the group — must be one of the group of bases described in the previous pages, I guess.

Q. So we were talking about the compounds at pages 1551 previously. Would that be previous pages?

MR. FRIEBEL: Same objection, beyond the scope of his original — of his second declaration.

A. (Perusing.) Yeah, I believe herein means one of the bases described in pages 48, 49 to 54, but I'm not sure. I mean, again, I'm not a chemist, so I don't — it's a tentative answer.

Ex. 1243, pp. 81–82, ll. 7–16.

Determining the scope of cross-examination is within the sound discretion of the administrative tribunal. *See, e.g., Guise v. Dep't of Justice*, 330 F.3d 1376, 1379 (Fed. Cir. 2003). Dr. De Francesco has

explicitly declared that he has studied Storer Exhibit 1003, the '350 application, as part of the preparation for giving his expert opinion. Ex. 1243, ¶ 10. Because Dr. De Francesco places no limiting language on this statement in his Declaration, we assume that he has reviewed the entire document and that questions concerning the contents of the document on cross-examination are not beyond the scope of his Declaration. Therefore, the contents of the '350 application are within the scope of his Declaration. The line of questioning in the disputed passages goes to the basis for the formation of that opinion, although his statements (“it would require a better understanding of chemistry than I have”) may undermine his credibility as an expert witness with respect to the chemistry of nucleoside bases. Nevertheless, the credibility of a witness’ opinion, and the probative weight we consequently ascribe to that testimony, is a substantive issue and not one of admissibility. We consequently deny Storer’s motion to exclude the contested passages of Exhibit 1243.

3. Storer Exhibit 1244

Storer Exhibit 1244⁷⁵ is the Second Deposition of Dr. Damha, taken on June 20, 2014. Storer moves to exclude certain passages in the Exhibit, *viz.*, page 26, line 19 to page 29, line 25; page 33, line 11 to page 36, line 2; and page 36, line 18 to page 40, line 15 as exceeding the scope of Dr. Damha’s direct testimony in his Declaration (Ex. 1200). Storer Misc. Motion 16, Paper 427 at 4. Specifically, Clark contends that Dr. Damha did not address, in his Declaration,

⁷⁵ Paper No. 545

Idenix's post-June 28, 2002 effort in synthesizing a 2'-fluoro-2'-methyl nucleoside, the subject of the questions posed by Clark's counsel in the contested passages. *Id.*

In response, Clark repeats the argument that it made with respect to Ex. 1195 *supra*: that the testimony that Storer seeks to exclude is relevant to determining whether Dr. Damha's direct testimony in Exhibit 1200 should be given any weight, and whether it is relevant to assessing Dr. Damha's credibility, particularly with regard to Dr. Damha's opinions about whether an artisan could have made 2'-fluoro-2'-methyl nucleosides without undue experimentation. Clark Opp. 16, Paper 430 at 5. Clark also contends that Dr. Damha's alleged failure to consider Idenix's extended efforts to synthesize the compounds affects his credibility as an expert witness. *Id.*

We agree with Clark. As we related *supra*, the lines of questioning objected to by Storer inquire as to the materials that formed the basis for Dr. Damha's opinion, as expressed in his Declaration and the extent of Dr. Damha's knowledge of Idenix's efforts at synthesis of 2'-fluoro-2'-methyl nucleosides. Moreover, Clark is entitled to attempt to impeach the credibility of Storer's expert in cross-examination. FRE 611(b). As such, it is neither beyond the scope of Dr. Damha's declaration, nor is it irrelevant. Storer's motion to exclude the cited passages of Storer's Exhibit 1194 is denied.

4. Clark Exhibit 2088

Clark Exhibit 2088⁷⁶ is the Declaration and curriculum vitae of Dr. Jean- Pierre Sommadossi, one of the inventors of Storer's '600 patent. Storer Misc. Motion 16, Paper 427 at 5. Storer argues that although Exhibit 2088 refers to Exhibit 1 (a copy of Tables 4 and 5 from Chapter Two of B.N. Fields et al., *Fields Virology*, Lippincott-Raven, Philadelphia (3rd ed. 1996)) at 3, ¶ 11.), Exhibit 2088 does not in fact contain an Exhibit 1. *Id.* Therefore, argues Storer, Exhibit 2088 is incomplete and should be excluded under Federal Rule of Evidence 106. *Id.*

Storer also argues that Clark relies on Exhibit 2088, and particularly ¶ 15, to prove that one cannot predict a compound's activity against another virus without testing it. Storer Misc. Motion 16, Paper 427 at 5 (citing Clark Substantive Motion 8⁷⁷, at 11, ll. 13–14). Consequently, argues Storer, Clark Exhibit 2088 is an out-of-court statement made by a declarant who has not testified in this proceeding and the statement is offered to prove its truth. *Id.* Therefore, Storer contends, Exhibit 2088 is also inadmissible as impermissible hearsay. *Id.* (citing FRE 802).

As an initial matter, Federal Rule 106 is not an exclusionary rule. Federal Rule 106 states: "If a party introduces all or part of a writing or recorded statement, an adverse party may require the introduction, at that time, of any other part – or any other writing or recorded statement – that in fairness ought to be considered at the same time." Fed. R. Evid. 106. Storer has not requested completion of the

⁷⁶ Paper No. 568

⁷⁷ Paper No. 155

record, and we therefore consider any such request waived.

5. Clark Exhibit 2100

Clark Exhibit 2100⁷⁸ is a document of the European Patent Office (“EPO”), purportedly reporting of a consultation by the EPO with applicant/representative Idenix Pharmaceuticals, Inc., the real party-in-interest in the instant interference, with respect to EPO Application No. 03 761 744.6.

Storer argues that Clark relies on Exhibit 2100 to prove that Exhibit 1002’s⁷⁹ Formula (IX) does not provide for R¹ to be di- or triphosphate and thus does not describe certain Storer claims. Storer Misc. Motion 16, Paper 427 at 5–6. As such, contends Storer, Exhibit 2100 constitutes impermissible hearsay and should be excluded. *Id.* at 6.

We do not see the relationship of Exhibit 2100 to the dispositive issue with respect to Storer’s involved claims, *viz.*, the enablement of a 2’-fluoro “down” nucleoside. Accordingly, we can discern no purpose for it to be included in this proceeding. We decline to consider it as an evidentiary matter and order that it be expunged from the record. Bd.R. 7(a) & 122(c)(1)(iii).

6. Summary

For the reasons set forth above, Storer’s Miscellaneous Motion 16 is denied.

⁷⁸ Paper No. 576

⁷⁹ Papers Nos. 319–22

IV. CONCLUSION

For the reasons set forth above:

1. Clark Substantive Motion 1 to deprive Storer of the benefit of its US Appl. No. 60/392,350 is GRANTED.
2. Clark Substantive Motion 2 to deprive Storer of the benefit accorded with respect to Count 1 of its U.S. Appl. No. 60/466,194 is GRANTED.
3. Clark Substantive Motion 3 to deprive Storer of the benefit accorded with respect to Count 1 of its U.S. Appl. No. 60/470,949 is GRANTED.
4. Clark Substantive Motion 10 to deprive Storer of the benefit accorded with respect to Count 1 of US Appl. No. 10/608,907 is DISMISSED.
5. Clark Substantive Motion 7 for judgment against Storer's US Patent No. 7,608,600 B2 on the grounds of unpatentability under 35 U.S.C. § 112, 1st paragraph for lack of enablement and written description is GRANTED.
6. Clark Substantive Motion 5 to substitute its proposed alternate count 2 for the present Count 1 of the interference is DISMISSED.
7. Clark Substantive Motion 8 for judgment against Storer's US Patent No. 7,608,600 B2 on the ground of unpatentability under 35 U.S.C. § 101, for lack of utility, and accordingly under 35 U.S.C. § 112, 1st paragraph, for lack of enablement is DISMISSED.
8. Clark Substantive Motion 9 for judgment against Storer's US Patent No. 7,608,600 B2 on the ground of unpatentability under 35 U.S.C. §§ 102(e) or 103 as being either anticipated by, or

obvious over, Clark's US Appl. No. 10/828,753 is DISMISSED.

9. Clark Miscellaneous Motion 18 to exclude evidence is DENIED. We *sua sponte* order that Storer Exhibits 1175, 1176, 1177, 1228, and 1229 be expunged.
10. Storer Substantive Motion 5 to substitute proposed count B for Count 1 is DENIED.
11. Storer Substantive Motion 11 for judgment against Clark on the grounds of unpatentability of all of Clark's involved claims as anticipated under 35 U.S.C. § 102(e) and/or 103 is DENIED.
12. Storer Contingent Motion 14 to add a new claim is DENIED.
13. Storer Contingent Motion 15 to add an application to the interference is DISMISSED.
14. Storer Miscellaneous Motion 16 to exclude evidence is DENIED. We *sua sponte* order that Clark Exhibit 2100 be expunged.
15. Party Clark shall be designated Senior Party for any further proceedings according to the Redecclaration issued herewith.

IT IS SO ORDERED

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UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND
APPEAL BOARD

RICHARD STORER, GILLES GOSSELIN, JEAN-
PIERRE SOMADOSSI, and PAOLA LACOLLA
Junior Party
(US 7,608,600 B2)

v.

JEREMY CLARK
Senior Party
(Application No. 11/854,218)

Interference No. 105,981 (JGN)
Technology Center 1600

REDECLARATION — BD.R. 203(c)

Before RICHARD E. SCHAFER, DEBORAH KATZ,
and JOHN G. NEW, *Administrative Patent Judges*.
NEW, *Administrative Patent Judge*.

A. REDECLARATION OF INTERFERENCE

A merits panel of the Board has entered an order –
– Decision on Motions – in the Substantive Motions
Phase of this interference. Paper 687.

As a result of the decision on motions, and to
conform the interference to that decision on motions,
the interference is redeclared as indicated below.

This redeclaration governs proceedings in the
Priority Phase of this interference. Bd.R. 41.203(c).

B. THE PARTIES TO THIS INTERFERENCE

Junior Party

Patent No.	US 7,608,600 B2, filed June 27, 2003 granted October 27, 2009
Title:	Modified 2' and 3' - Nucleoside Prodrugs for Treating <i>Flaviviridae</i> Infections
Inventors:	Richard Storer, of Kent in the United Kingdom, Gilles Gosselin, of Montpellier, France, Jean-Pierre Sommadossi, of Cambridge, MA Paola LaColla of Cagliari, Italy

Senior Party

Application No.	11/854,218, filed September 12, 2007
Title:	Modified Fluorinated Nucleoside Analogues
Inventors:	Jeremy Clark of Snellville, GA

Initiating Settlement Discussions: SO ¶ 126

Senior party Clark is now responsible to initiating settlement discussions.

C. COUNTS AND CLAIMS OF THE PARTIES

Count 2

The method of 11/854,218, claim 164.

The claims of the parties corresponding to the count are:

Clark: 164 and 165

Storer: Claims 1-12, 17, 18, 20, 33, 34, 36, 38,
49-57, 62, 64, and 76-85

The benefit accorded for Count 1:

Clark: 11/854,218: filed September 12, 2007
10/828,753: filed April 21, 2004
60/474,368: filed May 30, 2003

Storer: None

D. HEADING TO BE USED ON PAPERS; EXHIBIT NUMBERS

In the future, the heading set out above should be used in filing future paper.

The numbering of Exhibits shall continue as indicated below with the next available Exhibit number:

Junior party Storer: Exhibit Numbers: 1001-1999.

Senior party Clark: Exhibit Numbers: 200--2999.

Board: Exhibit Numbers: 3001-3999.

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UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND
APPEAL BOARD

RICHARD STORER, GILLES GOSSELIN, JEAN-
PIERRE SOMADOSSI, and PAOLA LACOLLA
Junior Party
(US 7,608,600 B2)

v.

JEREMY CLARK
Senior Party
(Application No. 11/854,218)

Interference No. 105,981 (JGN)
Technology Center 1600

Order to Show Cause – Bd.R. 104(a)

Before RICHARD E. SCHAFER, DEBORAH KATZ,
and JOHN G. NEW, *Administrative Patent Judges*.
NEW, *Administrative Patent Judge*.

On January 16, 2015, a merits panel of the Board entered its Decision on the Parties' Substantive Motions (the "Decision"). In the Decision, Storer was held not to be entitled to the benefit of the filing dates of its parent applications. As a result Clark became the senior party. The Decision also held that Storer's involved claims were unpatentable under 35 U.S.C. § 112, first paragraph, for lack of enablement and written description. Because the claims were found to be unpatentable, the Board substituted a new count that deleted Storer's now unpatentable claim 1 as an alternative.¹ The interference was redeclared reflecting the changed order of the parties and the new Count 2.²

The count of this interference is directed to a method of treating hepatitis C viral infection by administering a specified group of compounds defined in terms of structure and substituents at identified locations. Another interference, Interference 105,871 (the "'871 interference"), was between a different Clark application and a different "Storer" patent.³ The count in the '871 interference is directed to a specified group of compounds *per se*. The group of

¹ Original Count 1 stated: "The method of [Clark Application] 11/854, 218 claim 164 or [Storer Patent] US 7,608,600 B2 claim 1." Paper 1, p. 3.

² Paper 688.

³ The caption of '871 interference was *Clark v. Somadossi et al.* The real parties-in-interest and the named inventors are the same as those in this interference.

compounds in the '871 count is a subset of those recited in instant Count 2.⁴

The '871 interference concluded with a judgment on priority against Storer, holding that Storer had failed to prove either conception of the compounds or diligence to a reduction to practice. Specifically, the Board held that at the time of Storer's alleged conception, one skilled in the art would not have been able to make the compounds.⁵ Storer's priority statement in this interference⁶ asserts the same exact basis for priority as the priority statement in the '871 interference.⁷ In order to establish conception and diligence to reduction to practice of the method in this interference, Storer would necessarily have to prove prior conception and diligence of essentially the same compounds as in the '871 interference. Storer had an adequate opportunity and was unsuccessful in proving priority as to those compounds in the '871 interference. Under these circumstances, we see no reason proceed to priority in this interference and revisit those conception and diligence determinations.⁸ Accordingly, Storer is ordered to

⁴ Count 2 adds an additional substituent (H-phosphonate) to the listing of substituents at two locations of the compounds.

⁵ Interference 105,871, Paper 1007, pp. 17-25.

⁶ Paper 161

⁷ Interference 105,871, Paper 24.

⁸ We are aware that the decision in the '871 interference is undergoing judicial review. However, we perceive no adequate reason why the resources of the parties and the scarce resources of the Board should be expended on reviewing the same issues and evidence that is substantively the same as that presented in the '871 interference. *See* Bd. R. 41.1(b) and 41.104(b).

show cause why judgment on priority should not be awarded against the involved claims of Patent 7,608,600 B2, based on the priority determination in the '871 interference.

Storer shall respond to this order on or before **February 20, 2015**. No opposition or reply is authorized at this time. Storer's response must include (1) an explanation of why the decision on priority in '871 should not control the outcome in this interference, (2) provide a summary of all the arguments it will make to establish priority, (3) identify which of those arguments relate to the ability of a person skilled in the art to make the compounds recited in count that were not made in the '871, interference, (4) make a proffer summarizing the substance of any evidence related to the ability of a person skilled in the art to make the compounds that was not submitted in the '871 interference, and (5) explain why the new arguments and evidence could not have been submitted in the '871 interference.

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UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND
APPEAL BOARD

RICHARD STORER, GILLES GOSSELIN, JEAN-
PIERRE SOMADOSSI, and PAOLA LACOLLA

Junior Party
(US 7,608,600 B2)

v.

JEREMY CLARK

Senior Party
(Application No. 11/854,218)

Interference No. 105,981 (JGN)
Technology Center 1600

**JUDGMENT – REQUEST FOR ADVERSE
Bd.R. 127(b)(4)**

Before RICHARD SCHAFER, DEBORAH KATZ, and
JOHN G. NEW, *Administrative Patent Judges*.

NEW, Administrative Patent Judge

I.

On January 16, 2015, a merits panel of the Board entered a decision on then-Senior Party Richard Storer, Gilles Gosselin, Jean-Pierre Sommadossi, and Paola LaColla's ("Storer") and then-Junior Party Jeremy Clark's ("Clark") substantive motions.¹ Paper No. 687. The panel concluded, *inter alia*, that Storer's US Appl. No. 60/392,350 (the "350 application"), for which Storer had been accorded priority benefit, failed to enable any of the 2'-fluoro-2'-C-methyl nucleosides that are required by the count. *Id.* at 35–36. The panel consequently granted Clark's motion 1 to deprive Storer of the benefit accorded with respect to Count 1 of the '350 application. *Id.*

As a result, the interference was redeclared with Storer as the Junior Party, Clark as the Senior Party, and with Clark's involved claims 164 and 165 and Storer's involved claims 1–12, 17, 18, 20, 33, 34, 36, 38, 49–57, 62, 64, and 76–85 corresponding to the new Count 2. Paper No. 688. A scheduling order for the priority phase was also entered on January 16, 2015. Paper No. 689. Storer's priority motion was due on February 27, 2015. Paper 689, Appendix. Rather than filing its priority motion, Storer contacted the Board via email to indicate that it did not intend to file a priority motion. *See* Paper No. 692.

¹ On January 16, 2015, the Board also entered an order for Storer to show cause why, in view of the Board's decision on the parties' substantive motions, judgment should not be entered against it. Paper 690. Storer timely responded. Paper No. 691. Although the panel finds Storer's response to the order to show cause to be insufficient, Storer's response to the order to show cause played no role in the entry of this judgment.

II.

