

# Bright Ideas

A publication of the Intellectual Property Law Section  
of the New York State Bar Association

## Message from the Chair

I am thrilled to be the new Chair of the IP Law Section. My involvement in the Section started when I was a night student at Brooklyn Law School. I submitted a course paper for the Section's Law Student Writing Competition, and after winning an award, I was invited to co-chair the Young Lawyers Committee. I gladly accepted. Six years ago I was asked to get into succession planning for the chairmanship and went through two-year terms as Secretary, Treasurer, and then Vice-Chair. I have run the Law Student Writing Competition, gotten our bylaws amended to add a new committee (Pro Bono and Public Interest), initiated the creation of our Fellowship Program, and co-chaired the NYSBA President's Privacy Initiative to produce a report approved by the NYSBA House of Delegates.

As you can see, there are many ways to get involved in the Section and find something of interest to you both personally and professionally.

I enjoy being a member of NYSBA—and the IP Section in particular—because I believe in its mission to educate students, the public, other lawyers whose practice is not primarily IP, and in its work in the area of diversity. The Section's educational events include numerous CLE events throughout the year, and our signature annual events: a full day of programming at the NYSBA Annual Meeting, The Copyright Society Comes to NYC (run by immediate past Chair Paul Fakler), Women in IP (run by former Chair Joyce Creidy), and the multi-day Fall Meeting.

This year the Fall Meeting will be downstate in Manhattan for the first time so that it could be combined with the Section's twentieth anniversary gala. The theme of this year's Fall Meeting, developed by founder and past



Kelly M. Slavitt

Chair Rory Radding and Chair-Elect Charles Weigell, will prepare us for the next twenty years: "Intellectual Property Law and Policy—At the Fringe and Into the Future." Timely topics include the state of the IP world, predictive coding in e-discovery/forensics, the recent USPTO request for comments on how to address trademark bullying, ethical issues being played out in litigation, cross-border IP enforcement, design patents, and unlocking the value of IP. Scheduled speakers include the Director of the Bureau of Economic Affairs at the U.S. Department of Commerce, a former USPTO Examiner, a leading IP professor from Syracuse University, an expert on TLDs, partners from top firms, and leading in-house practitioners.

Sandwiched between the two days of programming is the Friday night sit-down dinner at Gotham Hall celebrating the Section's twentieth anniversary. The event will be complete with photos from the past twenty years (some taken with non-digital cameras, quaint as that now seems) and a parade of previous speakers, Law Student Writing Competition winners, and Section Chairs—and future speakers, Law Student Writing Competition winners, and Section Chairs.

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You won't want to miss this conference—or the dinner. Both are guaranteed to sell-out, so book now at <http://www.nysba.org/IPFallMtg2012>.

The diversity component of our educational efforts is substantial. The Section has a Diversity Initiative (run by Joyce Creidy) and a substantial presence at the Annual Meeting's Diversity Reception, and it was recently honored again as a "Section Diversity Challenge Leader" and presented with an award from NYSBA President Vincent Doyle. I'm extremely proud of both the men and the women in this Section who have encouraged and supported diversity so that three of our four current Section Officers are women: me, Treasurer Sheila Francis, and Secretary Erica Klein. Our law firm partnership and General Counsel statistics should be so high! Current and former Executive Committee members such as Tricia Semmelhack, Vicki Cundiff, Mimi Netter, and Bernice Leber—who went on to become President of NYSBA—helped make this possible, and for that I am personally grateful.

With two thousand members, including the highest number of attorneys admitted ten years or less of all the twenty-five NYSBA Sections, there are many new relationships you can develop with colleagues in the field of IP. As a result of my involvement with the IP Law Section, I have met alumni from my law schools, made colleagues and friends, developed excellent working relationships with adversaries, found mentors, and became a mentor.

Thank you to Paul Fakler for his leadership over the past two years, and thank you to Paul for agreeing to continue serving the Section as Co-Chair of the Copyright Law Committee. The continued involvement of so many former Chairs like Paul has allowed the Section to build on their knowledge and relationships and take the Section to where it is now after twenty successful years.

I look forward to the next two years and to all the things the Section will be able to accomplish. Thank you for taking the time to read this message and for helping the Section become what it is now and what it will be in the future.

Kelly M. Slavitt

## *Thank You*

**The Intellectual Property Law Section extends its gratitude to the following for their significant sponsorship over the past year:**

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# Mayo v. Prometheus: The Overlap Between Patent Eligibility and Patentability

By Teige P. Sheehan

## I. Introduction

In March 2012, the U.S. Supreme Court issued an important and potentially far-ranging holding on patent eligibility in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, ruling unanimously that the methods at issue—for determining the optimum dose of a particular class of drugs for individual patients—are not patent eligible.<sup>1</sup> *Prometheus* has attracted the attention of practitioners and members of the business community across multiple disciplines because of its ostensible breadth, its apparent break with Supreme Court precedent, and its potential to create widespread uncertainty as to patent validity.

The Court had most recently addressed patent eligibility in 2010 in *Bilski v. Kappos*,<sup>2</sup> in which it reiterated the patent ineligibility of abstract ideas. *Prometheus*, in turn, addressed the patent eligibility of inventions that invoke a purported natural law, and in doing so the Court appeared to import the patentability questions of novelty and obviousness into the patent-eligibility inquiry, despite having held in 1981 in *Diamond v. Diehr*<sup>3</sup> that those analyses should be conducted separately. In this regard, *Prometheus* could be relevant to evaluating the validity of claims that implicate exceptions to eligibility other than laws of nature,<sup>4</sup> including claims unrelated to medical treatment methods.