As Senior Party, Clark is entitled to the presumption under Bd.R. 207(a)(1) that it is the prior inventor. *See also* Bd.R. 201, definition of senior party. As the Junior Party, Storer therefore bears the burden of establishing a date of inventorship prior to Clark's accorded benefit date of May 30, 2003. *See* Bd. Rs. 121(b) and 208(b). By declining to file a priority motion and forgoing the opportunity to prove an earlier date of invention, Storer has effectively abandoned the contest. Storer's abandonment of the contest is construed as a request for adverse judgment. *See* Bd.R. 127(b)(4).

It is therefore—

ORDERED that judgment on priority be entered against Junior Party Storer for the subject matter of count 2;

FURTHER ORDERED that claims 1–12, 17, 18, 20, 33, 34, 36, 38, 49–57, 62, 64, and 76–85 of Storer's involved U.S. Patent No. US 7,608,600 B2 be CANCELED, 35 U.S.C. 135(a)²; and

FURTHER ORDERED that a copy of this judgment be entered in the administrative records of Storer's involved US 7,608,600 B2 patent and Clark's involved US Appl. No. 11/854,218.

FURTHER ORDERED that if a party seeks judicial review, the party must file a notice with the Board (37 C.F.R. § 41.8(b)) within seven days of initiating judicial review.

² As was in effect on March 15, 2013. *See* Pub. L. 112–29, § 3(n), 125 Stat. 284, 293 (2011).

We also direct the parties' attention to *Biogen Idec MA, Inc., v. Japanese Foundation for Cancer Research*, Civil No. 13-13061-FDS, 2014 WL 2167677 (D. Mass. May 22, 2014).

NOTICE: "Any agreement or understanding between parties to an interference, including any collateral agreements referred to therein, made in connection with or in contemplation of the termination of the interference, shall be in writing and a true copy thereof filed in the Patent and Trademark Office before the termination of the interference as between the said parties to the agreement or understanding." 35 U.S.C. 135(c); see also Bd.R. 205 (settlement agreements).

APPENDIX D

35 U.S.C. § 141. (pre-AIA)**Appeal to the Court of Appeals for the Federal Circuit**

An applicant dissatisfied with the decision in an appeal to the Board of Patent Appeals and Interferences under section 134 of this title may appeal the decision to the United States Court of Appeals for the Federal Circuit. By filing such an appeal the applicant waives his or her right to proceed under section 145 of this title. A patent owner, or a third-party requester in an inter partes reexamination proceeding, who is in any reexamination proceeding dissatisfied with the final decision in an appeal to the Board of Patent Appeals and Interferences under section 134 may appeal the decision only to the United States Court of Appeals for the Federal Circuit. A party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference may appeal the decision to the United States Court of Appeals for the Federal Circuit, but such appeal shall be dismissed if any adverse party to such interference, within twenty days after the appellant has filed notice of appeal in accordance with section 142 of this title, files notice with the Director that the party elects to have all further proceedings conducted as provided in section 146 of this title. If the appellant does not, within thirty days after filing of such notice by the adverse party, file a civil action

under section 146, the decision appealed from shall govern the further proceedings in the case.

35 U.S.C. § 141. (post-AIA)

Appeal to Court of Appeals for the Federal Circuit

(a) EXAMINATIONS.—An applicant who is dissatisfied with the final decision in an appeal to the Patent Trial and Appeal Board under section 134(a) may appeal the Board's decision to the United States Court of Appeals for the Federal Circuit. By filing such an appeal, the applicant waives his or her right to proceed under section 145.

(b) REEXAMINATIONS.—A patent owner who is dissatisfied with the final decision in an appeal of a reexamination to the Patent Trial and Appeal Board under section 134(a) may appeal the Board's decision only to the United States Court of Appeals for the Federal Circuit.

(c) POST-GRANT AND INTER PARTES REVIEWS.—A party to an inter partes review or a post-grant review who is dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) or 328(a) (as the case may be) may appeal the Board's decision only to the United States Court of Appeals for the Federal Circuit.

(d) DERIVATION PROCEEDINGS.—A party to a derivation proceeding who is dissatisfied with the final decision of the Patent Trial and Appeal Board in the proceeding may appeal the decision to the United States Court of Appeals for the Federal Circuit, but

such appeal shall be dismissed if any adverse party to such derivation proceeding, within 20 days after the appellant has filed notice of appeal in accordance with section 142, files notice with the Director that the party elects to have all further proceedings conducted as provided in section 146. If the appellant does not, within 30 days after the filing of such notice by the adverse party, file a civil action under section 146, the Board's decision shall govern the further proceedings in the case.

35 U.S.C. § 146. (pre-AIA)

Civil action in case of interference.

Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days, as the Director appoints or as provided in section 141, unless he has appealed to the United States Court of Appeals for the Federal Circuit, and such appeal is pending or has been decided. In such suits the record in the Patent and Trademark Office shall be admitted on motion of either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.

Such suit may be instituted against the party in interest as shown by the records of the Patent and

Trademark Office at the time of the decision complained of, but any party in interest may become a party to the action. If there be adverse parties residing in a plurality of districts not embraced within the same state, or an adverse party residing in a foreign country, the United States District Court for the Eastern District of Virginia shall have jurisdiction and may issue summons against the adverse parties directed to the marshal of any district in which any adverse party resides. Summons against adverse parties residing in foreign countries may be served by publication or otherwise as the court directs. The Director shall not be a necessary party but he shall be notified of the filing of the suit by the clerk of the court in which it is filed and shall have the right to intervene. Judgment of the court in favor of the right of an applicant to a patent shall authorize the Director to issue such patent on the filing in the Patent and Trademark Office of a certified copy of the judgment and on compliance with the requirements of law.

35 U.S.C. § 146. (post-AIA)

Civil action in case of derivation proceeding.

Any party to a derivation proceeding dissatisfied with the decision of the Patent Trial and Appeal Board on the derivation proceeding, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days, as the Director appoints or as provided in section 141, unless he has appealed to the United States Court of Appeals for the Federal Circuit, and such appeal is pending or has been decided. In such suits the record in the Patent and Trademark Office shall be admitted on motion of

either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.

Such suit may be instituted against the party in interest as shown by the records of the Patent and Trademark Office at the time of the decision complained of, but any party in interest may become a party to the action. If there be adverse parties residing in a plurality of districts not embraced within the same state, or an adverse party residing in a foreign country, the United States District Court for the Eastern District of Virginia shall have jurisdiction and may issue summons against the adverse parties directed to the marshal of any district in which any adverse party resides. Summons against adverse parties residing in foreign countries may be served by publication or otherwise as the court directs. The Director shall not be a necessary party but he shall be notified of the filing of the suit by the clerk of the court in which it is filed and shall have the right to intervene. Judgment of the court in favor of the right of an applicant to a patent shall authorize the Director to issue such patent on the filing in the Patent and Trademark Office of a certified copy of the judgment and on compliance with the requirements of law.

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APPENDIX E

PUBLIC LAW 112-29—SEPT. 16, 2011

LEAHY-SMITH AMERICA INVENTS ACT

To amend title 35, United States Code, to provide for patent reform.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Leahy-Smith America Invents Act”.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.
- Sec. 3. First inventor to file.
- Sec. 4. Inventor’s oath or declaration.
- Sec. 5. Defense to infringement based on prior commercial use.
- Sec. 6. Post-grant review proceedings.
- Sec. 7. Patent Trial and Appeal Board.
- Sec. 8. Preissuance submissions by third parties.
- Sec. 9. Venue.
- Sec. 10. Fee setting authority.
- Sec. 11. Fees for patent services.
- Sec. 12. Supplemental examination.
- Sec. 13. Funding agreements.
- Sec. 14. Tax strategies deemed within the prior art.
- Sec. 15. Best mode requirement.
- Sec. 16. Marking.
- Sec. 17. Advice of counsel.

Sec. 18. Transitional program for covered business method patents.

Sec. 19. Jurisdiction and procedural matters.

Sec. 20. Technical amendments.

Sec. 21. Travel expenses and payment of administrative judges.

Sec. 22. Patent and Trademark Office funding.

Sec. 23. Satellite offices.

Sec. 24. Designation of Detroit satellite office.

Sec. 25. Priority examination for important technologies.

Sec. 26. Study on implementation.

Sec. 27. Study on genetic testing.

Sec. 28. Patent Ombudsman Program for small business concerns.

Sec. 29. Establishment of methods for studying the diversity of applicants.

Sec. 30. Sense of Congress.

Sec. 31. USPTO study on international patent protections for small businesses.

Sec. 32. Pro bono program.

Sec. 33. Limitation on issuance of patents.

Sec. 34. Study of patent litigation.

Sec. 35. Effective date.

Sec. 36. Budgetary effects.

Sec. 37. Calculation of 60-day period for application of patent term extension.

SEC. 2. DEFINITIONS.

In this Act:

(1) DIRECTOR.—The term “Director” means the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

(2) OFFICE.—The term “Office” means the United States Patent and Trademark Office.

(3) PATENT PUBLIC ADVISORY COMMITTEE.—The term “Patent Public Advisory Committee” means the Patent Public Advisory Committee established under section 5(a) of title 35, United States Code.

(4) TRADEMARK ACT OF 1946.—The term “Trademark Act of 1946” means the Act entitled “An Act to provide for the registration and protection of trademarks used in commerce, to carry out the provisions of certain international conventions, and for other purposes”, approved July 5, 1946 (15 U.S.C. 1051 et seq.) (commonly referred to as the “Trademark Act of 1946” or the “Lanham Act”).

(5) TRADEMARK PUBLIC ADVISORY COMMITTEE.—The term “Trademark Public Advisory Committee” means the Trademark Public Advisory Committee established under section 5(a) of title 35, United States Code.

SEC. 3. FIRST INVENTOR TO FILE.

(a) DEFINITIONS.—Section 100 of title 35, United States Code, is amended—

(1) in subsection (e), by striking “or inter partes reexamination under section 311”; and

(2) by adding at the end the following:

“(f) The term ‘inventor’ means the individual or, if a joint invention, the individuals collectively who

invented or discovered the subject matter of the invention.

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

“(h) The term ‘joint research agreement’ means a written contract, grant, or cooperative agreement entered into by 2 or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

“(i)(1) The term ‘effective filing date’ for a claimed invention in a patent or application for patent means—

“(A) if subparagraph (B) does not apply, the actual filing date of the patent or the application for the patent containing a claim to the invention; or

“(B) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date under section 120, 121, or 365(c).

“(2) The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought.

“(j) The term ‘claimed invention’ means the subject matter defined by a claim in a patent or an application for a patent.”.

(b) CONDITIONS FOR PATENTABILITY.—

(1) IN GENERAL.—Section 102 of title 35, United States Code, is amended to read as follows:

“§ 102. Conditions for patentability; novelty

“(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

“(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

“(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

“(b) EXCEPTIONS.—

“(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

“(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

“(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another

who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

“(2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—

“(A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;

“(B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

“(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

“(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

“(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

“(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement;

and

“(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

“(d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—

“(1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or

“(2) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.”.

(2) CONTINUITY OF INTENT UNDER THE CREATE ACT.—The enactment of section 102(c) of title 35, United States Code, under paragraph (1) of this subsection is done with the same intent to promote joint research activities that was expressed, including in the legislative history, through the enactment of the Cooperative Research

and Technology Enhancement Act of 2004 (Public Law 108–453; the “CREATE Act”), the amendments of which are stricken by subsection (c) of this section. The United States Patent and Trademark Office shall administer section 102(c) of title 35, United States Code, in a manner consistent with the legislative history of the CREATE Act that was relevant to its administration by the United States Patent and Trademark Office.

(3) CONFORMING AMENDMENT.—The item relating to section 102 in the table of sections for chapter 10 of title 35, United States Code, is amended to read as follows:

“102. Conditions for patentability; novelty.”.

(c) CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.—Section 103 of title 35, United States Code, is amended to read as follows:

“§ 103. Conditions for patentability; non-obvious subject matter

“A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.”.

(d) REPEAL OF REQUIREMENTS FOR INVENTIONS MADE ABROAD.—Section 104 of title 35, United States Code, and the item relating to that

section in the table of sections for chapter 10 of title 35, United States Code, are repealed.

(e) REPEAL OF STATUTORY INVENTION REGISTRATION.—

(1) IN GENERAL.—Section 157 of title 35, United States Code, and the item relating to that section in the table of sections for chapter 14 of title 35, United States Code, are repealed.

(2) REMOVAL OF CROSS REFERENCES.—Section 111(b)(8) of title 35, United States Code, is amended by striking “sections 115, 131, 135, and 157” and inserting “sections 131 and 135”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any request for a statutory invention registration filed on or after that effective date.

(f) EARLIER FILING DATE FOR INVENTOR AND JOINT INVENTOR.—Section 120 of title 35, United States Code, is amended by striking “which is filed by an inventor or inventors named” and inserting “which names an inventor or joint inventor”.

(g) CONFORMING AMENDMENTS.—

(1) RIGHT OF PRIORITY —Section 172 of title 35, United States Code, is amended by striking “and the time specified in section 102(d)”.

(2) LIMITATION ON REMEDIES.—Section 287(c)(4) of title 35, United States Code, is amended by striking “the earliest effective filing date of which is prior to” and inserting “which has an effective filing date before”.

(3) INTERNATIONAL APPLICATION DESIGNATING THE UNITED STATES: EFFECT.—Section 363 of title 35, United States Code, is amended by striking “except as otherwise provided in section 102(e) of this title”.

(4) PUBLICATION OF INTERNATIONAL APPLICATION: EFFECT.—Section 374 of title 35, United States Code, is amended by striking “sections 102(e) and 154(d)” and inserting “section 154(d)”.

(5) PATENT ISSUED ON INTERNATIONAL APPLICATION: EFFECT.—The second sentence of section 375(a) of title 35, United States Code, is amended by striking “Subject to section 102(e) of this title, such” and inserting “Such”.

(6) LIMIT ON RIGHT OF PRIORITY.—Section 119(a) of title 35, United States Code, is amended by striking “; but no patent shall be granted” and all that follows through “one year prior to such filing”.

(7) INVENTIONS MADE WITH FEDERAL ASSISTANCE.—Section 202(c) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) by striking “publication, on sale, or public use,” and all that follows through “obtained in the United States” and inserting “the 1-year period referred to in section 102(b) would end before the end of that 2-year period”; and

(ii) by striking “prior to the end of the statutory” and inserting “before the end of that 1-year”; and

(B) in paragraph (3), by striking “any statutory bar date that may occur under this title due to publication, on sale, or public use” and inserting “the expiration of the 1-year period referred to in section 102(b)”.

(h) DERIVED PATENTS.—

(1) IN GENERAL.—Section 291 of title 35, United States Code, is amended to read as follows:

“§ 291. Derived Patents

“(a) IN GENERAL.—The owner of a patent may have relief by civil action against the owner of another patent that claims the same invention and has an earlier effective filing date, if the invention claimed in such other patent was derived from the inventor of the invention claimed in the patent owned by the person seeking relief under this section.

“(b) FILING LIMITATION.—An action under this section may be filed only before the end of the 1-year period beginning on the date of the issuance of the first patent containing a claim to the allegedly derived invention and naming an individual alleged to have derived such invention as the inventor or joint inventor.”.

(2) CONFORMING AMENDMENT.—The item relating to section 291 in the table of sections for chapter 29 of title 35, United States Code, is amended to read as follows:

“291. Derived patents.”.

(i) DERIVATION PROCEEDINGS.—Section 135 of title 35, United States Code, is amended to read as follows:

“§ 135. Derivation proceedings

“(a) INSTITUTION OF PROCEEDING.—An applicant for patent may file a petition to institute a derivation proceeding in the Office. The petition shall set forth with particularity the basis for finding that an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner’s application and, without authorization, the earlier application claiming such invention was filed. Any such petition may be filed only within the 1-year period beginning on the date of the first publication of a claim to an invention that is the same or substantially the same as the earlier application’s claim to the invention, shall be made under oath, and shall be supported by substantial evidence. Whenever the Director determines that a petition filed under this subsection demonstrates that the standards for instituting a derivation proceeding are met, the Director may institute a derivation proceeding. The determination by the Director whether to institute a derivation proceeding shall be final and nonappealable.

“(b) DETERMINATION BY PATENT TRIAL AND APPEAL BOARD.—

In a derivation proceeding instituted under subsection (a), the Patent Trial and Appeal Board shall determine whether an inventor named in the earlier application derived the claimed invention from an inventor named in the petitioner’s application and, without authorization, the earlier application claiming

such invention was filed. In appropriate circumstances, the Patent Trial and Appeal Board may correct the naming of the inventor in any application or patent at issue. The Director shall prescribe regulations setting forth standards for the conduct of derivation proceedings, including requiring parties to provide sufficient evidence to prove and rebut a claim of derivation.

“(c) DEFERRAL OF DECISION.—The Patent Trial and Appeal Board may defer action on a petition for a derivation proceeding until the expiration of the 3-month period beginning on the date on which the Director issues a patent that includes the claimed invention that is the subject of the petition. The Patent Trial and Appeal Board also may defer action on a petition for a derivation proceeding, or stay the proceeding after it has been instituted, until the termination of a proceeding under chapter 30, 31, or 32 involving the patent of the earlier applicant.

“(d) EFFECT OF FINAL DECISION.—The final decision of the Patent Trial and Appeal Board, if adverse to claims in an application for patent, shall constitute the final refusal by the Office on those claims. The final decision of the Patent Trial and Appeal Board, if adverse to claims in a patent, shall, if no appeal or other review of the decision has been or can be taken or had, constitute cancellation of those claims, and notice of such cancellation shall be endorsed on copies of the patent distributed after such cancellation.

“(e) SETTLEMENT.—Parties to a proceeding instituted under subsection (a) may terminate the proceeding by filing a written statement reflecting the

agreement of the parties as to the correct inventors of the claimed invention in dispute. Unless the Patent Trial and Appeal Board finds the agreement to be inconsistent with the evidence of record, if any, it shall take action consistent with the agreement. Any written settlement or understanding of the parties shall be filed with the Director. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents or applications, and shall be made available only to Government agencies on written request, or to any person on a showing of good cause.

“(f) ARBITRATION.—Parties to a proceeding instituted under subsection (a) may, within such time as may be specified by the Director by regulation, determine such contest or any aspect thereof by arbitration. Such arbitration shall be governed by the provisions of title 9, to the extent such title is not inconsistent with this section. The parties shall give notice of any arbitration award to the Director, and such award shall, as between the parties to the arbitration, be dispositive of the issues to which it relates. The arbitration award shall be unenforceable until such notice is given. Nothing in this subsection shall preclude the Director from determining the patentability of the claimed inventions involved in the proceeding.”.

(j) ELIMINATION OF REFERENCES TO INTERFERENCES.—(1) Sections 134, 145, 146, 154, and 305 of title 35, United States Code, are each amended by striking “Board of Patent Appeals and

Interferences” each place it appears and inserting “Patent Trial and Appeal Board”.

(2)(A) Section 146 of title 35, United States Code, is amended—

(i) by striking “an interference” and inserting “a derivation proceeding”; and

(ii) by striking “the interference” and inserting “the derivation proceeding”.

(B) The subparagraph heading for section 154(b)(1)(C) of title 35, United States Code, is amended to read as follows:

“(C) GUARANTEE OF ADJUSTMENTS FOR DELAYS DUE TO DERIVATION PROCEEDINGS, SECRECY ORDERS, AND APPEALS.—”.

(3) The section heading for section 134 of title 35, United States Code, is amended to read as follows:

“§ 134. Appeal to the Patent Trial and Appeal Board”.

(4) The section heading for section 146 of title 35, United States Code, is amended to read as follows:

“§ 146. Civil action in case of derivation proceeding”.

(5) The items relating to sections 134 and 135 in the table of sections for chapter 12 of title 35, United States Code, are amended to read as follows:

“134. Appeal to the Patent Trial and Appeal Board.
“135. Derivation proceedings.”.

(6) The item relating to section 146 in the table of sections for chapter 13 of title 35, United States Code, is amended to read as follows:

“146. Civil action in case of derivation proceeding.”.

(k) STATUTE OF LIMITATIONS.—

(1) IN GENERAL.—Section 32 of title 35, United States Code, is amended by inserting between the third and fourth sentences the following: “A proceeding under this section shall be commenced not later than the earlier of either the date that is 10 years after the date on which the misconduct forming the basis for the proceeding occurred, or 1 year after the date on which the misconduct forming the basis for the proceeding is made known to an officer or employee of the Office as prescribed in the regulations established under section 2(b)(2)(D).”.

(2) REPORT TO CONGRESS.—The Director shall provide on a biennial basis to the Judiciary Committees of the Senate and House of Representatives a report providing a short description of incidents made known to an officer or employee of the Office as prescribed in the regulations established under section 2(b)(2)(D) of title 35, United States Code, that reflect substantial evidence of misconduct before the Office but for which the Office was barred from commencing a proceeding under section 32 of title 35, United States Code, by the time limitation established by the fourth sentence of that section.

(3) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply in any case in which the time period for instituting a proceeding under section 32 of title 35, United States Code, had not lapsed before the date of the enactment of this Act.

(l) SMALL BUSINESS STUDY.—

(1) DEFINITIONS.—In this subsection—

(A) the term “Chief Counsel” means the Chief Counsel for Advocacy of the Small Business Administration;

(B) the term “General Counsel” means the General Counsel of the United States Patent and Trademark Office; and

(C) the term “small business concern” has the meaning given that term under section 3 of the Small Business Act (15 U.S.C. 632).

(2) STUDY.—

(A) IN GENERAL.—The Chief Counsel, in consultation with the General Counsel, shall conduct a study of the effects of eliminating the use of dates of invention in determining whether an applicant is entitled to a patent under title 35, United States Code.

(B) AREAS OF STUDY.—The study conducted under subparagraph (A) shall include examination of the effects of eliminating the use of invention dates, including examining—

(i) how the change would affect the ability of small business concerns to obtain patents and their costs of obtaining patents;

(ii) whether the change would create, mitigate, or exacerbate any disadvantages for applicants for patents that are small business concerns relative to applicants for patents that are not small business concerns, and whether the change would create any advantages for applicants for patents that are small business

concerns relative to applicants for patents that are not small business concerns;

(iii) the cost savings and other potential benefits to small business concerns of the change; and

(iv) the feasibility and costs and benefits to small business concerns of alternative means of determining whether an applicant is entitled to a patent under title 35, United States Code.

(3) REPORT.—Not later than the date that is 1 year after the date of the enactment of this Act, the Chief Counsel shall submit to the Committee on Small Business and Entrepreneurship and the Committee on the Judiciary of the Senate and the Committee on Small Business and the Committee on the Judiciary of the House of Representatives a report on the results of the study under paragraph (2).

(m) REPORT ON PRIOR USER RIGHTS.—

(1) IN GENERAL.—Not later than the end of the 4-month period beginning on the date of the enactment of this Act, the Director shall report, to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives, the findings and recommendations of the Director on the operation of prior user rights in selected countries in the industrialized world. The report shall include the following:

(A) A comparison between patent laws of the United States and the laws of other industrialized countries, including members of the European Union and Japan, Canada, and Australia.

(B) An analysis of the effect of prior user rights on innovation rates in the selected countries.

(C) An analysis of the correlation, if any, between prior user rights and start-up enterprises and the ability to attract venture capital to start new companies.

(D) An analysis of the effect of prior user rights, if any, on small businesses, universities, and individual inventors.

(E) An analysis of legal and constitutional issues, if any, that arise from placing trade secret law in patent law.

(F) An analysis of whether the change to a first-to file patent system creates a particular need for prior user rights.

(2) CONSULTATION WITH OTHER AGENCIES.—In preparing the report required under paragraph (1), the Director shall consult with the United States Trade Representative, the Secretary of State, and the Attorney General.

(n) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

(2) INTERFERING PATENTS.—The provisions of sections 102(g), 135, and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection, shall apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply, if such application or patent contains or contained at any time—

(A) a claim to an invention having an effective filing date as defined in section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

(o) SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from “first to invent” to a system of “first inventor to file” will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.

(p) SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from “first to invent” to a system of “first inventor to file” will improve the United States patent

system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries.

SEC. 4. INVENTOR'S OATH OR DECLARATION.

(a) INVENTOR'S OATH OR DECLARATION.—

(1) IN GENERAL.—Section 115 of title 35, United States Code, is amended to read as follows:

“§ 115. Inventor's oath or declaration

“(a) NAMING THE INVENTOR; INVENTOR'S OATH OR DECLARATION.—An application for patent that is filed under section 111(a) or commences the national stage under section 371 shall include, or be amended to include, the name of the inventor for any invention claimed in the application. Except as otherwise provided in this section, each individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application.

“(b) REQUIRED STATEMENTS.—An oath or declaration under subsection (a) shall contain statements that—

“(1) the application was made or was authorized to be made by the affiant or declarant; and

“(2) such individual believes himself or herself to be the original inventor or an original joint inventor of a claimed invention in the application.

“(c) ADDITIONAL REQUIREMENTS.—The Director may specify additional information relating to the inventor and the invention that is required to be included in an oath or declaration under subsection (a).

“(d) SUBSTITUTE STATEMENT.—

“(1) IN GENERAL.—In lieu of executing an oath or declaration under subsection (a), the applicant for patent may provide a substitute statement under the circumstances described in paragraph (2) and such additional circumstances that the Director may specify by regulation.

“(2) PERMITTED CIRCUMSTANCES.—A substitute statement under paragraph (1) is permitted with respect to any individual who—

“(A) is unable to file the oath or declaration under subsection (a) because the individual—

“(i) is deceased;

“(ii) is under legal incapacity; or

“(iii) cannot be found or reached after diligent effort; or

“(B) is under an obligation to assign the invention but has refused to make the oath or declaration required under subsection (a).

“(3) CONTENTS.—A substitute statement under this subsection shall—

“(A) identify the individual with respect to whom the statement applies;

“(B) set forth the circumstances representing the permitted basis for the filing of

the substitute statement in lieu of the oath or declaration under subsection (a); and

“(C) contain any additional information, including any showing, required by the Director.

“(e) MAKING REQUIRED STATEMENTS IN ASSIGNMENT OF RECORD.—An individual who is under an obligation of assignment of an application for patent may include the required statements under subsections (b) and (c) in the assignment executed by the individual, in lieu of filing such statements separately.

“(f) TIME FOR FILING.—A notice of allowance under section 151 may be provided to an applicant for patent only if the applicant for patent has filed each required oath or declaration under subsection (a) or has filed a substitute statement under subsection (d) or recorded an assignment meeting the requirements of subsection (e).

“(g) EARLIER-FILED APPLICATION CONTAINING REQUIRED STATEMENTS OR SUBSTITUTE STATEMENT.—

“(1) EXCEPTION.—The requirements under this section shall not apply to an individual with respect to an application for patent in which the individual is named as the inventor or a joint inventor and who claims the benefit under section 120, 121, or 365(c) of the filing of an earlier-filed application, if—”

(A) an oath or declaration meeting the requirements of subsection (a) was executed by the individual and was filed in connection with the earlier-filed application;

“(B) a substitute statement meeting the requirements of subsection (d) was filed in connection with the earlier filed application with respect to the individual; or

“(C) an assignment meeting the requirements of subsection (e) was executed with respect to the earlier-filed application by the individual and was recorded in connection with the earlier-filed application.

“(2) COPIES OF OATHS, DECLARATIONS, STATEMENTS, OR ASSIGNMENTS.—Notwithstanding paragraph (1), the Director may require that a copy of the executed oath or declaration, the substitute statement, or the assignment filed in connection with the earlier-filed application be included in the later-filed application.

“(h) SUPPLEMENTAL AND CORRECTED STATEMENTS; FILING ADDITIONAL STATEMENTS.—

“(1) IN GENERAL.—Any person making a statement required under this section may withdraw, replace, or otherwise correct the statement at any time. If a change is made in the naming of the inventor requiring the filing of 1 or more additional statements under this section, the Director shall establish regulations under which such additional statements may be filed.

“(2) SUPPLEMENTAL STATEMENTS NOT REQUIRED.—If an individual has executed an oath or declaration meeting the requirements of subsection (a) or an assignment meeting the requirements of subsection (e) with respect to an application for patent, the Director may not thereafter require that

individual to make any additional oath, declaration, or other statement equivalent to those required by this section in connection with the application for patent or any patent issuing thereon.

“(3) SAVINGS CLAUSE.—A patent shall not be invalid or unenforceable based upon the failure to comply with a requirement under this section if the failure is remedied as provided under paragraph (1).

“(i) ACKNOWLEDGMENT OF PENALTIES.—Any declaration or statement filed pursuant to this section shall contain an acknowledgment that any willful false statement made in such declaration or statement is punishable under section 1001 of title 18 by fine or imprisonment of not more than 5 years, or both.”.

(2) RELATIONSHIP TO DIVISIONAL APPLICATIONS.—Section 121 of title 35, United States Code, is amended by striking “If a divisional application” and all that follows through “inventor.”.

(3) REQUIREMENTS FOR NONPROVISIONAL APPLICATIONS.—Section 111(a) of title 35, United States Code, is amended—

(A) in paragraph (2)(C), by striking “by the applicant” and inserting “or declaration”;

(B) in the heading for paragraph (3), by inserting “OR DECLARATION” after “AND OATH”; and

(C) by inserting “or declaration” after “and oath” each place it appears.

(4) CONFORMING AMENDMENT.—The item relating to section 115 in the table of sections for chapter 11 of title 35, United States Code, is amended to read as follows:

“115. Inventor’s oath or declaration.”.

(b) FILING BY OTHER THAN INVENTOR.—

(1) IN GENERAL.—Section 118 of title 35, United States Code, is amended to read as follows:

“§ 118. Filing by other than inventor

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

(2) CONFORMING AMENDMENT.—Section 251 of title 35, United States Code, is amended in the third undesignated paragraph by inserting “or the application for the original patent was filed by the assignee of the entire interest” after “claims of the original patent”.

(c) SPECIFICATION.—Section 112 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “The specification” and inserting “(a) IN GENERAL.—The specification”; and

(B) by striking “of carrying out his invention” and inserting “or joint inventor of carrying out the invention”;

(2) in the second undesignated paragraph—

(A) by striking “The specification” and inserting “(b) CONCLUSION.—The specification”; and

(B) by striking “applicant regards as his invention” and inserting “inventor or a joint inventor regards as the invention”;

(3) in the third undesignated paragraph, by striking “A claim” and inserting “(c) FORM.—A claim”;

(4) in the fourth undesignated paragraph, by striking “Subject to the following paragraph,” and inserting “(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e),”;

(5) in the fifth undesignated paragraph, by striking “A claim” and inserting “(e) REFERENCE IN MULTIPLE DEPENDENT FORM.—A claim”; and

(6) in the last undesignated paragraph, by striking “An element” and inserting “(f) ELEMENT IN CLAIM FOR A COMBINATION.—An element”.

(d) CONFORMING AMENDMENTS.—

(1) Sections 111(b)(1)(A) of title 35, United States Code, is amended by striking “the first paragraph of section 112 of this title” and inserting “section 112(a)”.

(2) Section 111(b)(2) of title 35, United States Code, is amended by striking “the second through fifth paragraphs of section 112,” and inserting “subsections (b) through (e) of section 112,”.

(e) **EFFECTIVE DATE.**—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent application that is filed on or after that effective date.

SEC. 5. DEFENSE TO INFRINGEMENT BASED ON PRIOR COMMERCIAL USE.

(a) **IN GENERAL.**—Section 273 of title 35, United States Code, is amended to read as follows:

“§ 273. Defense to infringement based on prior commercial use

“(a) **IN GENERAL.**—A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—

“(1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use; and

“(2) such commercial use occurred at least 1 year before the earlier of either—

“(A) the effective filing date of the claimed invention; or

“(B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).

“(b) BURDEN OF PROOF.—A person asserting a defense under this section shall have the burden of establishing the defense by clear and convincing evidence.

“(c) ADDITIONAL COMMERCIAL USES.—

“(1) PREMARKETING REGULATORY REVIEW.—Subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established, including any period specified in section 156(g), shall be deemed to be commercially used for purposes of subsection (a)(1) during such regulatory review period.

“(2) NONPROFIT LABORATORY USE.—A use of subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary, shall be deemed to be a commercial use for purposes of subsection (a)(1), except that a defense under this section may be asserted pursuant to this paragraph only for continued and noncommercial use by and in the laboratory or other nonprofit entity.

“(d) EXHAUSTION OF RIGHTS.—Notwithstanding subsection (e)(1), the sale or other disposition of a useful end result by a person entitled to assert a defense under this section in connection with a patent with respect to that useful end result shall exhaust the patent owner’s rights under the patent to the extent that such rights would have been exhausted had such sale or other disposition been made by the patent owner.

“(e) LIMITATIONS AND EXCEPTIONS.—

”(1) PERSONAL DEFENSE.—

“(A) IN GENERAL.—A defense under this section may be asserted only by the person who performed or directed the performance of the commercial use described in subsection (a), or by an entity that controls, is controlled by, or is under common control with such person.

“(B) TRANSFER OF RIGHT.—Except for any transfer to the patent owner, the right to assert a defense under this section shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.

“(C) RESTRICTION ON SITES.—A defense under this section, when acquired by a person as part of an assignment or transfer described in subparagraph (B), may only be asserted for uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.

“(2) DERIVATION.—A person may not assert a defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.

“(3) NOT A GENERAL LICENSE.—The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter for which it has been established that a commercial use that qualifies under this section occurred, except that the

defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.

“(4) ABANDONMENT OF USE.—A person who has abandoned commercial use (that qualifies under this section) of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken on or after the date of such abandonment.

“(5) UNIVERSITY EXCEPTION.—

“(A) IN GENERAL.—A person commercially using subject matter to which subsection (a) applies may not assert a defense under this section if the claimed invention with respect to which the defense is asserted was, at the time the invention was made, owned or subject to an obligation of assignment to either an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education.

“(B) EXCEPTION.—Subparagraph (A) shall not apply if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government.

“(f) UNREASONABLE ASSERTION OF DEFENSE.—If the defense under this section is pleaded by a person who is found to infringe the patent

and who subsequently fails to demonstrate a reasonable basis for asserting the defense, the court shall find the case exceptional for the purpose of awarding attorney fees under section 285.

“(g) INVALIDITY.—A patent shall not be deemed to be invalid under section 102 or 103 solely because a defense is raised or established under this section.”.

(b) CONFORMING AMENDMENT.—The item relating to section 273 in the table of sections for chapter 28 of title 35, United States Code, is amended to read as follows:

“273. Defense to infringement based on prior commercial use.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to any patent issued on or after the date of the enactment of this Act.

SEC. 6. POST-GRANT REVIEW PROCEEDINGS.

(a) INTER PARTES REVIEW.—Chapter 31 of title 35, United States Code, is amended to read as follows:

“CHAPTER 31—INTER PARTES REVIEW

“Sec.

“311. Inter partes review.

“312. Petitions.

“313. Preliminary response to petition.

“314. Institution of inter partes review.

“315. Relation to other proceedings or actions.

“316. Conduct of inter partes review.

“317. Settlement.

“318. Decision of the Board.

“319. Appeal.

“§ 311. Inter partes review

“(a) IN GENERAL.—Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review.

“(b) SCOPE.—A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.

“(c) FILING DEADLINE.—A petition for inter partes review shall be filed after the later of either—

“(1) the date that is 9 months after the grant of a patent or issuance of a reissue of a patent; or

“(2) if a post-grant review is instituted under chapter 32, the date of the termination of such post-grant review.