This article discusses *Prometheus* in the context of the ongoing, recently reinvigorated development of patent-eligibility jurisprudence.<sup>5</sup> Part II summarizes the Court's holding, while Parts III and IV present analyses of its legal and policy-based justifications, respectively. Part V discusses the uncertain fate of the Federal Circuit's "machine-or-transformation" test of patent eligibility in light of *Prometheus*. Part VI addresses the potential relevance of *Prometheus* to other current patent-eligibility debates, and Part VII provides guidance for claiming patent-eligible inventions in accordance with *Prometheus*.

It is to be hoped that as lower courts and the PTO implement the teachings of *Prometheus* in a constructive and meaningful way, the anxiety induced in the patent community by the Court's holding will be assuaged.

## II. Summary of *Prometheus*

The claims at issue in *Prometheus* were drawn to methods of determining an optimal thiopurine drug dose for use in treating a patient suffering from an autoimmune-related gastrointestinal disorder. At the time of invention, administering thiopurine drugs to treat such disorders was known. However, because rates of

metabolism of such drugs differ from patient to patient, it was difficult to predict in the abstract a dose that was high enough to be effective for a given patient but not so high as to cause harmful side effects. The inventors identified correlations between an individual's blood levels of thiopurine metabolites following drug administration and the effectiveness or harmfulness of the administered dose, and they claimed using these relationships to calculate what dose to administer on a patient-by-patient basis.<sup>6</sup>

*Prometheus Laboratories, Inc.*, the exclusive licensee of the patents at issue, sued Mayo Collaborative Services (hereinafter "Mayo") for patent infringement, but the case was dismissed on summary judgment on the ground that the claimed inventions were not eligible for patent protection.<sup>7</sup> On appeal, the Federal Circuit reversed, and Mayo petitioned for certiorari.<sup>8</sup> The Supreme Court granted certiorari, vacated the Federal Circuit's holding, and remanded the case for further proceedings in light of *Bilski*, which it had handed down in the interim.<sup>9</sup> On remand, the Federal Circuit again held the claimed inventions to be patent eligible, and Mayo again petitioned for certiorari, which the Court granted.<sup>10</sup>

In an opinion by Justice Breyer, the Court considered the eligibility of the following claim, which it deemed sufficiently representative of all the claims at issue:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a [thiopurine] drug...to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of [a thiopurine metabolite] in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of [said metabolite below a specific level] indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of [said metabolite above a specific level] indicates a need to decrease the amount of said drug subsequently administered to said subject.<sup>11</sup>

In deciding that the claimed invention was not patent eligible, the Court characterized the correlations the inventors had identified between metabolite levels and

effectiveness and harmfulness as laws of nature.<sup>12</sup> It thus cast the claim as falling within an exception to the broad scope of patent-eligible subject matter established under 35 U.S.C. § 101,<sup>13</sup> having stated in prior opinions that there are “three specific exceptions to § 101’s broad principles: ‘laws of nature, physical phenomena, and abstract ideas.’”<sup>14</sup> The Court described the claim as containing an “‘administering’ step [that] simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs... ‘wherein’ clauses [that] simply tell a doctor about the relevant natural laws, [and a] ‘determining’ step [that] tells the doctor to determine the level of the relevant metabolite in the blood.”<sup>15</sup> The Court thus held that the effect was “simply to tell doctors to apply the law[s of nature] somehow when treating their patients.”<sup>16</sup>

### III. The Law of Nature Exclusion, Patent Eligibility, and Patentability

Arguably, the correlations made use of in the claimed methods are not laws of nature to begin with, at least not in the patent-ineligibility sense, in which case the Court’s characterization of them as such would represent the “most damaging misstep” in the decision.<sup>17</sup> Although they describe to some degree how the human body responds to exposure to thiopurine drugs, which response itself depends upon the body’s natural metabolic processes and autoimmune pathology, the correlations do not directly co-opt those underlying principles of thiopurine pharmacokinetics and pharmacodynamics per se.<sup>18</sup> In this respect, the claimed processes are very different from those employing mathematical algorithms that were held to be patent ineligible for preempting laws of nature in prior Supreme Court decisions.<sup>19</sup> The broad conception of what qualifies as a law of nature for purposes of the patent-eligibility inquiry adopted in *Prometheus* could well engulf a wide swath of issued claims; the Court itself recognized that “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”<sup>20</sup>

However, even assuming the claimed methods did make use of natural laws in a way that threatened their patent eligibility, the Court acknowledged that such use is not by itself fatal to validity.<sup>21</sup> Rather, the Court stated that a claim to “a process that focuses upon the use of a natural law [must] also contain other elements or a combination of elements...sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”<sup>22</sup> The Court thus required that the steps in addition to the use of a natural law must be parsed and examined to determine whether they provide something more than “well-understood, routine, conventional activity previously engaged in by researchers in the field,”<sup>23</sup> rather than something “purely ‘conventional or obvious.’”<sup>24</sup> The Court “recognize[d] that, in evaluating the significance of additional steps, the [35 U.S.C.] § 101 patent-eligibility inquiry and, say,

the § 102 novelty inquiry might sometimes overlap.”<sup>25</sup> Because, according to the Court, the aspects of the disputed claims in *Prometheus* other than the purported manifestations of natural laws merely told doctors to “engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field,” the claims did not “add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws.”<sup>26</sup>