“§ 312. Petitions

“(a) REQUIREMENTS OF PETITION.—A petition filed under section 311 may be considered only if—

“(1) the petition is accompanied by payment of the fee established by the Director under section 311;

“(2) the petition identifies all real parties in interest;

“(3) the petition identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the

evidence that supports the grounds for the challenge to each claim, including---

“(A) copies of patents and printed publications that the petitioner relies upon in support of the petition; and

“(B) affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions;

“(4) the petition provides such other information as the Director may require by regulation; and

“(5) the petitioner provides copies of any of the documents required under paragraphs (2), (3), and (4) to the patent owner or, if applicable, the designated representative of the patent owner.

“(b) PUBLIC AVAILABILITY.—As soon as practicable after the receipt of a petition under section 311, the Director shall make the petition available to the public.

“§ 313. Preliminary response to petition

“If an inter partes review petition is filed under section 311, the patent owner shall have the right to file a preliminary response to the petition, within a time period set by the Director, that sets forth reasons why no inter partes review should be instituted based upon the failure of the petition to meet any requirement of this chapter.

“§ 314. Institution of inter partes review

“(a) THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there

is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

“(b) TIMING.—The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months after—

(1) receiving a preliminary response to the petition under section 313; or

“(2) if no such preliminary response is filed, the last date on which such response may be filed.

“(c) NOTICE.—The Director shall notify the petitioner and patent owner, in writing, of the Director’s determination under subsection (a), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

“(d) NO APPEAL.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

“§ 315. Relation to other proceedings or actions

“(a) INFRINGER’S CIVIL ACTION.—

“(1) INTER PARTES REVIEW BARRED BY CIVIL ACTION.—An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

“(2) STAY OF CIVIL ACTION.—If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for inter partes

review of the patent, that civil action shall be automatically stayed until either—

“(A) the patent owner moves the court to lift the stay;

“(B) the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or

“(C) the petitioner or real party in interest moves the court to dismiss the civil action.

“(3) TREATMENT OF COUNTERCLAIM.—A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

“(b) PATENT OWNER’S ACTION.—An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).

“(c) JOINDER.—If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

“(d) MULTIPLE PROCEEDINGS.—

Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

“(e) ESTOPPEL.—

“(1) PROCEEDINGS BEFORE THE OFFICE.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

“(2) CIVIL ACTIONS AND OTHER PROCEEDINGS.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

“§ 316. Conduct of inter partes review

“(a) REGULATIONS.—The Director shall prescribe regulations—

”(1) providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion;

”(2) setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a);

”(3) establishing procedures for the submission of supplemental information after the petition is filed;

”(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title;

”(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to—

”(A) the deposition of witnesses submitting affidavits or declarations; and

”(B) what is otherwise necessary in the interest of justice;

”(6) prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an

unnecessary increase in the cost of the proceeding;

“(7) providing for protective orders governing the exchange and submission of confidential information;

“(8) providing for the filing by the patent owner of a response to the petition under section 313 after an inter partes review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response;

“(9) setting forth standards and procedures for allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d) is made available to the public as part of the prosecution history of the patent;

“(10) providing either party with the right to an oral hearing as part of the proceeding;

“(11) requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 315(c);

“(12) setting a time period for requesting joinder under section 315(c); and “(13) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.

“(b) CONSIDERATIONS.—In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.

“(c) PATENT TRIAL AND APPEAL BOARD.—The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

“(d) AMENDMENT OF THE PATENT.—

“(1) IN GENERAL.—During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

“(A) Cancel any challenged patent claim.

“(B) For each challenged claim, propose a reasonable number of substitute claims.

“(2) ADDITIONAL MOTIONS.—Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 317, or as permitted by regulations prescribed by the Director.

“(3) SCOPE OF CLAIMS.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

“(e) EVIDENTIARY STANDARDS.—In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

“§ 317. Settlement

“(a) IN GENERAL.—An inter partes review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed. If the inter partes review is terminated with respect to a petitioner under this section, no estoppel under section 315(e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner’s institution of that inter partes review. If no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision under section 318(a).

“(b) AGREEMENTS IN WRITING.—Any agreement or understanding between the patent owner and a petitioner, including any collateral agreements referred to in such agreement or understanding, made in connection with, or in contemplation of, the termination of an inter partes review under this section shall be in writing and a true copy of such agreement or understanding shall be filed in the Office before the termination of the inter partes review as between the parties. At the request of a

party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents, and shall be made available only to Federal Government agencies on written request, or to any person on a showing of good cause.

“§ 318. Decision of the Board

“(a) FINAL WRITTEN DECISION.—If an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d).

“(b) CERTIFICATE.—If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

“(c) INTERVENING RIGHTS.—Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes review under this chapter shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by

such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

“(d) DATA ON LENGTH OF REVIEW.—The Office shall make available to the public data describing the length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each inter partes review.

“§ 319. Appeal

“A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) may appeal the decision pursuant to sections 141 through 144. Any party to the inter partes review shall have the right to be a party to the appeal.”.

(b) CONFORMING AMENDMENT.—The table of chapters for part III of title 35, United States Code, is amended by striking the item relating to chapter 31 and inserting the following:

“31. Inter Partes Review 311”.

(c) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—The Director shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out chapter 31 of title 35, United States Code, as amended by subsection (a) of this section.

(2) APPLICABILITY.—

(A) IN GENERAL.—The amendments made by subsection (a) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

(B) GRADUATED IMPLEMENTATION.

— The Director may impose a limit on the number of inter partes reviews that may be instituted under chapter 31 of title 35, United States Code, during each of the first 4 1-year periods in which the amendments made by subsection (a) are in effect, if such number in each year equals or exceeds the number of inter partes reexaminations that are ordered under chapter 31 of title 35, United States Code, in the last fiscal year ending before the effective date of the amendments made by subsection (a).

(3) TRANSITION.—

(A) IN GENERAL.—Chapter 31 of title 35, United States Code, is amended—

(i) in section 312—

(I) in subsection (a)—

(aa) in the first sentence, by striking “a substantial new question of patentability affecting any claim of the patent concerned is raised by the request,” and inserting “the information presented in the request shows that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request,”; and

(bb) in the second sentence, by striking “The existence of a substantial new question of patentability” and inserting “A

showing that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request”; and

(II) in subsection (c), in the second sentence, by striking “no substantial new question of patentability has been raised,” and inserting “the showing required by subsection (a) has not been made,”; and

(ii) in section 313, by striking “a substantial new question of patentability affecting a claim of the patent is raised” and inserting “it has been shown that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request”.

(B) APPLICATION.—The amendments made by this paragraph—

(i) shall take effect on the date of the enactment of this Act; and

(ii) shall apply to requests for inter partes reexamination that are filed on or after such date of enactment, but before the effective date set forth in paragraph (2)(A) of this subsection.

(C) CONTINUED APPLICABILITY OF PRIOR PROVISIONS.—The provisions of chapter 31 of title 35, United States Code, as amended by this paragraph, shall continue to

apply to requests for inter partes reexamination that are filed before the effective date set forth in paragraph (2)(A) as if subsection (a) had not been enacted.

(d) POST-GRANT REVIEW.—Part III of title 35, United States Code, is amended by adding at the end the following:

“CHAPTER 32—POST-GRANT REVIEW

“Sec.

“321. Post-grant review.

“322. Petitions.

“323. Preliminary response to petition.

“324. Institution of post-grant review.

“325. Relation to other proceedings or actions.

“326. Conduct of post-grant review.

“327. Settlement.

“328. Decision of the Board.

“329. Appeal.

“§ 321. Post-grant review

“(a) IN GENERAL.—Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute a post-grant review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the post-grant review.

“(b) SCOPE.—A petitioner in a post-grant review may request to cancel as unpatentable 1 or more claims of a patent on any ground that could be raised

under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim).

“(c) **FILING DEADLINE.**—A petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be).

“§ 322. Petitions

“(a) **REQUIREMENTS OF PETITION.**—A petition filed under section 321 may be considered only if—

“(1) the petition is accompanied by payment of the fee established by the Director under section 321;

“(2) the petition identifies all real parties in interest;

“(3) the petition identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim, including—

“(A) copies of patents and printed publications that the petitioner relies upon in support of the petition; and

“(B) affidavits or declarations of supporting evidence and opinions, if the petitioner relies on other factual evidence or on expert opinions;

“(4) the petition provides such other information as the Director may require by regulation; and

“(5) the petitioner provides copies of any of the documents required under paragraphs (2), (3), and (4) to the patent owner or, if applicable, the designated representative of the patent owner.

“(b) PUBLIC AVAILABILITY.—As soon as practicable after the receipt of a petition under section 321, the Director shall make the petition available to the public.

“§ 323. Preliminary response to petition

“If a post-grant review petition is filed under section 321, the patent owner shall have the right to file a preliminary response to the petition, within a time period set by the Director, that sets forth reasons why no post-grant review should be instituted based upon the failure of the petition to meet any requirement of this chapter.

“§ 324. Institution of post-grant review

“(a) THRESHOLD.—The Director may not authorize a post-grant review to be instituted unless the Director determines that the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.

“(b) ADDITIONAL GROUNDS.—The determination required under subsection (a) may also be satisfied by a showing that the petition raises a novel or unsettled legal question that is important to other patents or patent applications.

“(c) TIMING.—The Director shall determine whether to institute a post-grant review under this chapter pursuant to a petition filed under section 321 within 3 months after—

“(1) receiving a preliminary response to the petition under section 323; or

“(2) if no such preliminary response is filed, the last date on which such response may be filed.

“(d) NOTICE.—The Director shall notify the petitioner and patent owner, in writing, of the Director’s determination under subsection (a) or (b), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

“(e) NO APPEAL.—The determination by the Director whether to institute a post-grant review under this section shall be final and nonappealable.

“§ 325. Relation to other proceedings or actions

“(a) INFRINGER’S CIVIL ACTION.—

“(1) POST-GRANT REVIEW BARRED BY CIVIL ACTION.—A post-grant review may not be instituted under this chapter if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

“(2) STAY OF CIVIL ACTION.—If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for post-grant review of the patent, that civil action shall be automatically stayed until either—

“(A) the patent owner moves the court to lift the stay;

“(B) the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or

“(C) the petitioner or real party in interest moves the court to dismiss the civil action.

“(3) TREATMENT OF COUNTERCLAIM.—A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

“(b) PRELIMINARY INJUNCTIONS.—If a civil action alleging infringement of a patent is filed within 3 months after the date on which the patent is granted, the court may not stay its consideration of the patent owner’s motion for a preliminary injunction against infringement of the patent on the basis that a petition for post-grant review has been filed under this chapter or that such a post-grant review has been instituted under this chapter.

“(c) JOINDER.—If more than 1 petition for a post-grant review under this chapter is properly filed against the same patent and the Director determines that more than 1 of these petitions warrants the institution of a post-grant review under section 324, the Director may consolidate such reviews into a single post-grant review.

“(d) MULTIPLE PROCEEDINGS.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of any post-grant review under this chapter, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the post-grant review or other proceeding or matter may proceed, including providing for the stay, transfer, consolidation, or termination of any such matter or proceeding. In determining whether to institute or

order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

“(e) ESTOPPEL.—

“(1) PROCEEDINGS BEFORE THE OFFICE.—The petitioner in a post-grant review of a claim in a patent under this chapter that results in a final written decision under section 328(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that post-grant review.

“(2) CIVIL ACTIONS AND OTHER PROCEEDINGS.—The petitioner in a post-grant review of a claim in a patent under this chapter that results in a final written decision under section 328(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that post-grant review.

“(f) REISSUE PATENTS.—A post-grant review may not be instituted under this chapter if the petition requests cancellation of a claim in a reissue patent that is identical to or narrower than a claim in the original patent from which the reissue patent was issued, and the time limitations in section 321(c)

would bar filing a petition for a post-grant review for such original patent.

“§ 326. Conduct of post-grant review

“(a) REGULATIONS.—The Director shall prescribe regulations—

“(1) providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion;

“(2) setting forth the standards for the showing of sufficient grounds to institute a review under subsections (a) and (b) of section 324;

“(3) establishing procedures for the submission of supplemental information after the petition is filed;

“(4) establishing and governing a post-grant review under this chapter and the relationship of such review to other proceedings under this title;

“(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to evidence directly related to factual assertions advanced by either party in the proceeding;

“(6) prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding;

“(7) providing for protective orders governing the exchange and submission of confidential information;

“(8) providing for the filing by the patent owner of a response to the petition under section 323 after a post-grant review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response;

“(9) setting forth standards and procedures for allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d) is made available to the public as part of the prosecution history of the patent;

“(10) providing either party with the right to an oral hearing as part of the proceeding;

“(11) requiring that the final determination in any post-grant review be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 325(c); and

“(12) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.

“(b) CONSIDERATIONS.—In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.

“(c) PATENT TRIAL AND APPEAL BOARD.—The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each post-grant review instituted under this chapter.

“(d) AMENDMENT OF THE PATENT.—

“(1) IN GENERAL.—During a post-grant review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

“(A) Cancel any challenged patent claim.

“(B) For each challenged claim, propose a reasonable number of substitute claims.

“(2) ADDITIONAL MOTIONS.—Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 327, or upon the request of the patent owner for good cause shown.

“(3) SCOPE OF CLAIMS.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

“(e) EVIDENTIARY STANDARDS.—In a post-grant review instituted under this chapter, the petitioner shall have the burden of proving a

proposition of unpatentability by a preponderance of the evidence.

“§ 327. Settlement

“(a) IN GENERAL.—A post-grant review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed. If the post-grant review is terminated with respect to a petitioner under this section, no estoppel under section 325(e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner’s institution of that post-grant review. If no petitioner remains in the post-grant review, the Office may terminate the post-grant review or proceed to a final written decision under section 328(a).

“(b) AGREEMENTS IN WRITING.—Any agreement or understanding between the patent owner and a petitioner, including any collateral agreements referred to in such agreement or understanding, made in connection with, or in contemplation of, the termination of a post-grant review under this section shall be in writing, and a true copy of such agreement or understanding shall be filed in the Office before the termination of the post-grant review as between the parties. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents, and shall be made available only to Federal Government agencies on

written request, or to any person on a showing of good cause.

“§ 328. Decision of the Board

“(a) FINAL WRITTEN DECISION.—If a post-grant review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 326(d).

“(b) CERTIFICATE.—If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

“(c) INTERVENING RIGHTS.—Any proposed amended or new claim determined to be patentable and incorporated into a patent following a post-grant review under this chapter shall have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

“(d) DATA ON LENGTH OF REVIEW.—The Office shall make available to the public data describing the

length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each post-grant review.

“§ 329. Appeal

“A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 328(a) may appeal the decision pursuant to sections 141 through 144. Any party to the post-grant review shall have the right to be a party to the appeal.”.

(e) CONFORMING AMENDMENT.—The table of chapters for part III of title 35, United States Code, is amended by adding at the end the following:

“32. Post-Grant Review 321”.

(f) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—The Director shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out chapter 32 of title 35, United States Code, as added by subsection (d) of this section.

(2) APPLICABILITY.—

(A) IN GENERAL.—The amendments made by subsection (d) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and, except as provided in section 18 and in paragraph (3), shall apply only to patents described in section 3(n)(1).

(B) LIMITATION.—The Director may impose a limit on the number of post-grant reviews that may be instituted under chapter 32 of title 35, United States Code, during each of the first 4 1-year periods in which the

amendments made by subsection (d) are in effect.

(3) PENDING INTERFERENCES.—

(A) PROCEDURES IN GENERAL.—The Director shall determine, and include in the regulations issued under paragraph (1), the procedures under which an interference commenced before the effective date set forth in paragraph (2)(A) is to proceed, including whether such interference—

(i) is to be dismissed without prejudice to the filing of a petition for a post-grant review under chapter 32 of title 35, United States Code; or

(ii) is to proceed as if this Act had not been enacted.

(B) PROCEEDINGS BY PATENT TRIAL AND APPEAL BOARD.—For purposes of an interference that is commenced before the effective date set forth in paragraph (2)(A), the Director may deem the Patent Trial and Appeal Board to be the Board of Patent Appeals and Interferences, and may allow the Patent Trial and Appeal Board to conduct any further proceedings in that interference.

(C) APPEALS.—The authorization to appeal or have remedy from derivation proceedings in sections 141(d) and 146 of title 35, United States Code, as amended by this Act, and the jurisdiction to entertain appeals from derivation proceedings in section 1295(a)(4)(A) of title 28, United States Code, as amended by this Act, shall be deemed to extend to any final

decision in an interference that is commenced before the effective date set forth in paragraph (2)(A) of this subsection and that is not dismissed pursuant to this paragraph.

(g) CITATION OF PRIOR ART AND WRITTEN STATEMENTS.—

(1) IN GENERAL.—Section 301 of title 35, United States Code, is amended to read as follows:

“§ 301. Citation of prior art and written statements

“(a) IN GENERAL.—Any person at any time may cite to the Office in writing—

“(1) prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent; or

“(2) statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent.

“(b) OFFICIAL FILE.—If the person citing prior art or written statements pursuant to subsection (a) explains in writing the pertinence and manner of applying the prior art or written statements to at least 1 claim of the patent, the citation of the prior art or written statements and the explanation thereof shall become a part of the official file of the patent.

“(c) ADDITIONAL INFORMATION.—A party that submits a written statement pursuant to subsection (a)(2) shall include any other documents, pleadings, or evidence from the proceeding in which the statement was filed that addresses the written statement.

“(d) LIMITATIONS.—A written statement submitted pursuant to subsection (a)(2), and additional information submitted pursuant to subsection (c), shall not be considered by the Office for any purpose other than to determine the proper meaning of a patent claim in a proceeding that is ordered or instituted pursuant to section 304, 314, or 324. If any such written statement or additional information is subject to an applicable protective order, such statement or information shall be redacted to exclude information that is subject to that order.