In reaching this conclusion, the Court upset its own long-standing rule, derived from both the statutory language and legislative history of the 1952 Patent Act, that the determination of patent eligibility under 35 U.S.C. § 101 is entirely separate from and unaffected by whether the conditions of patentability set forth in 35 U.S.C. §§ 102 (novelty) and 103 (nonobviousness) are met.<sup>27</sup> Although the Court recently had held in *Bilski* that dependent claims that merely add “well-known...techniques” and “token postsolution components” to an abstract concept recited in a patent-ineligible independent claim do not “make the concept patentable,” it did not in *Bilski* expressly reverse its holding from thirty years ago that patent eligibility and patentability are distinct inquiries,<sup>28</sup> as it appears to have done in *Prometheus*.

And yet, although the Court in *Prometheus* asserted that patent-eligibility and patentability analyses may overlap, it explicitly declined to perform a patentability analysis under, for example, section 102. Rather, it confined its analysis and discussion of what was routine and conventional in the art to the supposedly “better established inquiry under § 101.”<sup>29</sup> Avoiding a patent-eligibility analysis in favor of patentability analysis, the Court warned, “would make the ‘law of nature’ exception to § 101 patentability a dead letter.”<sup>30</sup>

This conflation of patent-eligibility and patentability analysis threatens to create substantial uncertainty as to patent validity, for a number of reasons. First, most practitioners likely disagree with the Court and believe that patentability jurisprudence developed under sections 102, 103, and 112 is far more well developed than the patent-eligibility jurisprudence under section 101.<sup>31</sup> Second, the Court appears to endorse the view that invalidity arguments that previously would have been within the purview of sections 102, 103, or 112—and therefore required claim construction as part of the analysis—can now be brought under section 101 without the court having to construe the claims.<sup>32</sup> Third, if patent-eligibility and patentability analyses do overlap, parties may unjustifiably take advantage of the additional opportunity to challenge claims under section 101 on the basis of prior art that is more traditionally relevant under sections 102 or 103, requiring multiple responses to what is essentially the same, duplicative argument and reducing judicial efficiency.<sup>33</sup> Fourth, the Court’s method of concluding that the claimed inventions were patent ineligible by dissecting the claims into their constituent parts and finding



each on its own to be lacking in sufficient inventiveness contrasts sharply with the long-standing doctrine that claims are to be considered as a whole.<sup>34</sup>

Finally, the Court evinced a dispiriting lack of appreciation for the function of claims in protecting economic incentives, stating that its holding was necessary to safeguard innovation from the apparently mischievous influences of the “‘draftsman’s art.”<sup>35</sup> Rather than bring clarity to the patent-eligibility issue, however, the decision instead has the potential to substantially destabilize long-standing, well-established doctrines.

Notably, however, in a post-*Prometheus* decision, the Federal Circuit emphasized the “distinctly different role[s]” played by sections 101, 102, 103, and 112.<sup>36</sup> Subsequent to *Bilski*, in which the Supreme Court characterized section 101 as a “threshold test” of validity,<sup>37</sup> but before *Prometheus*, the Federal Circuit had stated that sections 102, 103, and 112 are capable of weeding out patents that could otherwise pass through the “coarse eligibility filter” of section 101.<sup>38</sup> *Prometheus* undercuts this position, asserting that some claims to subject matter that is patent ineligible under section 101 still could satisfy the requirements of these other sections, perhaps signaling the pre-eminent importance of the patent-eligibility inquiry over other questions of validity.<sup>39</sup>

In emphasizing the different functions served by section 101 as compared to sections 102, 103, and 112, the Federal Circuit held that “a district court properly acts within its discretion in deciding when to address the diverse statutory challenges to validity” and that section 101 issues “need not always be addressed first, particularly when other sections might be discerned by the trial judge as having the promise to resolve a dispute more expeditiously or with more clarity and predictability.”<sup>40</sup> Thus, whatever the relative importance of section 101 in light of *Bilski* and *Prometheus*, the Federal Circuit maintains that a patent-eligibility analysis need not always be performed if, for example, discretionary considerations of judicial economy favor dispensing with cases on the basis of other validity requirements.

#### IV. Safeguarding Innovation

The Supreme Court’s principal justification for its holding is the policy against allowing patentees to monopolize fundamental natural laws through the grant of a patent, thereby preempting entire domains of innovation.<sup>41</sup> As the Court acknowledged, the quid pro quo of the U.S. patent regime allows an inventor a limited-time right to exclude others from practicing his or her invention so as to incentivize innovation and, in time, to stimulate successive technological improvements.<sup>42</sup> To avoid tilting the balance too far toward monopolization, to the detriment of innovation, the Court has historically limited patent eligibility by denying patents that have the effect of excluding others from applying fundamental laws of nature.<sup>43</sup>

There was, however, a notable absence of factual evidence presented in *Prometheus* to support the Court’s protectiveness of innovation. Beyond the exclusionary right that is an integral aspect of the patent regime in general,<sup>44</sup> was there any record evidence that the claims at issue in the case did in fact prevent others from using fundamental laws of nature relating to pharmacokinetics and pharmacodynamics outside of the application claimed by the patentees? This question is not as impertinent as it may seem, particularly with respect to the preemption concern. The Court acknowledged that the “laws of nature at issue...are narrow laws that may have limited applications.”<sup>45</sup> It nevertheless stated that there is a “bright-line prohibition against patenting laws of nature” irrespective of the breadth of preemption<sup>46</sup>—a statement that seems at odds with the Court’s ostensible policy concerns.<sup>47</sup> That is, arguably the disincentive of a “bright-line” rule against claims to inventions that apply narrowly circumscribed natural laws is at least as likely to diminish the patent regime’s ability to stimulate innovation as is allowing patentees to preemptively claim such laws.