“(e) CONFIDENTIALITY.—Upon the written request of the person citing prior art or written statements pursuant to subsection (a), that person’s identity shall be excluded from the patent file and kept confidential.”.

(2) CONFORMING AMENDMENT.—The item relating to section 301 in the table of sections for chapter 30 of title 35, United States Code, is amended to read as follows:

“301. Citation of prior art and written statements.”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

(h) REEXAMINATION.—

(1) DETERMINATION BY DIRECTOR.—

(A) IN GENERAL.—Section 303(a) of title 35, United States Code, is amended by

striking “section 301 of this title” and inserting “section 301 or 302”.

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

(2) APPEAL.—

(A) IN GENERAL.—Section 306 of title 35, United States Code, is amended by striking “145” and inserting “144”.

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall take effect on the date of the enactment of this Act and shall apply to any appeal of a reexamination before the Board of Patent Appeals and Interferences or the Patent Trial and Appeal Board that is pending on, or brought on or after, the date of the enactment of this Act.

SEC. 7. PATENT TRIAL AND APPEAL BOARD.

(a) COMPOSITION AND DUTIES.—

(1) IN GENERAL.—Section 6 of title 35, United States Code, is amended to read as follows:

“§ 6. Patent Trial and Appeal Board

“(a) IN GENERAL.—There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal

knowledge and scientific ability who are appointed by the Secretary, in consultation with the Director. Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.

“(b) DUTIES.—The Patent Trial and Appeal Board shall—

“(1) on written appeal of an applicant, review adverse decisions of examiners upon applications for patents pursuant to section 134(a);

“(2) review appeals of reexaminations pursuant to section 134(b);

“(3) conduct derivation proceedings pursuant to section 135;

“(4) conduct inter partes reviews and post-grant reviews pursuant to chapters 31 and 32.

“(c) 3-MEMBER PANELS.—Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings.

“(d) TREATMENT OF PRIOR APPOINTMENTS.—The Secretary of Commerce may, in the Secretary’s discretion, deem the appointment of an administrative patent judge who, before the date of the enactment of this subsection, held office pursuant to an appointment by the Director to take effect on the date on which the Director initially appointed the administrative patent judge. It shall be a defense to a

challenge to the appointment of an administrative patent judge on the basis of the judge's having been originally appointed by the Director that the administrative patent judge so appointed was acting as a de facto officer.”.

(2) CONFORMING AMENDMENT.—The item relating to section 6 in the table of sections for chapter 1 of title 35, United States Code, is amended to read as follows:

“6. Patent Trial and Appeal Board.”.

(b) ADMINISTRATIVE APPEALS.—Section 134 of title 35, United States Code, is amended—

(1) in subsection (b), by striking “any reexamination proceeding” and inserting “a reexamination”; and

(2) by striking subsection (c).

(c) CIRCUIT APPEALS.—

(1) IN GENERAL.—Section 141 of title 35, United States Code, is amended to read as follows:

“§ 141. Appeal to Court of Appeals for the Federal Circuit

“(a) EXAMINATIONS.—An applicant who is dissatisfied with the final decision in an appeal to the Patent Trial and Appeal Board under section 134(a) may appeal the Board's decision to the United States Court of Appeals for the Federal Circuit. By filing such an appeal, the applicant waives his or her right to proceed under section 145.

“(b) REEXAMINATIONS.—A patent owner who is dissatisfied with the final decision in an appeal of a reexamination to the Patent Trial and Appeal Board under section 134(b) may appeal the Board's decision

only to the United States Court of Appeals for the Federal Circuit.

“(c) POST-GRANT AND INTER PARTES REVIEWS.—A party to an inter partes review or a post-grant review who is dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) or 328(a) (as the case may be) may appeal the Board’s decision only to the United States Court of Appeals for the Federal Circuit.

“(d) DERIVATION PROCEEDINGS.—A party to a derivation proceeding who is dissatisfied with the final decision of the Patent Trial and Appeal Board in the proceeding may appeal the decision to the United States Court of Appeals for the Federal Circuit, but such appeal shall be dismissed if any adverse party to such derivation proceeding, within 20 days after the appellant has filed notice of appeal in accordance with section 142, files notice with the Director that the party elects to have all further proceedings conducted as provided in section 146. If the appellant does not, within 30 days after the filing of such notice by the adverse party, file a civil action under section 146, the Board’s decision shall govern the further proceedings in the case.”.

(2) JURISDICTION.—Section 1295(a)(4)(A) of title 28, United States Code, is amended to read as follows:

“(A) the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to a patent application, derivation proceeding, reexamination, post-grant review, or inter partes review under title 35, at the instance of a party who exercised that party’s

right to participate in the applicable proceeding before or appeal to the Board, except that an applicant or a party to a derivation proceeding may also have remedy by civil action pursuant to section 145 or 146 of title 35; an appeal under this subparagraph of a decision of the Board with respect to an application or derivation proceeding shall waive the right of such applicant or party to proceed under section 145 or 146 of title 35;”.

(3) PROCEEDINGS ON APPEAL.—Section 143 of title 35, United States Code, is amended—

(A) by striking the third sentence and inserting the following: “In an ex parte case, the Director shall submit to the court in writing the grounds for the decision of the Patent and Trademark Office, addressing all of the issues raised in the appeal. The Director shall have the right to intervene in an appeal from a decision entered by the Patent Trial and Appeal Board in a derivation proceeding under section 135 or in an inter partes or postgrant review under chapter 31 or 32.”; and

(B) by striking the last sentence.

(d) CONFORMING AMENDMENTS.—

(1) ATOMIC ENERGY ACT OF 1954.—Section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182) is amended in the third undesignated paragraph—

(A) by striking “Board of Patent Appeals and Interferences” each place it appears and inserting “Patent Trial and Appeal Board”; and

(B) by inserting “and derivation” after “established for interference”.

(2) TITLE 51.—Section 20135 of title 51, United States Code, is amended—

(A) in subsections (e) and (f), by striking “Board of Patent Appeals and Interferences” each place it appears and inserting “Patent Trial and Appeal Board”; and

(B) in subsection (e), by inserting “and derivation” after “established for interference”.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to proceedings commenced on or after that effective date, except that—

(1) the extension of jurisdiction to the United States Court of Appeals for the Federal Circuit to entertain appeals of decisions of the Patent Trial and Appeal Board in reexaminations under the amendment made by subsection (c)(2) shall be deemed to take effect on the date of the enactment of this Act and shall extend to any decision of the Board of Patent Appeals and Interferences with respect to a reexamination that is entered before, on, or after the date of the enactment of this Act;

(2) the provisions of sections 6, 134, and 141 of title 35, United States Code, as in effect on the day before the effective date of the amendments made by this section shall continue to apply to inter partes reexaminations that are requested under section 311 of such title before such effective date;

(3) the Patent Trial and Appeal Board may be deemed to be the Board of Patent Appeals and Interferences for purposes of appeals of inter partes reexaminations that are requested under section 311 of title 35, United States Code, before the effective date of the amendments made by this section; and

(4) the Director's right under the fourth sentence of section 143 of title 35, United States Code, as amended by subsection (c)(3) of this section, to intervene in an appeal from a decision entered by the Patent Trial and Appeal Board shall be deemed to extend to inter partes reexaminations that are requested under section 311 of such title before the effective date of the amendments made by this section.

SEC. 8. PREISSUANCE SUBMISSIONS BY THIRD PARTIES.

(a) IN GENERAL.—Section 122 of title 35, United States Code, is amended by adding at the end the following:

“(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.”.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent application filed before, on, or after that effective date.

SEC. 9. VENUE.

(a) TECHNICAL AMENDMENTS RELATING TO VENUE.—Sections 32, 145, 146, 154(b)(4)(A), and 293 of title 35, United States Code, and section 21(b)(4) of the Trademark Act of 1946 (15 U.S.C. 1071(b)(4)), are each amended by striking “United States District Court for the District of Columbia” each place that term appears and inserting “United States District Court for the Eastern District of Virginia”.

(b) **EFFECTIVE DATE.**—The amendments made by this section shall take effect on the date of the enactment of this Act and shall apply to any civil action commenced on or after that date.

SEC. 10. FEE SETTING AUTHORITY.

(a) **FEE SETTING.**—

(1) **IN GENERAL.**—The Director may set or adjust by rule any fee established, authorized, or charged under title 35, United States Code, or the Trademark Act of 1946 (15 U.S.C. 1051 et seq.), for any services performed by or materials furnished by, the Office, subject to paragraph (2).

(2) **FEES TO RECOVER COSTS.**—Fees may be set or adjusted under paragraph (1) only to recover the aggregate estimated costs to the Office for processing, activities, services, and materials relating to patents (in the case of patent fees) and trademarks (in the case of trademark fees), including administrative costs of the Office with respect to such patent or trademark fees (as the case may be).

(b) **SMALL AND MICRO ENTITIES.**—The fees set or adjusted under subsection (a) for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents shall be reduced by 50 percent with respect to the application of such fees to any small entity that qualifies for reduced fees under section 41(h)(1) of title 35, United States Code, and shall be reduced by 75 percent with respect to the application of such fees to any micro entity as defined in section 123 of that title (as added by subsection (g) of this section).

(c) REDUCTION OF FEES IN CERTAIN FISCAL YEARS.—In each fiscal year, the Director—

(1) shall consult with the Patent Public Advisory Committee and the Trademark Public Advisory Committee on the advisability of reducing any fees described in subsection (a); and

(2) after the consultation required under paragraph (1), may reduce such fees.

(d) ROLE OF THE PUBLIC ADVISORY COMMITTEE.—The Director shall—

(1) not less than 45 days before publishing any proposed fee under subsection (a) in the Federal Register, submit the proposed fee to the Patent Public Advisory Committee or the Trademark Public Advisory Committee, or both, as appropriate;

(2)(A) provide the relevant advisory committee described in paragraph (1) a 30-day period following the submission of any proposed fee, in which to deliberate, consider, and comment on such proposal;

(B) require that, during that 30-day period, the relevant advisory committee hold a public hearing relating to such proposal; and

(C) assist the relevant advisory committee in carrying out that public hearing, including by offering the use of the resources of the Office to notify and promote the hearing to the public and interested stakeholders;

(3) require the relevant advisory committee to make available to the public a written report setting forth in detail the comments, advice, and recommendations of the committee regarding the proposed fee; and

(4) consider and analyze any comments, advice, or recommendations received from the relevant advisory committee before setting or adjusting (as the case may be) the fee.

(e) PUBLICATION IN THE FEDERAL REGISTER.—

(1) PUBLICATION AND RATIONALE.—The Director shall—

(A) publish any proposed fee change under this section in the Federal Register;

(B) include, in such publication, the specific rationale and purpose for the proposal, including the possible expectations or benefits resulting from the proposed change; and

(C) notify, through the Chair and Ranking Member of the Committees on the Judiciary of the Senate and the House of Representatives, the Congress of the proposed change not later than the date on which the proposed change is published under subparagraph (A).

(2) PUBLIC COMMENT PERIOD.—The Director shall, in the publication under paragraph (1), provide the public a period of not less than 45 days in which to submit comments on the proposed change in fees.

(3) PUBLICATION OF FINAL RULE.—The final rule setting or adjusting a fee under this section shall be published in the Federal Register and in the Official Gazette of the Patent and Trademark Office.

(4) CONGRESSIONAL COMMENT
PERIOD.—A fee set or adjusted under subsection (a) may not become effective—

(A) before the end of the 45-day period beginning on the day after the date on which the Director publishes the final rule adjusting or setting the fee under paragraph (3); or

(B) if a law is enacted disapproving such fee.

(5) RULE OF CONSTRUCTION.—Rules prescribed under this section shall not diminish—

(A) the rights of an applicant for a patent under title 35, United States Code, or for a mark under the Trademark Act of 1946; or

(B) any rights under a ratified treaty.

(f) RETENTION OF AUTHORITY.—The Director retains the authority under subsection (a) to set or adjust fees only during such period as the Patent and Trademark Office remains an agency within the Department of Commerce.

(g) MICRO ENTITY DEFINED.—

(1) IN GENERAL.—Chapter 11 of title 35, United States Code, is amended by adding at the end the following new section:

“§ 123. Micro entity defined

“(a) IN GENERAL.—For purposes of this title, the term ‘micro entity’ means an applicant who makes a certification that the applicant—

“(1) qualifies as a small entity, as defined in regulations issued by the Director;

“(2) has not been named as an inventor on more than 4 previously filed patent applications, other than applications filed in another country, provisional applications under section 111(b), or international applications filed under the treaty defined in section 351(a) for which the basic national fee under section 41(a) was not paid;

“(3) did not, in the calendar year preceding the calendar year in which the applicable fee is being paid, have a gross income, as defined in section 61(a) of the Internal Revenue Code of 1986, exceeding 3 times the median household income for that preceding calendar year, as most recently reported by the Bureau of the Census; and

“(4) has not assigned, granted, or conveyed, and is not under an obligation by contract or law to assign, grant, or convey, a license or other ownership interest in the application concerned to an entity that, in the calendar year preceding the calendar year in which the applicable fee is being paid, had a gross income, as defined in section 61(a) of the Internal Revenue Code of 1986, exceeding 3 times the median household income for that preceding calendar year, as most recently reported by the Bureau of the Census.

“(b) APPLICATIONS RESULTING FROM PRIOR EMPLOYMENT.—An applicant is not considered to be named on a previously filed application for purposes of subsection (a)(2) if the applicant has assigned, or is under an obligation by contract or law to assign, all ownership rights in the application as the result of the applicant’s previous employment.

“(c) FOREIGN CURRENCY EXCHANGE RATE.—

If an applicant’s or entity’s gross income in the preceding calendar year is not in United States dollars, the average currency exchange rate, as reported by the Internal Revenue Service, during that calendar year shall be used to determine whether the applicant’s or entity’s gross income exceeds the threshold specified in paragraphs (3) or (4) of subsection (a).

“(d) INSTITUTIONS OF HIGHER EDUCATION.—

For purposes of this section, a micro entity shall include an applicant who certifies that—

“(1) the applicant’s employer, from which the applicant obtains the majority of the applicant’s income, is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)); or

“(2) the applicant has assigned, granted, conveyed, or is under an obligation by contract or law, to assign, grant, or convey, a license or other ownership interest in the particular applications to such an institution of higher education.

“(e) DIRECTOR’S AUTHORITY.—In addition to the limits imposed by this section, the Director may, in the Director’s discretion, impose income limits, annual filing limits, or other limits on who may qualify as a micro entity pursuant to this section if the Director determines that such additional limits are reasonably necessary to avoid an undue impact on other patent applicants or owners or are otherwise reasonably necessary and appropriate. At least 3 months before any limits proposed to be imposed pursuant to this subsection take effect, the Director

shall inform the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate of any such proposed limits.”.

(2) CONFORMING AMENDMENT.—

Chapter 11 of title 35, United States Code, is amended by adding at the end the following new item:

“123. Micro entity defined.”.

(h) ELECTRONIC FILING INCENTIVE.—

(1) IN GENERAL.—Notwithstanding any other provision of this section, an additional fee of \$400 shall be established for each application for an original patent, except for a design, plant, or provisional application, that is not filed by electronic means as prescribed by the Director. The fee established by this subsection shall be reduced by 50 percent for small entities that qualify for reduced fees under section 41(h)(1) of title 35, United States Code. All fees paid under this subsection shall be deposited in the Treasury as an offsetting receipt that shall not be available for obligation or expenditure.

(2) EFFECTIVE DATE.—This subsection shall take effect upon the expiration of the 60-day period beginning on the date of the enactment of this Act.

(i) EFFECTIVE DATE; SUNSET.—

(1) EFFECTIVE DATE.—Except as provided in subsection (h), this section and the amendments made by this section shall take effect on the date of the enactment of this Act.

(2) **SUNSET.**—The authority of the Director to set or adjust any fee under subsection (a) shall terminate upon the expiration of the 7-year period beginning on the date of the enactment of this Act.

(3) **PRIOR REGULATIONS NOT AFFECTED.**—The termination of authority under this subsection shall not affect any regulations issued under this section before the effective date of such termination or any rulemaking proceeding for the issuance of regulations under this section that is pending on such date.

SEC. 11. FEES FOR PATENT SERVICES.

(a) **GENERAL PATENT SERVICES.**—Subsections (a) and (b) of section 41 of title 35, United States Code, are amended to read as follows:

“(a) **GENERAL FEES.**—The Director shall charge the following fees:

“(1) **FILING AND BASIC NATIONAL FEES.**—

“(A) On filing each application for an original patent, except for design, plant, or provisional applications, \$330.

“(B) On filing each application for an original design patent, \$220.

“(C) On filing each application for an original plant patent, \$220.

“(D) On filing each provisional application for an original patent, \$220.

“(E) On filing each application for the reissue of a patent, \$330.

“(F) The basic national fee for each international application filed under the treaty

defined in section 351(a) entering the national stage under section 371, \$330.

“(G) In addition, excluding any sequence listing or computer program listing filed in an electronic medium as prescribed by the Director, for any application the specification and drawings of which exceed 100 sheets of paper (or equivalent as prescribed by the Director if filed in an electronic medium), \$270 for each additional 50 sheets of paper (or equivalent as prescribed by the Director if filed in an electronic medium) or fraction thereof.

“(2) EXCESS CLAIMS FEES.—

“(A) IN GENERAL.—In addition to the fee specified in paragraph (1)—

“(i) on filing or on presentation at any other time, \$220 for each claim in independent form in excess of 3;

“(ii) on filing or on presentation at any other time, \$52 for each claim (whether dependent or independent) in excess of 20; and

“(iii) for each application containing a multiple dependent claim, \$390.

“(B) MULTIPLE DEPENDENT CLAIMS.—For the purpose of computing fees under subparagraph (A), a multiple dependent claim referred to in section 112 or any claim depending therefrom shall be considered as separate dependent claims in accordance with the number of claims to which reference is made.

“(C) REFUNDS; ERRORS IN PAYMENT.—The Director may by regulation provide for a refund of any part of the fee specified in subparagraph (A) for any claim that is canceled before an examination on the merits, as prescribed by the Director, has been made of the application under section 131. Errors in payment of the additional fees under this paragraph may be rectified in accordance with regulations prescribed by the Director.

“(3) EXAMINATION FEES.—

”(A) IN GENERAL.—

“(i) For examination of each application for an original patent, except for design, plant, provisional, or international applications, \$220.

“(ii) For examination of each application for an original design patent, \$140.

“(iii) For examination of each application for an original plant patent, \$170.

“(iv) For examination of the national stage of each international application, \$220.

“(v) For examination of each application for the reissue of a patent, \$650.

“(B) APPLICABILITY OF OTHER FEE PROVISIONS.—The provisions of paragraphs (3) and (4) of section 111(a) relating to the payment of the fee for filing the application

shall apply to the payment of the fee specified in subparagraph (A) with respect to an application filed under section 111(a). The provisions of section 371(d) relating to the payment of the national fee shall apply to the payment of the fee specified in subparagraph (A) with respect to an international application.

“(4) ISSUE FEES.—

“(A) For issuing each original patent, except for design or plant patents, \$1,510.

“(B) For issuing each original design patent, \$860.

“(C) For issuing each original plant patent, \$1,190.

“(D) For issuing each reissue patent, \$1,510.

“(5) DISCLAIMER FEE.—On filing each disclaimer, \$140.

“(6) APPEAL FEES.—

“(A) On filing an appeal from the examiner to the Patent Trial and Appeal Board, \$540.

“(B) In addition, on filing a brief in support of the appeal, \$540, and on requesting an oral hearing in the appeal before the Patent Trial and Appeal Board, \$1,080.

“(7) REVIVAL FEES.—On filing each petition for the revival of an unintentionally abandoned application for a patent, for the unintentionally delayed payment of the fee for issuing each patent, or for an unintentionally delayed response by the patent owner in any reexamination proceeding,

\$1,620, unless the petition is filed under section 133 or 151, in which case the fee shall be \$540.

“(8) EXTENSION FEES.—For petitions for 1-month extensions of time to take actions required by the Director in an application—

“(A) on filing a first petition, \$130;

“(B) on filing a second petition, \$360; and

“(C) on filing a third or subsequent petition, \$620.

“(b) MAINTENANCE FEES.—

“(1) IN GENERAL.—The Director shall charge the following fees for maintaining in force all patents based on applications filed on or after December 12, 1980:

“(A) Three years and 6 months after grant, \$980.

“(B) Seven years and 6 months after grant, \$2,480.

“(C) Eleven years and 6 months after grant, \$4,110.

“(2) GRACE PERIOD; SURCHARGE.—Unless payment of the applicable maintenance fee under paragraph (1) is received in the Office on or before the date the fee is due or within a grace period of 6 months thereafter, the patent shall expire as of the end of such grace period. The Director may require the payment of a surcharge as a condition of accepting within such 6-month grace period the payment of an applicable maintenance fee.

“(3) NO MAINTENANCE FEE FOR DESIGN OR PLANT PATENT.—

No fee may be established for maintaining a design or plant patent in force.”.

(b) DELAYS IN PAYMENT.—Subsection (c) of section 41 of title 35, United States Code, is amended—

(1) by striking “(c)(1) The Director” and inserting:

“(c) DELAYS IN PAYMENT OF MAINTENANCE FEES.—

“(1) ACCEPTANCE.—The Director”; and

(2) by striking “(2) A patent” and inserting:

“(2) EFFECT ON RIGHTS OF OTHERS.—A patent”.

(c) PATENT SEARCH FEES.—Subsection (d) of section 41 of title 35, United States Code, is amended to read as follows:

“(d) PATENT SEARCH AND OTHER FEES.—

”(1) PATENT SEARCH FEES.—

“(A) IN GENERAL.—The Director shall charge the fees specified under subparagraph (B) for the search of each application for a patent, except for provisional applications. The Director shall adjust the fees charged under this paragraph to ensure that the fees recover an amount not to exceed the estimated average cost to the Office of searching applications for patent by Office personnel.

“(B) SPECIFIC FEES.—The fees referred to in subparagraph (A) are—

“(i) \$540 for each application for an original patent, except for design, plant, provisional, or international applications;

“(ii) \$100 for each application for an original design patent;

“(iii) \$330 for each application for an original plant patent;

“(iv) \$540 for the national stage of each international application; and

“(v) \$540 for each application for the reissue of a patent.

“(C) APPLICABILITY OF OTHER PROVISIONS.—The provisions of paragraphs (3) and (4) of section 111(a) relating to the payment of the fee for filing the application shall apply to the payment of the fee specified in this paragraph with respect to an application filed under section 111(a). The provisions of section 371(d) relating to the payment of the national fee shall apply to the payment of the fee specified in this paragraph with respect to an international application.

“(D) REFUNDS.—The Director may by regulation provide for a refund of any part of the fee specified in this paragraph for any applicant who files a written declaration of express abandonment as prescribed by the Director before an examination has been made of the application under section 131.

“(2) OTHER FEES.—

“(A) IN GENERAL.—The Director shall establish fees for all other processing, services,

or materials relating to patents not specified in this section to recover the estimated average cost to the Office of such processing, services, or materials, except that the Director shall charge the following fees for the following services:

“(i) For recording a document affecting title, \$40 per property.

“(ii) For each photocopy, \$.25 per page.

“(iii) For each black and white copy of a patent, \$3.

“(B) COPIES FOR LIBRARIES.—The yearly fee for providing a library specified in section 12 with uncertified printed copies of the specifications and drawings for all patents in that year shall be \$50.”.

(d) FEES FOR SMALL ENTITIES.—Subsection (h) of section 41 of title 35, United States Code, is amended to read as follows:

“(h) FEES FOR SMALL ENTITIES.—

“(1) REDUCTIONS IN FEES.—Subject to paragraph (3), fees charged under subsections (a), (b), and (d)(1) shall be reduced by 50 percent with respect to their application to any small business concern as defined under section 3 of the Small Business Act, and to any independent inventor or nonprofit organization as defined in regulations issued by the Director.

“(2) SURCHARGES AND OTHER FEES.—With respect to its application to any entity described in paragraph (1), any surcharge or fee charged under subsection (c) or (d) shall not be

higher than the surcharge or fee required of any other entity under the same or substantially similar circumstances.

“(3) REDUCTION FOR ELECTRONIC FILING.—The fee charged under subsection (a)(1)(A) shall be reduced by 75 percent with respect to its application to any entity to which paragraph (1) applies, if the application is filed by electronic means as prescribed by the Director.”.

(e) TECHNICAL AMENDMENTS.—Section 41 of title 35, United States Code, is amended—

(1) in subsection (e), in the first sentence, by striking “The Director” and inserting “WAIVER OF FEES; COPIES REGARDING NOTICE.—The Director”;

(2) in subsection (f), by striking “The fees” and inserting “ADJUSTMENT OF FEES.—The fees”;

(3) by repealing subsection (g); and

(4) in subsection (i)—

(A) by striking “(i)(1) The Director” and inserting the following:

“(i) ELECTRONIC PATENT AND TRADEMARK DATA.—

“(1) MAINTENANCE OF COLLECTIONS.—The Director”;

(B) by striking “(2) The Director” and inserting the following:

“(2) AVAILABILITY OF AUTOMATED SEARCH SYSTEMS.—The Director”;

(C) by striking “(3) The Director” and inserting the following:

“(3) ACCESS FEES.—The Director”; and

(D) by striking “(4) The Director” and inserting the following:

“(4) ANNUAL REPORT TO CONGRESS.—The Director”.

(f) ADJUSTMENT OF TRADEMARK FEES.—Section 802(a) of division B of the Consolidated Appropriations Act, 2005 (Public Law 108–447) is amended—

(1) in the first sentence, by striking “During fiscal years 2005, 2006, and 2007,” and inserting “Until such time as the Director sets or adjusts the fees otherwise,”; and

(2) in the second sentence, by striking “During fiscal years 2005, 2006, and 2007, the” and inserting “The”.

(g) EFFECTIVE DATE, APPLICABILITY, AND TRANSITION PROVISIONS.—Section 803(a) of division B of the Consolidated Appropriations Act, 2005 (Public Law 108–447) is amended by striking “and shall apply only with respect to the remaining portion of fiscal year 2005 and fiscal year 2006”.

(h) PRIORITIZED EXAMINATION FEE.—

(1) IN GENERAL.—

(A) FEE.—

(i) PRIORITIZED EXAMINATION FEE.—A fee of \$4,800 shall be established for filing a request, pursuant to section 2(b)(2)(G) of title 35, United States Code, for prioritized examination of a nonprovisional application for an original utility or plant patent.

(ii) ADDITIONAL FEES.—In addition to the prioritized examination fee under clause (i), the fees due on an application for which prioritized examination is being sought are the filing, search, and examination fees (including any applicable excess claims and application size fees), processing fee, and publication fee for that application.

(B) REGULATIONS; LIMITATIONS.—

(i) REGULATIONS.—The Director may by regulation prescribe conditions for acceptance of a request under subparagraph (A) and a limit on the number of filings for prioritized examination that may be accepted.

(ii) LIMITATION ON CLAIMS.—Until regulations are prescribed under clause (i), no application for which prioritized examination is requested may contain or be amended to contain more than 4 independent claims or more than 30 total claims.

(iii) LIMITATION ON TOTAL NUMBER OF REQUESTS.—The Director may not accept in any fiscal year more than 10,000 requests for prioritization until regulations are prescribed under this subparagraph setting another limit.

(2) REDUCTION IN FEES FOR SMALL ENTITIES.—The Director shall reduce fees for providing prioritized examination of nonprovisional applications for original utility and plant patents by

50 percent for small entities that qualify for reduced fees under section 41(h)(1) of title 35, United States Code.

(3) DEPOSIT OF FEES.—All fees paid under this subsection shall be credited to the United States Patent and Trademark Office Appropriation Account, shall remain available until expended, and may be used only for the purposes specified in section 42(c)(3)(A) of title 35, United States Code.

(4) EFFECTIVE DATE AND TERMINATION.—

(A) EFFECTIVE DATE.—This subsection shall take effect on the date that is 10 days after the date of the enactment of this Act.

(B) TERMINATION.—The fee imposed under paragraph (1)(A)(i), and the reduced fee under paragraph (2), shall terminate on the effective date of the setting or adjustment of the fee under paragraph (1)(A)(i) pursuant to the exercise of the authority under section 10 for the first time with respect to that fee.

(i) APPROPRIATION ACCOUNT TRANSITION FEES.—

(1) SURCHARGE.—

(A) IN GENERAL.—There shall be a surcharge of 15 percent, rounded by standard arithmetic rules, on all fees charged or authorized by subsections (a), (b), and (d)(1) of section 41, and section 132(b), of title 35, United States Code. Any surcharge imposed under this subsection is, and shall be construed to be,

separate from and in addition to any other surcharge imposed under this Act or any other provision of law.

(B) DEPOSIT OF AMOUNTS.—Amounts collected pursuant to the surcharge imposed under subparagraph (A) shall be credited to the United States Patent and Trademark Appropriation Account, shall remain available until expended, and may be used only for the purposes specified in section 42(c)(3)(A) of title 35, United States Code.

(2) EFFECTIVE DATE AND TERMINATION OF SURCHARGE.—

The surcharge provided for in paragraph (1)—

(A) shall take effect on the date that is 10 days after the date of the enactment of this Act; and

(B) shall terminate, with respect to a fee to which paragraph (1)(A) applies, on the effective date of the setting or adjustment of that fee pursuant to the exercise of the authority under section 10 for the first time with respect to that fee.

(j) EFFECTIVE DATE.—Except as otherwise provided in this section, this section and the amendments made by this section shall take effect on the date of the enactment of this Act.

SEC. 12. SUPPLEMENTAL EXAMINATION.

(a) IN GENERAL.—Chapter 25 of title 35, United States Code, is amended by adding at the end the following:

“§ 257. Supplemental examinations to consider, reconsider, or correct information

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

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

“(c) EFFECT.—

“(1) IN GENERAL.—A patent shall not be held unenforceable on the basis of conduct relating to

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

“(2) EXCEPTIONS.—

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

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

“(d) FEES AND REGULATIONS.—

“(1) FEES.—The Director shall, by regulation, establish fees for the submission of a request for supplemental examination of a patent, and to consider each item of information submitted in the request. If reexamination is ordered under subsection (b), fees established and applicable to ex parte reexamination proceedings under chapter 30 shall be paid, in addition to fees applicable to supplemental examination.

“(2) REGULATIONS.—The Director shall issue regulations governing the form, content, and other requirements of requests for supplemental examination, and establishing procedures for reviewing information submitted in such requests.

“(e) FRAUD.—If the Director becomes aware, during the course of a supplemental examination or reexamination proceeding ordered under this section, that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate. Any such referral shall be treated as confidential, shall not be included in the file of the patent, and shall not be disclosed to the public unless the United States charges a person with a criminal offense in connection with such referral.

“(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

“(1) to preclude the imposition of sanctions based upon criminal or antitrust laws (including section 1001(a) of title 18, the first section of the Clayton Act, and section 5 of the Federal Trade Commission Act to the extent that section relates to unfair methods of competition);

“(2) to limit the authority of the Director to investigate issues of possible misconduct and impose sanctions for misconduct in connection with matters or proceedings before the Office; or

“(3) to limit the authority of the Director to issue regulations under chapter 3 relating to sanctions for misconduct by representatives practicing before the Office.”.

(b) CONFORMING AMENDMENT.—The table of sections for chapter 25 of title 35, United States Code, is amended by adding at the end the following new item:

“257. Supplemental examinations to consider, reconsider, or correct information.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that effective date.

SEC. 13. FUNDING AGREEMENTS.

(a) IN GENERAL.—Section 202(c)(7)(E)(i) of title 35, United States Code, is amended—

(1) by striking “75 percent” and inserting “15 percent”;

(2) by striking “25 percent” and inserting “85 percent”;

and

(3) by striking “as described above in this clause (D);” and inserting “described above in this clause;”.

(b) **EFFECTIVE DATE.**—The amendments made by this section shall take effect on the date of the enactment of this Act and shall apply to any patent issued before, on, or after that date.

SEC. 14. TAX STRATEGIES DEEMED WITHIN THE PRIOR ART.

(a) **IN GENERAL.**—For purposes of evaluating an invention under section 102 or 103 of title 35, United States Code, any strategy for reducing, avoiding, or deferring tax liability, whether known or unknown at the time of the invention or application for patent, shall be deemed insufficient to differentiate a claimed invention from the prior art.

(b) **DEFINITION.**—For purposes of this section, the term “tax liability” refers to any liability for a tax under any Federal, State, or local law, or the law of any foreign jurisdiction, including any statute, rule, regulation, or ordinance that levies, imposes, or assesses such tax liability.

(c) **EXCLUSIONS.**—This section does not apply to that part of an invention that—

(1) is a method, apparatus, technology, computer program product, or system, that is used solely for preparing a tax or information return or other tax filing, including one that records, transmits, transfers, or organizes data related to such filing; or

(2) is a method, apparatus, technology, computer program product, or system used solely for financial management, to the extent that it is severable from any tax strategy or does not limit the use of any tax strategy by any taxpayer or tax advisor.

(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed to imply that other business methods are patentable or that other business method patents are valid.

(e) **EFFECTIVE DATE; APPLICABILITY.**—This section shall take effect on the date of the enactment of this Act and shall apply to any patent application that is pending on, or filed on or after, that date, and to any patent that is issued on or after that date.

SEC. 15. BEST MODE REQUIREMENT.

(a) **IN GENERAL.**—Section 282 of title 35, United States Code, is amended in the second undesignated paragraph by striking paragraph (3) and inserting the following:

“(3) Invalidity of the patent or any claim in suit for failure to comply with—

“(A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or

“(B) any requirement of section 251.”.

(b) **CONFORMING AMENDMENT.**—Sections 119(e)(1) and 120 of title 35, United States Code, are each amended by striking “the first paragraph of section 112 of this title” and inserting “section 112(a)

(other than the requirement to disclose the best mode)”).

(c) **EFFECTIVE DATE.**—The amendments made by this section shall take effect upon the date of the enactment of this Act and shall apply to proceedings commenced on or after that date.

SEC. 16. MARKING.

(a) **VIRTUAL MARKING.**—

(1) **IN GENERAL.**—Section 287(a) of title 35, United States Code, is amended by striking “or when,” and inserting “or by fixing thereon the word ‘patent’ or the abbreviation ‘pat.’ together with an address of a posting on the Internet, accessible to the public without charge for accessing the address, that associates the patented article with the number of the patent, or when,”.

(2) **EFFECTIVE DATE.**—The amendment made by this subsection shall apply to any case that is pending on, or commenced on or after, the date of the enactment of this Act.

(3) **REPORT.**—Not later than the date that is 3 years after the date of the enactment of this Act, the Director shall submit a report to Congress that provides—

(A) an analysis of the effectiveness of “virtual marking”, as provided in the amendment made by paragraph (1) of this subsection, as an alternative to the physical marking of articles;

(B) an analysis of whether such virtual marking has limited or improved the ability of

the general public to access information about patents;

(C) an analysis of the legal issues, if any, that arise from such virtual marking; and

(D) an analysis of the deficiencies, if any, of such virtual marking.

(b) FALSE MARKING.—

(1) CIVIL PENALTY.—Section 292(a) of title 35, United States Code, is amended by adding at the end the following: “Only the United States may sue for the penalty authorized by this subsection.”.