Also notably absent from *Prometheus* is any discussion of either the presumption of validity that issued patents enjoy or of the clear and convincing evidentiary standard required to invalidate a patent.<sup>48</sup> After *Prometheus*, however, the Federal Circuit has reiterated the evidentiary burden required to prevail on a claim of invalidity under section 101, stating that “when—after taking all of the claim recitations into consideration—it is not manifestly evident that a claim is directed to a patent ineligible abstract idea, that claim must not be deemed for that reason to be inadequate under § 101,” and “[u]nless the single most reasonable understanding is that a claim is directed to nothing more than fundamental truth or disembodied concept, with no limitations in the claim attaching that idea to a specific application, it is inappropriate to hold that the claim is directed to a patent ineligible ‘abstract idea.’”<sup>49</sup>

#### V. Evisceration of the Machine-or-Transformation Test

The *Prometheus* Court also addressed whether satisfying the Federal Circuit’s “machine-or-transformation” test would render the claims at issue eligible for patent, apparently answering in the negative.<sup>50</sup> The Federal Circuit had enunciated the machine-or-transformation test as way to determine whether a claimed process was patent eligible: a process is only patent eligible if “(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”<sup>51</sup> On appeal in *Bilski*, the Supreme Court disagreed, stating that while “the machine-or-transformation test is a useful and important clue, [it] is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”<sup>52</sup>

The machine-or-transformation test having thereby been declared by the Supreme Court as a permissible,

if non-exclusive, test of patent eligibility, the Federal Circuit in *Prometheus* “reasoned that the claimed processes are therefore patent eligible, since they involve transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels.”<sup>53</sup> But the Supreme Court, in reviewing that decision, took a very different position than it had in *Bilski*, stating that the machine-or-transformation test does not “trump[] the ‘law of nature’ exclusion” from patent eligibility and “the test fails here.”<sup>54</sup> Thus, in addition to having been declared unnecessary as a litmus test of patent eligibility in *Bilski*, under *Prometheus* the machine-or-transformation test appears to have been deemed insufficient as a screen as well. Its status as a very “useful and important clue” of patent eligibility therefore seems doubtful.<sup>55</sup> Note, however, that the machine-or-transformation test, if on life support, is not quite dead yet, as the Federal Circuit applied it post-*Prometheus* in finding that claims to using a computer system to mitigate risk in financial transactions were patent eligible.<sup>56</sup>

## VI. Implications for Other Disputes

Soon after issuing *Prometheus*, the Supreme Court agreed to hear two other cases involving patent eligibility, vacated the Federal Circuit holdings that the claims at issue in those cases were patent eligible, and remanded the cases to the Federal Circuit for further proceedings in light of *Prometheus*.<sup>57</sup> In *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.* a divided panel of the Federal Circuit had held that claims to isolated sequences of DNA were patent eligible because the process of isolating them so altered them from their native state that they were no longer products of nature and therefore were patent eligible.<sup>58</sup> And in *Ultramercial, LLC v. Hulu, LLC* the Federal Circuit had held that a method for distributing copyrighted material over the Internet was patent eligible because it involved “an extensive computer interface” for practically applying “the age-old idea that advertising can serve as currency.”<sup>59</sup> Considering that the requirement of *Prometheus* that patent-ineligible facets of claims require additional recitation of some non-obvious or unconventional element or limitation, these bases for upholding the biotechnological and computer software claims in *Myriad* and *Ultramercial*, respectively, are likely called into question.<sup>60</sup>

## VII. Implementing *Prometheus*

After *Prometheus* was handed down, the PTO issued guidance to its corps of patent examiners for determining patent eligibility of process claims.<sup>61</sup> The guidelines set out a series of three inquiries that should be made to determine whether a claim in a patent application is patent eligible under *Prometheus*. The first inquiry asks whether the claim is to a method. If so, the guidelines are applicable. The second inquiry asks whether the claim focuses “on use of a natural principle, i.e., a law of nature,

a natural phenomenon, or naturally-occurring relation or correlation” as “a limiting feature of the claim.” If so, then the third inquiry is made: “Is [the claim] more than a law of nature [plus] the general instruction to simply ‘apply it?’” If not, the claim is not patent eligible.<sup>62</sup>

The most straightforward, if glib, response to the admonitions in *Prometheus* is to ensure that, where a natural law is relied upon in a claimed process, additional claim elements require applying it in a manner that is not merely routine or conventional.<sup>63</sup> In this regard, the holding in *Prometheus* may not be as broadly applicable as it may appear. One important aspect of the decision was the Court’s reference to the fact that the claims do not require administering a higher or lower dose of a thiopurine drug on the basis of the detected metabolite blood levels.<sup>64</sup> The claim clauses stating that “wherein [metabolite levels] indicate[] a need to increase [or] decrease the amount of [thiopurine] drug subsequently administered” do not actually require that any activity be taken once metabolite blood levels have been determined, such as subsequent administration of a thiopurine drug, at any dose at all, irrespective of whether metabolite blood levels were detected to be below or above the levels stated in the “wherein” clauses.<sup>65</sup>