(2) CIVIL ACTION FOR DAMAGES.—Subsection (b) of section 292 of title 35, United States Code, is amended to read as follows:

“(b) A person who has suffered a competitive injury as a result of a violation of this section may file a civil action in a district court of the United States for recovery of damages adequate to compensate for the injury.”.

(3) EXPIRED PATENTS.—Section 292 of title 35, United States Code, is amended by adding at the end the following:

“(c) The marking of a product, in a manner described in subsection (a), with matter relating to a patent that covered that product but has expired is not a violation of this section.”.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to all cases, without exception, that are pending on, or commenced on or after, the date of the enactment of this Act.

SEC. 17. ADVICE OF COUNSEL.

(a) IN GENERAL.—Chapter 29 of title 35, United States Code, is amended by adding at the end the following:

“§ 298. Advice of counsel

“The failure of an infringer to obtain the advice of counsel with respect to any allegedly infringed patent, or the failure of the infringer to present such advice to the court or jury, may not be used to prove that the accused infringer willfully infringed the patent or that the infringer intended to induce infringement of the patent.”.

(b) CONFORMING AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, is amended by adding at the end the following:

“298. Advice of counsel.”.

SEC. 18. TRANSITIONAL PROGRAM FOR COVERED BUSINESS METHOD PATENTS.

(a) TRANSITIONAL PROGRAM.—

(1) ESTABLISHMENT.—Not later than the date that is 1 year after the date of the enactment of this Act, the Director shall issue regulations establishing and implementing a transitional postgrant review proceeding for review of the validity of covered business method patents. The transitional proceeding implemented pursuant to this subsection shall be regarded as, and shall employ the standards and procedures of, a postgrant review under chapter 32 of title 35, United States Code, subject to the following:

(A) Section 321(c) of title 35, United States Code, and subsections (b), (e)(2), and (f)

of section 325 of such title shall not apply to a transitional proceeding.

(B) A person may not file a petition for a transitional proceeding with respect to a covered business method patent unless the person or the person's real party in interest or privy has been sued for infringement of the patent or has been charged with infringement under that patent.

(C) A petitioner in a transitional proceeding who challenges the validity of 1 or more claims in a covered business method patent on a ground raised under section 102 or 103 of title 35, United States Code, as in effect on the day before the effective date set forth in section 3(n)(1), may support such ground only on the basis of—

(i) prior art that is described by section 102(a) of such title (as in effect on the day before such effective date); or

(ii) prior art that—

(I) discloses the invention more than 1 year before the date of the application for patent in the United States; and

(II) would be described by section 102(a) of such title (as in effect on the day before the effective date set forth in section 3(n)(1)) if the disclosure had been made by another before the invention thereof by the applicant for patent.

(D) The petitioner in a transitional proceeding that results in a final written

decision under section 328(a) of title 35, United States Code, with respect to a claim in a covered business method patent, or the petitioner's real party in interest, may not assert, either in a civil action arising in whole or in part under section 1338 of title 28, United States Code, or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), that the claim is invalid on any ground that the petitioner raised during that transitional proceeding.

(E) The Director may institute a transitional proceeding only for a patent that is a covered business method patent.

(2) **EFFECTIVE DATE.**—The regulations issued under paragraph (1) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any covered business method patent issued before, on, or after that effective date, except that the regulations shall not apply to a patent described in section 6(f)(2)(A) of this Act during the period in which a petition for post-grant review of that patent would satisfy the requirements of section 321(c) of title 35, United States Code.

(3) **SUNSET.**—

(A) **IN GENERAL.**—This subsection, and the regulations issued under this subsection, are repealed effective upon the expiration of the 8-year period beginning on the date that the regulations issued under to paragraph (1) take effect.

(B) APPLICABILITY.—

Notwithstanding subparagraph (A), this subsection and the regulations issued under this subsection shall continue to apply, after the date of the repeal under subparagraph (A), to any petition for a transitional proceeding that is filed before the date of such repeal.

(b) REQUEST FOR STAY.—

(1) IN GENERAL.—If a party seeks a stay of a civil action alleging infringement of a patent under section 281 of title 35, United States Code, relating to a transitional proceeding for that patent, the court shall decide whether to enter a stay based on—

(A) whether a stay, or the denial thereof, will simplify the issues in question and streamline the trial;

(B) whether discovery is complete and whether a trial date has been set;

(C) whether a stay, or the denial thereof, would unduly prejudice the nonmoving party or present a clear tactical advantage for the moving party; and

(D) whether a stay, or the denial thereof, will reduce the burden of litigation on the parties and on the court.

(2) REVIEW.—A party may take an immediate interlocutory appeal from a district court's decision under paragraph (1). The United States Court of Appeals for the Federal Circuit shall review the district court's decision to ensure

consistent application of established precedent, and such review may be de novo.

(c) **ATM EXEMPTION FOR VENUE PURPOSES.**—In an action for infringement under section 281 of title 35, United States Code, of a covered business method patent, an automated teller machine shall not be deemed to be a regular and established place of business for purposes of section 1400(b) of title 28, United States Code.

(d) **DEFINITION.**—

(1) **IN GENERAL.**—For purposes of this section, the term “covered business method patent” means a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.

(2) **REGULATIONS.**—To assist in implementing the transitional proceeding authorized by this subsection, the Director shall issue regulations for determining whether a patent is for a technological invention.

(e) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed as amending or interpreting categories of patent-eligible subject matter set forth under section 101 of title 35, United States Code.

SEC. 19. JURISDICTION AND PROCEDURAL MATTERS.

(a) **STATE COURT JURISDICTION.**—Section 1338(a) of title 28, United States Code, is amended by striking the second sentence and inserting the

following: “No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights. For purposes of this subsection, the term ‘State’ includes any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands.”.

(b) COURT OF APPEALS FOR THE FEDERAL CIRCUIT.—Section 1295(a)(1) of title 28, United States Code, is amended to read as follows:

“(1) of an appeal from a final decision of a district court of the United States, the District Court of Guam, the District Court of the Virgin Islands, or the District Court of the Northern Mariana Islands, in any civil action arising under, or in any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents or plant variety protection;”.

(c) REMOVAL.—

(1) IN GENERAL.—Chapter 89 of title 28, United States Code, is amended by adding at the end the following new section:

“§ 1454. Patent, plant variety protection, and copyright cases

“(a) IN GENERAL.—A civil action in which any party asserts a claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights may be removed to the district court of the United States for the district and division embracing the place where the action is pending.

“(b) SPECIAL RULES.—The removal of an action under this section shall be made in accordance with section 1446, except that if the removal is based solely on this section—

“(1) the action may be removed by any party; and

“(2) the time limitations contained in section 1446(b) may be extended at any time for cause shown.

“(c) CLARIFICATION OF JURISDICTION IN CERTAIN CASES.—The court to which a civil action is removed under this section is not precluded from hearing and determining any claim in the civil action because the State court from which the civil action is removed did not have jurisdiction over that claim.

“(d) REMAND.—If a civil action is removed solely under this section, the district court—

“(1) shall remand all claims that are neither a basis for removal under subsection (a) nor within the original or supplemental jurisdiction of the district court under any Act of Congress; and

“(2) may, under the circumstances specified in section 1367(c), remand any claims within the supplemental jurisdiction of the district court under section 1367.”.

(2) CONFORMING AMENDMENT.—The table of sections for chapter 89 of title 28, United States Code, is amended by adding at the end the following new item:

“1454. Patent, plant variety protection, and copyright cases.”.

(d) PROCEDURAL MATTERS IN PATENT CASES.—

(1) JOINDER OF PARTIES AND STAY OF ACTIONS.—Chapter 29 of title 35, United States Code, as amended by this Act, is further amended by adding at the end the following new section:

“§ 299. Joinder of parties

“(a) JOINDER OF ACCUSED INFRINGERS.—With respect to any civil action arising under any Act of Congress relating to patents, other than an action or trial in which an act of infringement under section 271(e)(2) has been pled, parties that are accused infringers may be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, or counterclaim defendants only if—

“(1) any right to relief is asserted against the parties jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process; and

“(2) questions of fact common to all defendants or counterclaim defendants will arise in the action.

“(b) ALLEGATIONS INSUFFICIENT FOR JOINDER.—For purposes of this subsection, accused infringers may not be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, based solely on allegations that they each have infringed the patent or patents in suit.

“(c) WAIVER.—A party that is an accused infringer may waive the limitations set forth in this section with respect to that party.”.

(2) CONFORMING AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, as amended by this Act, is further amended by adding at the end the following new item:

“299. Joinder of parties.”.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to any civil action commenced on or after the date of the enactment of this Act.

SEC. 20. TECHNICAL AMENDMENTS.

(a) JOINT INVENTIONS.—Section 116 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph, by striking “When” and inserting “(a) JOINT INVENTIONS.—When”;

(2) in the second undesignated paragraph, by striking “If a joint inventor” and inserting “(b) OMITTED INVENTOR.—If a joint inventor”; and

(3) in the third undesignated paragraph—

(A) by striking “Whenever”

and inserting “(c) CORRECTION OF ERRORS IN APPLICATION.—Whenever”; and

(B) by striking “and such error arose without any deceptive intention on his part,”.

(b) FILING OF APPLICATION IN FOREIGN COUNTRY.—Section 184 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “Except when” and inserting “(a) FILING IN FOREIGN COUNTRY.—Except when”; and

(B) by striking “and without deceptive intent”;

(2) in the second undesignated paragraph, by striking “The term” and inserting “(b) APPLICATION.—The term”; and

(3) in the third undesignated paragraph, by striking “The scope” and inserting “(c) SUBSEQUENT MODIFICATIONS, AMENDMENTS, AND SUPPLEMENTS.—The scope”.

(c) FILING WITHOUT A LICENSE.—Section 185 of title 35, United States Code, is amended by striking “and without deceptive intent”.

(d) REISSUE OF DEFECTIVE PATENTS.—Section 251 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “Whenever” and inserting “(a) IN GENERAL.—Whenever”; and

(B) by striking “without any deceptive intention”;

(2) in the second undesignated paragraph, by striking “The Director” and inserting

“(b) MULTIPLE REISSUED PATENTS.—The Director”;

(3) in the third undesignated paragraph, by striking “The provisions” and inserting “(c) APPLICABILITY OF THIS TITLE.—The provisions”; and

(4) in the last undesignated paragraph, by striking “No reissued patent” and inserting “(d) REISSUE PATENT ENLARGING SCOPE OF CLAIMS.—No reissued patent”.

(e) EFFECT OF REISSUE.—Section 253 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph, by striking “Whenever, without any deceptive intention,” and inserting “(a) IN GENERAL.—Whenever”; and

(2) in the second undesignated paragraph, by striking “In like manner” and inserting “(b) ADDITIONAL DISCLAIMER OR DEDICATION.—In the manner set forth in subsection (a),”.

(f) CORRECTION OF NAMED INVENTOR.—Section 256 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “Whenever” and inserting “(a) CORRECTION.—Whenever”; and

(B) by striking “and such error arose without any deceptive intention on his part”; and

(2) in the second undesignated paragraph, by striking “The error” and inserting “(b) PATENT VALID IF ERROR CORRECTED.—The error”.

(g) PRESUMPTION OF VALIDITY.—Section 282 of title 35, United States Code, is amended—

(1) in the first undesignated paragraph—

(A) by striking “A patent” and inserting “(a) IN GENERAL.—A patent”; and

(B) by striking the third sentence;

(2) in the second undesignated paragraph—

(A) by striking “The following” and inserting “(b) DEFENSES.—The following”;

(B) in paragraph (1), by striking “unforceability,” and inserting “unenforceability.”; and

(C) in paragraph (2), by striking “patentability,” and inserting “patentability.” ; and

(3) in the third undesignated paragraph—

(A) by striking “In actions involving the validity or infringement of a patent” and inserting “(c) NOTICE OF ACTIONS; ACTIONS DURING EXTENSION OF PATENT TERM.—In an action involving the validity or infringement of a patent”; and

(B) by striking “Claims Court” and inserting “Court of Federal Claims”.

(h) ACTION FOR INFRINGEMENT.—Section 288 of title 35, United States Code, is amended by striking “, without deceptive intention,”.

(i) REVISER’S NOTES.—

(1) Section 3(e)(2) of title 35, United States Code, is amended by striking “this Act,” and inserting “that Act,”.

(2) Section 202 of title 35, United States Code, is amended—

(A) in subsection (b)(3), by striking “the section 203(b)” and inserting “section 203(b)”; and

(B) in subsection (c)(7)(D), by striking “except where it proves” and all that follows through “small business firms; and” and inserting: “except where it is determined to be infeasible following a reasonable inquiry, a preference in the licensing of subject inventions shall be given to small business firms; and”.

(3) Section 209(d)(1) of title 35, United States Code, is amended by striking “nontransferrable” and inserting “nontransferable”.

(4) Section 287(c)(2)(G) of title 35, United States Code, is amended by striking “any state” and inserting “any State”.

(5) Section 371(b) of title 35, United States Code, is amended by striking “of the treaty” and inserting “of the treaty.”.

(j) UNNECESSARY REFERENCES.—

(1) IN GENERAL.—Title 35, United States Code, is amended by striking “of this title” each place that term appears.

(2) EXCEPTION.—The amendment made by paragraph (1) shall not apply to the use of such term in the following sections of title 35, United States Code:

- (A) Section 1(c).
- (B) Section 101.
- (C) Subsections (a) and (b) of section 105.
- (D) The first instance of the use of such term in section 111(b)(8).
- (E) Section 161.
- (F) Section 164.
- (G) Section 171.
- (H) Section 251(c), as so designated by this section.
- (I) Section 261.
- (J) Subsections (g) and (h) of section 271.
- (K) Section 287(b)(1).
- (L) Section 289.
- (M) The first instance of the use of such term in section 375(a).

(k) **ADDITIONAL TECHNICAL AMENDMENTS.**—Sections 155 and 155A of title 35, United States Code, and the items relating to those sections in the table of sections for chapter 14 of such title, are repealed.

(l) **EFFECTIVE DATE.**—The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to proceedings commenced on or after that effective date.

SEC. 21. TRAVEL EXPENSES AND PAYMENT OF ADMINISTRATIVE JUDGES.

(a) **AUTHORITY TO COVER CERTAIN TRAVEL RELATED EXPENSES.**—Section 2(b)(11) of title 35,

United States Code, is amended by inserting “, and the Office is authorized to expend funds to cover the subsistence expenses and travel-related expenses, including per diem, lodging costs, and transportation costs, of persons attending such programs who are not Federal employees” after “world”.

(b) PAYMENT OF ADMINISTRATIVE JUDGES.—Section 3(b) of title 35, United States Code, is amended by adding at the end the following:

“(6) ADMINISTRATIVE PATENT JUDGES AND ADMINISTRATIVE TRADEMARK JUDGES.—The Director may fix the rate of basic pay for the administrative patent judges appointed pursuant to section 6 and the administrative trademark judges appointed pursuant to section 17 of the Trademark Act of 1946 (15 U.S.C. 1067) at not greater than the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5. The payment of a rate of basic pay under this paragraph shall not be subject to the pay limitation under section 5306(e) or 5373 of title 5.”.

SEC. 22. PATENT AND TRADEMARK OFFICE FUNDING.

(a) IN GENERAL.—Section 42(c) of title 35, United States Code, is amended—

- (1) by striking “(c)” and inserting “(c)(1)”;
- (2) in the first sentence, by striking “shall be available” and inserting “shall, subject to paragraph (3), be available”;
- (3) by striking the second sentence; and
- (4) by adding at the end the following:

“(2) There is established in the Treasury a Patent and Trademark Fee Reserve Fund. If fee collections by the Patent and Trademark Office for a fiscal year exceed the amount appropriated to the Office for that fiscal year, fees collected in excess of the appropriated amount shall be deposited in the Patent and Trademark Fee Reserve Fund. To the extent and in the amounts provided in appropriations Acts, amounts in the Fund shall be made available until expended only for obligation and expenditure by the Office in accordance with paragraph (3).

“(3)(A) Any fees that are collected under sections 41, 42, and 376, and any surcharges on such fees, may only be used for expenses of the Office relating to the processing of patent applications and for other activities, services, and materials relating to patents and to cover a share of the administrative costs of the Office relating to patents.

“(B) Any fees that are collected under section 31 of the Trademark Act of 1946, and any surcharges on such fees, may only be used for expenses of the Office relating to the processing of trademark registrations and for other activities, services, and materials relating to trademarks and to cover a share of the administrative costs of the Office relating to trademarks.”.

(b) **EFFECTIVE DATE.**—The amendments made by this section shall take effect on October 1, 2011.

SEC. 23. SATELLITE OFFICES.

(a) **ESTABLISHMENT.**—Subject to available resources, the Director shall, by not later than the date that is 3 years after the date of the enactment of this Act, establish 3 or more satellite offices in the United States to carry out the responsibilities of the Office.

(b) **PURPOSES.**—The purposes of the satellite offices established under subsection (a) are to—

- (1) increase outreach activities to better connect patent filers and innovators with the Office;
- (2) enhance patent examiner retention;
- (3) improve recruitment of patent examiners;
- (4) decrease the number of patent applications waiting for examination; and
- (5) improve the quality of patent examination.

(c) **REQUIRED CONSIDERATIONS.**—

(1) **IN GENERAL.**—In selecting the location of each satellite office to be established under subsection (a), the Director—

(A) shall ensure geographic diversity among the offices, including by ensuring that such offices are established in different States and regions throughout the Nation;

(B) may rely upon any previous evaluations by the Office of potential locales for satellite offices, including any evaluations prepared as part of the Office's Nationwide Workforce Program that resulted in the 2010 selection of Detroit, Michigan, as the first satellite office of the Office;

(C) shall evaluate and consider the extent to which the purposes of satellite offices listed under subsection (b) will be achieved;

(D) shall consider the availability of scientific and technically knowledgeable personnel in the region from which to draw new patent examiners at minimal recruitment cost; and

(E) shall consider the economic impact to the region.

(2) OPEN SELECTION PROCESS.—Nothing in paragraph (1) shall constrain the Office to only consider its evaluations in selecting the Detroit, Michigan, satellite office.

(d) REPORT TO CONGRESS.—Not later than the end of the third fiscal year that begins after the date of the enactment of this Act, the Director shall submit a report to Congress on—

(1) the rationale of the Director in selecting the location of any satellite office required under subsection (a), including an explanation of how the selected location will achieve the purposes of satellite offices listed under subsection (b) and how the required considerations listed under subsection (c) were met;

(2) the progress of the Director in establishing all such satellite offices; and

(3) whether the operation of existing satellite offices is achieving the purposes under subsection (b).

SEC. 24. DESIGNATION OF DETROIT SATELLITE OFFICE.

(a) DESIGNATION.—The satellite office of the United States Patent and Trademark Office to be located in Detroit, Michigan, shall be known and designated as the “Elijah J. McCoy United States Patent and Trademark Office”.

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the satellite office of the United States Patent and Trademark Office to be located in Detroit, Michigan, referred to in subsection (a) shall be deemed to be a reference to the “Elijah J. McCoy United States Patent and Trademark Office”.

SEC. 25. PRIORITY EXAMINATION FOR IMPORTANT TECHNOLOGIES.

Section 2(b)(2) of title 35, United States Code, is amended—

(1) in subparagraph (E), by striking “and” after the semicolon;

(2) in subparagraph (F), by inserting “and” after the semicolon; and

(3) by adding at the end the following:

“(G) may, subject to any conditions prescribed by the Director and at the request of the patent applicant, provide for prioritization of examination of applications for products, processes, or technologies that are important to the national economy or national competitiveness without recovering the aggregate extra cost of providing such

prioritization, notwithstanding section 41 or any other provision of law;”.

SEC. 26. STUDY ON IMPLEMENTATION.

(a) PTO STUDY.—The Director shall conduct a study on the manner in which this Act and the amendments made by this Act are being implemented by the Office, and on such other aspects of the patent policies and practices of the Federal Government with respect to patent rights, innovation in the United States, competitiveness of United States markets, access by small businesses to capital for investment, and such other issues, as the Director considers appropriate.

(b) REPORT TO CONGRESS.—The Director shall, not later than the date that is 4 years after the date of the enactment of this Act, submit to the Committees on the Judiciary of the House of Representatives and the Senate a report on the results of the study conducted under subsection (a), including recommendations for any changes to laws and regulations that the Director considers appropriate.

SEC. 27. STUDY ON GENETIC TESTING.

(a) IN GENERAL.—The Director shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.

(b) ITEMS INCLUDED IN STUDY.—The study shall include an examination of at least the following:

- (1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to

patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses.

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test.

(3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to: the interpretation of testing results and performance of testing procedures.

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

(c) **CONFIRMING GENETIC DIAGNOSTIC TEST ACTIVITY DEFINED.**—For purposes of this section, the term “confirming genetic diagnostic test activity” means the performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider’s prior performance of the test on the individual.

(d) **REPORT.**—Not later than 9 months after the date of enactment of this Act, the Director shall report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on the findings of the study and provide recommendations for establishing the availability of such independent confirming genetic diagnostic test activity.

SEC. 28. PATENT OMBUDSMAN PROGRAM FOR SMALL BUSINESS CONCERNS.

Using available resources, the Director shall establish and maintain in the Office a Patent Ombudsman Program. The duties of the Program's staff shall include providing support and services relating to patent filings to small business concerns and independent inventors.

SEC. 29. ESTABLISHMENT OF METHODS FOR STUDYING THE DIVERSITY OF APPLICANTS.

The Director shall, not later than the end of the 6-month period beginning on the date of the enactment of this Act, establish methods for studying the diversity of patent applicants, including those applicants who are minorities, women, or veterans. The Director shall not use the results of such study to provide any preferential treatment to patent applicants.

SEC. 30. SENSE OF CONGRESS.

It is the sense of Congress that the patent system should promote industries to continue to develop new technologies that spur growth and create jobs across the country which includes protecting the rights of small businesses and inventors from predatory behavior that could result in the cutting off of innovation.

SEC. 31. USPTO STUDY ON INTERNATIONAL PATENT PROTECTIONS FOR SMALL BUSINESSES.

(a) STUDY REQUIRED.—The Director, in consultation with the Secretary of Commerce and the Administrator of the Small Business Administration,

shall, using the existing resources of the Office, carry out a study---

(1) to determine how the Office, in coordination with other Federal departments and agencies, can best help small businesses with international patent protection; and

(2) whether, in order to help small businesses pay for the costs of filing, maintaining, and enforcing international patent applications, there should be established either---

(A) a revolving fund loan program to make loans to small businesses to defray the costs of such applications, maintenance, and enforcement and related technical assistance; or

(B) a grant program to defray the costs of such applications, maintenance, and enforcement and related technical assistance.

(b) REPORT.—Not later than 120 days after the date of the enactment of this Act, the Director shall issue a report to the Congress containing---

(1) all findings and determinations made in carrying out the study required under subsection (a);

(2) a statement of whether the determination was made that---

(A) a revolving fund loan program described under subsection (a)(2)(A) should be established;

(B) a grant program described under subsection (a)(2)(B) should be established; or

(C) neither such program should be established; and

(3) any legislative recommendations the Director may have developed in carrying out such study.

SEC. 32. PRO BONO PROGRAM.

(a) IN GENERAL.—The Director shall work with and support intellectual property law associations across the country in the establishment of pro bono programs designed to assist financially under-resourced independent inventors and small businesses.

(b) EFFECTIVE DATE.—This section shall take effect on the date of the enactment of this Act.

SEC. 33. LIMITATION ON ISSUANCE OF PATENTS.

(a) LIMITATION.—Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Subsection (a) shall apply to any application for patent that is pending on, or filed on or after, the date of the enactment of this Act.

(2) PRIOR APPLICATIONS.—Subsection (a) shall not affect the validity of any patent issued on an application to which paragraph (1) does not apply.

SEC. 34. STUDY OF PATENT LITIGATION.

(a) GAO STUDY.—The Comptroller General of the United States shall conduct a study of the

consequences of litigation by nonpracticing entities, or by patent assertion entities, related to patent claims made under title 35, United States Code, and regulations authorized by that title.

(b) CONTENTS OF STUDY.—The study conducted under this section shall include the following:

(1) The annual volume of litigation described in subsection (a) over the 20-year period ending on the date of the enactment of this Act.

(2) The volume of cases comprising such litigation that are found to be without merit after judicial review.

(3) The impacts of such litigation on the time required to resolve patent claims.

(4) The estimated costs, including the estimated cost of defense, associated with such litigation for patent holders, patent licensors, patent licensees, and inventors, and for users of alternate or competing innovations.

(5) The economic impact of such litigation on the economy of the United States, including the impact on inventors, job creation, employers, employees, and consumers.

(6) The benefit to commerce, if any, supplied by non-practicing entities or patent assertion entities that prosecute such litigation.

(c) REPORT TO CONGRESS.—The Comptroller General shall, not later than the date that is 1 year after the date of the enactment of this Act, submit to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary

of the Senate a report on the results of the study required under this section, including recommendations for any changes to laws and regulations that will minimize any negative impact of patent litigation that was the subject of such study.

SEC. 35. EFFECTIVE DATE.

Except as otherwise provided in this Act, the provisions of this Act shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent issued on or after that effective date.

SEC. 36. BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled “Budgetary Effects of PAYGO Legislation” for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

SEC. 37. CALCULATION OF 60-DAY PERIOD FOR APPLICATION OF PATENT TERM EXTENSION.

(a) IN GENERAL.—Section 156(d)(1) of title 35, United States Code, is amended by adding at the end the following flush sentence: “For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding

sentence, the term ‘business day’ means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.”.

(b) APPLICABILITY.—The amendment made by subsection (a) shall apply to any application for extension of a patent term under section 156 of title 35, United States Code, that is pending on, that is filed after, or as to which a decision regarding the application is subject to judicial review on, the date of the enactment of this Act.

Approved September 16, 2011.

LEGISLATIVE HISTORY—H.R. 1249:

HOUSE REPORTS: No. 112–98, Pt. 1 (Comm. on the Judiciary).

CONGRESSIONAL RECORD, Vol. 157 (2011):

June 22, 23, considered and passed House.

Sept. 7, 8, considered and passed Senate.

DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS (2011):

Sept. 16, Presidential remarks.

235a

APPENDIX F

PUBLIC LAW 112-274—JAN. 14, 2013

LEAHY-SMITH AMERICA INVENTS
TECHNICAL CORRECTIONS

Public Law 112–274

112th Congress

An Act

To correct and improve certain provisions of the
Leahy-Smith America Invents Act and title 35,
United States Code.

*Be it enacted by the Senate and House of
Representatives of the United States of America in
Congress assembled,*

SECTION 1. TECHNICAL CORRECTIONS.

(a) **ADVICE OF COUNSEL.**—Notwithstanding section 35 of the Leahy-Smith America Invents Act (35 U.S.C. 1 note), section 298 of title 35, United States Code, shall apply to any civil action commenced on or after the date of the enactment of this Act.

(b) **TRANSITIONAL PROGRAM FOR COVERED BUSINESS METHOD PATENTS.**—Section 18 of the Leahy-Smith America Invents Act (35 U.S.C. 321 note) is amended—

(1) in subsection (a)(1)(C)(i), by striking “of such title” the second place it appears; and

(2) in subsection (d)(2), by striking “subsection” and inserting “section”.

(c) **JOINDER OF PARTIES.**—Section 299(a) of title 35, United States Code, is amended in the matter preceding paragraph (1) by striking “or counterclaim defendants only if” and inserting “only if”.

(d) **DEAD ZONES.**—

(1) **INTER PARTES REVIEW.**—Section 311(c) of title 35, United States Code, shall not apply to a petition to institute an inter partes review of a patent that

is not a patent described in section 3(n)(1) of the Leahy-Smith America Invents Act (35 U.S.C. 100 note).

(2) REISSUE.—Section 311(c)(1) of title 35, United States Code, is amended by striking “or issuance of a reissue of a patent”.

(e) CORRECT INVENTOR.—

(1) IN GENERAL.—Section 135(e) of title 35, United States Code, as amended by section 3(i) of the Leahy-Smith America Invents Act, is amended by striking “correct inventors” and inserting “correct inventor”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall be effective as if included in the amendment made by section 3(i) of the Leahy-Smith America Invents Act.

(f) INVENTOR’S OATH OR DECLARATION.—Section 115 of title 35, United States Code, as amended by section 4 of the Leahy-Smith America Invents Act, is amended—

(1) by striking subsection (f) and inserting the following: “(f) TIME FOR FILING.—The applicant for patent shall provide each required oath or declaration under subsection (a), substitute statement under subsection (d), or recorded assignment meeting the requirements of subsection (e) no later than the date on which the issue fee for the patent is paid.”; and

(2) in subsection (g)(1), by striking “who claims” and inserting “that claims”.

(g) TRAVEL EXPENSES AND PAYMENT OF ADMINISTRATIVE JUDGES.—Notwithstanding section

35 of the Leahy-Smith America Invents Act (35 U.S.C. 1 note), the amendments made by section 21 of the Leahy-Smith America Invents Act (Public Law 112–29; 125 Stat. 335) shall be effective as of September 16, 2011.

(h) PATENT TERM ADJUSTMENTS.—Section 154(b) of title 35, United States Code, is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)(i)(II), by striking “on which an international application fulfilled the requirements of section 371 of this title” and inserting “of commencement of the national stage under section 371 in an international application”; and

(B) in subparagraph (B), in the matter preceding clause (i), by striking “the application in the United States” and inserting “the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application”;

(2) in paragraph (3)(B)(i), by striking “with the written notice of allowance of the application under section 151” and inserting “no later than the date of issuance of the patent”; and

(3) in paragraph (4)(A)—

(A) by striking “a determination made by the Director under paragraph (3) shall have remedy” and inserting “the Director’s decision on the applicant’s request for reconsideration under

paragraph (3)(B)(ii) shall have exclusive remedy”;
and

(B) by striking “the grant of the patent” and
inserting “the date of the Director’s decision on
the applicant’s request for reconsideration”.

(i) IMPROPER APPLICANT.—Section 373 of title 35,
United States Code, and the item relating to that
section in the table of sections for chapter 37 of such
title, are repealed.

(j) FINANCIAL MANAGEMENT CLARIFICATIONS.—
Section 42(c)(3) of title 35, United States Code, is
amended—

(1) in subparagraph (A)—

(A) by striking “sections 41, 42, and 376,” and
inserting “this title,”; and

(B) by striking “a share of the administrative
costs of the Office relating to patents” and
inserting “a proportionate share of the
administrative costs of the Office”; and

(2) in subparagraph (B), by striking “a share of
the administrative costs of the Office relating to
trademarks” and inserting “a proportionate share of
the administrative costs of the Office”.

(k) DERIVATION PROCEEDINGS.—

(1) IN GENERAL.—Section 135(a) of title 35, United
States Code, as amended by section 3(i) of the
Leahy-Smith America Invents Act, is amended to
read as follows:

“(a) INSTITUTION OF PROCEEDING.—

“(1) IN GENERAL.—An applicant for patent may
file a petition with respect to an invention to

institute a derivation proceeding in the Office. The petition shall set forth with particularity the basis for finding that an individual named in an earlier application as the inventor or a joint inventor derived such invention from an individual named in the petitioner's application as the inventor or a joint inventor and, without authorization, the earlier application claiming such invention was filed. Whenever the Director determines that a petition filed under this subsection demonstrates that the standards for instituting a derivation proceeding are met, the Director may institute a derivation proceeding.

“(2) TIME FOR FILING.—A petition under this section with respect to an invention that is the same or substantially the same invention as a claim contained in a patent issued on an earlier application, or contained in an earlier application when published or deemed published under section 122(b), may not be filed unless such petition is filed during the 1-year period following the date on which the patent containing such claim was granted or the earlier application containing such claim was published, whichever is earlier.

“(3) EARLIER APPLICATION.—For purposes of this section, an application shall not be deemed to be an earlier application with respect to an invention, relative to another application, unless a claim to the invention was or could have been made in such application having an effective filing date that is earlier than the effective filing date of any claim to the invention that was or could have been made in such other application.

“(4) NO APPEAL.—A determination by the Director whether to institute a derivation proceeding under paragraph (1) shall be final and not appealable.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall be effective as if included in the amendment made by section 3(i) of the Leahy-Smith America Invents Act.

(3) REVIEW OF INTERFERENCE DECISIONS.—The provisions of sections 6 and 141 of title 35, United States Code, and section 1295(a)(4)(A) of title 28, United States Code, as in effect on September 15, 2012, shall apply to interference proceedings that are declared after September 15, 2012, under section 135 of title 35, United States Code, as in effect before the effective date under section 3(n) of the Leahy-Smith America Invents Act. The Patent Trial and Appeal Board may be deemed to be the Board of Patent Appeals and Interferences for purposes of such interference proceedings.

(l) PATENT AND TRADEMARK PUBLIC ADVISORY COMMITTEES.—

(1) IN GENERAL.—Section 5(a) of title 35, United States Code, is amended—

(A) in paragraph (1), by striking “Members of” and all that follows through “such appointments.” and inserting the following: “In each year, 3 members shall be appointed to each Advisory Committee for 3-year terms that shall begin on December 1 of that year. Any vacancy on an Advisory Committee shall be filled within 90 days after it occurs. A new member who is appointed to fill a vacancy shall be appointed to serve for the remainder of the predecessor’s term.”;

(B) by striking paragraph (2) and inserting the following:

“(2) CHAIR.—The Secretary of Commerce, in consultation with the Director, shall designate a Chair and Vice Chair of each Advisory Committee from among the members appointed under paragraph (1). If the Chair resigns before the completion of his or her term, or is otherwise unable to exercise the functions of the Chair, the Vice Chair shall exercise the functions of the Chair.”; and

(C) by striking paragraph (3).

(2) TRANSITION.—

(A) IN GENERAL.—The Secretary of Commerce shall, in the Secretary’s discretion, determine the time and manner in which the amendments made by paragraph (1) shall take effect, except that, in each year following the year in which this Act is enacted, 3 members shall be appointed to each Advisory Committee (to which such amendments apply) for 3-year terms that begin on December 1 of that year, in accordance with section 5(a) of title 35, United States Code, as amended by paragraph (1) of this subsection.

(B) DEEMED TERMINATION OF TERMS.—In order to implement the amendments made by paragraph (1), the Secretary of Commerce may determine that the term of an existing member of an Advisory Committee under section 5 of title 35, United States Code, shall be deemed to terminate on December 1 of a year beginning after the date of the enactment of this Act, regardless of whether December 1 is before or after the date on

which such member's term would terminate if this Act had not been enacted.

(m) CLERICAL AMENDMENT.—Section 123(a) of title 35, United States Code, is amended in the matter preceding paragraph (1) by inserting “of this title” after “For purposes”.

(n) EFFECTIVE DATE.—Except as otherwise provided in this Act, the amendments made by this Act shall take effect on the date of enactment of this Act, and shall apply to proceedings commenced on or after such date of enactment.

Approved January 14, 2013.

LEGISLATIVE HISTORY—H.R. 6621:

CONGRESSIONAL RECORD:

Vol. 158 (2012):	Dec. 18, considered and passed House. Dec. 28, considered and passed Senate, amended. Dec. 30, House considered concurring in Senate amendment.
Vol. 158 (2013):	Jan. 1, House concurred in Senate amendment.