These clauses arguably need not have been considered by the Court in its analysis.<sup>66</sup> Indeed, the step of administering a thiopurine drug to a patient, by itself, would surely be patent eligible, irrespective of issues of novelty and nonobviousness.<sup>67</sup> It is odd, then, that adding *more* to the claims removed them from patent eligibility.<sup>68</sup> Perhaps the Court’s disapproval of the claims was predominantly the result of the presence of these “wherein” clauses that merely intimated the supposed laws of nature without adding actionable substance to the claims. Notwithstanding the Court’s suggestion that the addition of “less conventional” steps to these claims would be required for them to attain patent eligibility, it ultimately may not hold the claims of other patents to that seemingly heightened standard.<sup>69</sup>

## VIII. Conclusion

After several decades of relative lack of involvement by the Supreme Court in patent eligibility issues, the Court in *Prometheus*, following *Bilski*, introduced substantial analytical changes. As was the case following *Bilski*, there is a widespread sense that previously established principles and settled expectations and interests have been upset by a bold decision that lacks practical guidance. It may be a long time before the full ramifications of *Prometheus* are understood and felt by the patent community. One hopes that the worst fears expressed in the immediate wake of the decision will prove unfounded.

## Endnotes

1. 132 S. Ct. 1289.
2. 130 S. Ct. 3218.

3. 450 U.S. 175.
4. See *infra* note 14 and associated text.
5. *MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1258 (Fed. Cir. 2012) (noting “what has become a plethora of opinions adding to...§ 101 jurisprudence”).
6. *Prometheus*, 132 S. Ct. at 1294-95.
7. *Id.* at 1295-96.
8. *Id.* at 1296.
9. *Id.*
10. *Id.*
11. *Id.* at 1295.
12. *Id.* at 1296-97.
13. “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101.
14. *Bilski*, 130 S. Ct. at 3221 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)). The Court has not always been consistent in identifying which exception operates to render a given invention patent ineligible. For example, in *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972), the Court rejected as patent ineligible a claim that recited a mathematical algorithm because it was too “abstract,” but the holding in *Benson* was subsequently characterized in *Parker v. Flook*, 437 U.S. 584, 589 (1978), as applying “the established rule that a law of nature cannot be the subject of a patent.” The Court in *Flook*, in turn, held a claim to a process using an algorithm to be patent ineligible because it was drawn to a law of nature (437 U.S. at 589-90), but the Court in *Bilski* characterized *Flook* as pertaining to the exemption of abstract ideas from patent eligibility (130 S. Ct. at 3230). Thus, the Court does not appear to consider the boundaries between these exemptions to be particularly restrictive and somewhat freely cross-applies analytical frameworks between them.
15. *Prometheus*, 132 S. Ct. at 1297.
16. *Id.* at 1299-1300.
17. Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html> (Mar 26, 2012) (hereinafter “*Sachs I*”).
18. See *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1067 (Fed. Cir. 2012) (“Pharmacokinetics is the study of what a person’s body does to a drug after administration [and pharmacodynamics] describes the effect that a drug renders on a person’s body.”).
19. *Flook*, 437 U.S. at 589-90. See also *Benson*, 409 U.S. at 68 and *supra*, note 14.
20. *Prometheus*, 132 S. Ct. at 1293; See *Sachs I*, *supra* note 17 (noting that the Court’s erroneous characterization of the dosage-efficacy-safety correlations as laws of nature rather than applications of such laws or, perhaps, of natural phenomena, puts many patents at risk); Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-part-ii-what-is-a-claim.html> (Mar 27, 2012) (hereinafter “*Sachs II*”) (“Patents which only last week had been utterly ordinary, run of the mill, *Landis on Mechanics of Patent Claim Drafting*-certified claims are now suspect, merely because they do what every claim ought to do: comply with the laws of thermodynamics.”).
21. *Prometheus*, 132 S. Ct. at 1294.
22. *Id.*
23. *Id.*
24. *Id.* at 1299 (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)).
25. *Prometheus*, 132 S. Ct. at 1304.
26. *Id.* at 1289, 1298. See *Sachs II*, *supra* note 20 (“Reducing the claim to this ‘instruction manual’ allows the Court to analogize the claim to Einstein ‘telling linear accelerator operators about his basic law’ [*Prometheus*, 132 S. Ct. at 1297]—a low point in modern legal reasoning.”).
27. *Diehr*, 450 U.S. at 1058-59. See also *Diamond v. Chakrabarty*, 447 U.S. 303, 307 n.5 (1980) (“This [patent-eligibility] case does not involve the other ‘conditions and requirements’ of the patent laws, such as novelty and nonobviousness. 35 U.S.C. §§ 102, 103.”); *In re Bergy*, 596 F.2d 952, 960-61 (C.C.P.A. 1979) (arguing that the legislative history of the 1952 Patent Act supports separating patent-eligibility inquiries under 35 U.S.C. § 101 from patentability inquiries under other sections of Title 35); Harold C. Wegner, *Patent-Eligibility from Benson to Diehr (1972-1981): Patenting Biotechnology “Nylon,”* at 32-34, (May 14, 2012), [http://www.grayonclaims.com/storage/Wegner\\_PaentEligibility\\_May14.pdf](http://www.grayonclaims.com/storage/Wegner_PaentEligibility_May14.pdf) (noting that the Supreme Court, in *Chakrabarty* and *Diehr*, adopted the rule that patent-eligibility and patentability inquiries should be separate inquiries in accordance with the holding in *Bergy*, which was authored by Judge Rich, a principal author of the 1952 Patent Act).
28. 130 S. Ct. at 3231.
29. *Prometheus*, 132 S. Ct. at 1304.
30. *Id.* at 1303.
31. See Lynn C. Tyler, *Section III of Mayo v. Prometheus: Better Left Unwritten?*, [2012] 83 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2059 (Apr. 6, 2012), at 841 (hereinafter “*Tyler*”) (“It is simply hard to know what the court meant by this statement” that the § 101 inquiry is better established than other, patentability inquiries); *Sachs II*, *supra* note 20 (“What is especially Kafkaesque is the Court’s intimation that analysis under §§ 102 and 103 is somehow significantly more uncertain than under § 101.”); *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, No. 2011-1301, 2012 WL 2708400, at \*7 (Fed. Cir. 2012) (“Notwithstanding...well-intentioned efforts and the great volume of pages in the Federal Reporters treating the abstract ideas exception, the dividing line between inventions that are directed to patent ineligible abstract ideas and those that are not remains elusive.”).
32. James R. Klaiber & Stephen M. Goodman, *Diagnosing Patent Ineligibility: The Supreme Court’s Mayo v. Prometheus Decision and Computer-Implemented Claims*, [2012] 83 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2062 (Apr 27, 2012), at 969 (hereinafter “*Klaiber*”). Although the Court did refer to the claim construction that had been conducted by the district court (132 S. Ct. at 1296), it did not explicitly rely on or refer to such claim construction in much of its opinion, leaving the question of the importance of claim construction in a § 101 inquiry unsettled.
33. Christine Willgoos, *Lessons of Mayo v. Prometheus: Did the Supreme Court Clarify or Confuse the Patent Eligibility of Biotechnology Inventions?*, [2012] 84 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2065, at 121-22 (May 18, 2012) (hereinafter “*Willgoos*”) (“Where does the Section 101 inquiry end and the Section 102/103 inquiry begin? The *Mayo* decision offers little guidance on this matter.”); *Klaiber*, *supra* note 32 at 969; Harold C. Wegner, *Mayo v. Prometheus: Implications for “Composition[s] of Matter,”* at 71-74, April 27, 2012, [http://www.grayonclaims.com/storage/Wegner\\_Mayo\\_v\\_Prometheus\\_April27REV.pdf](http://www.grayonclaims.com/storage/Wegner_Mayo_v_Prometheus_April27REV.pdf) (“The model thus goes around in a meaningless circle of redundant effort.”).
34. *Diehr*, 450 U.S. at 188 (“In determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.”); *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 2012 WL 2708400, at \*12 (“The limitations of the claims as a whole...are what place meaningful boundaries on the meaning of the claims.”); *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183



- F.3d 1369, 1374 (Fed. Cir. 1999) (“Proper claim construction... demands interpretation of the entire claim in context, not a single element in isolation.”); *Sachs II*, *supra* note 20; William K. Merkel, *Understanding Mayo v. Prometheus*, LAW360, July 10, 2012, <http://www.law360.com/ip/articles/350658/understanding-mayo-v-prometheus> (subscription required) (“What competent patent attorney, patent agent or pro se applicant would draft a claim to patentable subject matter and then further limit its scope by adding an element reciting a law of nature? It is reasonable to expect the vast majority of issued and pending treatment, and diagnostic, claims will fail to demonstrate an inventive concept in any subset of claim elements, and will instead define an incomplete process missing an essential element.”).
35. *Prometheus*, 132 S. Ct. at 1294 (quoting *Flook*, 437 U.S. at 593); *Sachs II*, *supra* note 20 (“The Court’s suggestion that patent attorneys engage in ‘drafting effort[s] designed to monopolize [a] law of nature itself is absurd. We draft claims that read on actual infringers in the real world. Intentionally drafting a claim that read[s] on an abstract idea or a law of nature itself would be foolish at best and malpractice at worst, for there would be no infringers. No one makes, sells, or uses an abstract idea.”) (emphasis in original); Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-part-iv-machine-or-transformation-we-hardly-knew-thee.html> (Mar 31, 2012) (“For some reason the Court seems to delight in denigrating the role of patent counsel in drafting claims, treating patent attorneys as either mere scribes or crafty manipulators of words and phrases, clauses and conjunctions.”); Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/04/punishing-prometheus-part-v-the-long-punt-and-the-improbable-return.html> (Apr. 4, 2012) (“[T]he Court should... understand [that] the entire purpose of the patent law is to encourage innovation through economic incentives.”) (emphasis removed) (hereinafter “*Sachs V*”).
  36. *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, No. 2011-1301, 2012 WL 2708400, at \*6 (Fed. Cir. July 9, 2012).
  37. *Bilski*, 130 S. Ct. at 3225.
  38. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066 (Fed. Cir. 2011); *Research Corp. Technologies, Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010).
  39. *Prometheus*, 132 S. Ct. at 1303-04.
  40. *CLS Bank Int’l*, 2012 WL 2708400, at \*6.
  41. *Prometheus*, 132 S. Ct. at 1289 (“The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible.”).
  42. *Id.* at 1301.
  43. *Id.*
  44. *Sachs II*, *supra* note 20 (“By definition claims preempt, that is what they are designed to do: to preclude one from making, using, selling etc., the invention.”) (emphasis in original).
  45. *Prometheus*, 132 S. Ct. at 1302.
  46. *Id.* at 1303.
  47. See Tyler, *supra* note 31, at 840.
  48. *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011).
  49. *CLS Bank Int’l*, 2012 WL 2708400, at \*10. See also *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d at 1057 (claims not patent ineligible unless they “are so manifestly abstract ‘as to override the broad statutory categories of eligible subject matter’” (quoting *Research Corp. Technologies, Inc. v. Microsoft Corp.*, 627 F.3d at 868)).
  50. *Prometheus*, 132 S. Ct. at 1303.
  51. *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008).
  52. *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010).
  53. *Prometheus*, 132 S. Ct. at 1302.
  54. *Id.* at 1303.
  55. See Tyler, *supra* note 31, at 840; Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-part-iv-machine-or-transformation-we-hardly-knew-thee.html> (Mar 31, 2012).
  56. *CLS Bank Int’l*, 2012 WL 2708400, at \*8, 12-13.
  57. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 132 S. Ct. 1794 (2012); *WildTangent, Inc. v. Ultramercial, LLC*, 132 S. Ct. 2431 (2012).
  58. 653 F.3d 1329, 1350 (Fed. Cir. 2011).
  59. 657 F.3d 1323, 1328 (Fed. Cir. 2011).
  60. *High Court’s Mayo Standards Applicable to Myriad Remand Stakeholders Say*, [2012] 83 Pat. Trademark & Copyright J. (BNA) No. 2062, at 809 (Apr 6, 2012); *Willgoos*, *supra* note 33 at 122-23; *Klaiber*, *supra* note 32 at 969-71; Posting by Dennis Crouch to Patently-O, <http://www.patentlyo.com/patent/2012/05/patentable-subject-matter-supreme-court-challenges-chief-judge-raders-broad-notion-of-software-patentability.html> (May 21, 2012).
  61. 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature, Andrew H. Hirschfeld, Deputy Commissioner for Patent Examination Policy, USPTO (July 3, 2012) (available at [http://www.uspto.gov/patents/law/exam/2012\\_interim\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf)).
  62. *Id.* at 3.
  63. *Sachs V*, *supra* note 35; *Klaiber*, *supra* note 32, at 970.
  64. *Prometheus*, 132 S. Ct. at 1296.
  65. John Witherspoon, *The Real Tragedy in Mayo v. Prometheus* [2012], 83 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2061 (Apr. 20, 2012), at 926-27.
  66. *Id.*
  67. Posting by Courtenay Brinckerhoff to PharmaPatents, <http://www.pharmapatentsblog.com/2012/05/24/puzzled-by-prometheus/> (Apr. 24, 2012).
  68. *Id.*
  69. Mayo, Myriad *Subject to Debate, Professors, IP Practitioners Argue*, 84 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2063 (May 4, 2012), at 21 (“Prometheus never walked away from the expressed fear that any physician, any researcher who thought about the level of metabolites in connection with a potential therapeutic result or marker would simply by virtue of thinking about that would be infringing. And I think that’s what nine justices find unacceptable, and all the rest I believe is mischief,” quoting Seth P. Waxman, former U.S. solicitor general, who opined that the Court thinks its holding is narrower than many people fear). See *Prometheus*, 132 S. Ct. at 1302 (“[These claims] tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor’s subsequent treatment decision *whether that treatment does, or does not, change* in light of the inference he has drawn using the correlations.” (emphasis added)).

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# *Kappos v. Hyatt* and the Endangered Right of De Novo Judicial Review of Agency Decisions in the Wake of the America Invents Act

By Charles E. Miller

## I. Introduction

On April 18, 2012, the U.S. Supreme Court in *Kappos v. Hyatt*<sup>1</sup> unanimously affirmed the Federal Circuit's en banc holding<sup>2</sup> that there are no restrictions beyond those spelled out in the Federal Rules of Evidence and the Federal Rules of Civil Procedure on the ability of an aggrieved patent applicant to introduce in district court evidence relevant to a disputed administrative finding of fact underlying the PTO's rejection of a patent application. Consistent with the right to proffer additional evidence, the court must make its own de novo fact-findings, taking into account the additional evidence together with the evidence already in the PTO administrative record, regardless of whether the additional evidence in and of itself suggests that the agency's findings were erroneous.

*Hyatt* is an important bulwark against the PTO's proclivity toward insulating its fact-finding from de novo district court review,<sup>3</sup> where, as *Hyatt* makes clear, all relevant non-cumulative evidence must be considered. The Supreme Court was not persuaded by the PTO's advocacy of the exclusion of evidence that could have been—but for whatever reason was not—presented during the administrative (examination) stage of the proceeding. Had the agency prevailed, it would have diminished, devalued, and discouraged the exercise of the right of aggrieved parties to challenge adverse PTO decisions—in *Hyatt* the rejection of a patent application—in an Article III court.<sup>4</sup>

In this article, I examine *Hyatt* and explain how it informs a number of principles and “best practices” that are of paramount practical importance to the well-being of the U.S. patent system.

## II. Background

On June 6, 1995, on the eve of the effective date of the 20-year-from-filing patent term provisions of the Uruguay Round Agreements Act (URAA),<sup>5</sup> an electrical engineer, businessman, and registered patent agent named Gilbert P. Hyatt applied for a U.S. patent as the sole designated inventor of a computer system for processing and displaying visual image information. The patent application, No. 08/471,702, entitled “Improved Memory Architecture Having a Multiple Buffer Output Arrangement,” had antecedents going back at least as far as 1984 that included a 238-page specification with 15 claims (eventually increased during prosecution to 117 claims occupy-

ing 79 pages) and 40 sheets of drawings. The PTO examiner rejected many of Hyatt's claims for lack of descriptive support in the specification as required by 35 U.S.C. § 112, ¶ 1. The rejection listed 13 multi-word limitations in 79 of the 117 claims that purportedly had no support in the specification. Hyatt, prosecuting his application pro se, replied to the rejection by submitting a tabulation of the individual words in the claim limitations together with representative pages and line numbers of the specification where those words appeared—but without pointing out the substance of the limitations themselves.

Hyatt's reply failed to persuade the examiner to withdraw the rejection, and Hyatt appealed to the Board in September 1998.

In an unpublished, non-precedential decision issued in July 2002, the Board ruled that Hyatt's traversal of the section 112 rejection was insufficient, characterizing it as being unhelpful, in part misleading, and merely akin to citing pages in a dictionary where particular words can be found in order to explain the meaning of passages in a book containing combinations of those words.

In his post-appeal brief in support of a request for rehearing, Hyatt offered new, claim-by-claim arguments in support of his traversal of the rejection. The Board denied the request on the ground that under the PTO's rules Hyatt had waived his right to present the arguments because they could and should have been made to the examiner and in Hyatt's initial administrative appeal brief.

In April 2003, Hyatt, now represented by counsel, sued the PTO in the U.S. District Court for the District of Columbia. His decision to pursue a civil action in district court—which he had to pay for out of his own pocket—rather than to appeal directly to the Federal Circuit presumably was motivated by the need to buttress his case with the additional information the Board had refused to consider. This would not have been possible in a direct appeal to the Federal Circuit under section 141, since the court's review would have been confined by section 144 to the administrative record. Nor was the filing of a continuing application indicated in order to adduce the required additional evidence, since doing so would have forfeited Hyatt's right to a patent term of 17 years from issuance if his application ultimately were granted.<sup>6</sup>

The PTO moved for summary judgment on the ground that the Board's affirmance was supported by the requisite “substantial evidence” in the administrative re-

cord, which justified deference to the PTO's fact-findings. Hyatt countered that there were genuine issues of material fact and submitted a written declaration setting forth the information he had initially presented to the Board in his petition for rehearing and that the Board had refused to consider because it was deemed untimely. The district court, in an unpublished memorandum opinion,<sup>7</sup> granted the PTO's motion after sustaining the PTO's objection to Hyatt's evidentiary declaration on the grounds that, *inter alia*, it constituted the presentation of new facts without justification for having failed to present them to the PTO. Under its interpretation of section 145, the court excluded the declaration as inexcusably late because it could have been presented during the prosecution of the application.<sup>8</sup>

### III. Federal Circuit Proceedings

Following the district court's denial of his motion for reconsideration, Hyatt appealed to the Federal Circuit. In a split decision, the panel (consisting of Judges Michel, Dyk, and Moore) affirmed, with Judge Moore dissenting.<sup>9</sup> The majority held that the district court did not abuse its discretion in excluding Hyatt's declaration evidence because Hyatt had *willfully* (not negligently, as the district court found) withheld it from the PTO, and the evidence of record before the PTO was substantial enough to warrant summary judgment.<sup>10</sup>

The majority noted that the court had never squarely addressed the issue of what standard governed district courts in ruling on the admissibility of evidence withheld during examination in the PTO.<sup>11</sup> It observed that although in some circumstances new evidence can be submitted, the right to do so is not unfettered and that there are situations in which new evidence can be excluded:<sup>12</sup> "[I]t has been the general practice of federal courts for over eighty years in certain circumstances to exclude evidence which a party could and should have introduced before the Patent Office but did not despite an obligation to do so."<sup>13</sup> In responding to the dissent's argument that a new trial is required when non-cumulative relevant new evidence is presented to the trial court, the majority attached considerable importance to the holding in *Barrett Co. v. Koppers Co.*<sup>14</sup> that "'the plaintiffs in this action...are estopped to offer evidence which was wholly within their possession and control at the interference proceeding and which they withheld from that proceeding.'"<sup>15</sup>

In addressing the Administrative Procedure Act (APA) (which the trial court did not do), the majority acknowledged that "[t]he usual rule...that judicial review of agency action should be on the agency record, regardless of whether the action is in the court of appeals or in district court"<sup>16</sup> could be overridden if the statute explicitly provides for adjudication and trial de novo. The opinion concluded that section 145 does not do this, noting that "[t]he ambiguous silence of § 145 on the admissi-

bility of evidence does not meet the high bar the Supreme Court has set for implying trial de novo."<sup>17</sup>

As to when new evidence may be introduced, the majority referred to *Citizens to Preserve Overton Park Inc. v. Volpe*.<sup>18</sup>

As the Supreme Court stated in *Overton Park*, where "agency factfinding procedures are inadequate," the APA allows a district court to take additional evidence. For example, the PTO does not take oral testimony in an examination of a patent application. In some cases credibility determinations will be very important to the resolution of the case, for example, where there is a question about the date of reduction to practice which will determine what is, or is not, prior art. In such circumstances, it makes sense to permit the district court to hear live testimony under *Overton Park* to resolve credibility issues because the PTO procedures are inadequate.<sup>19</sup>

The court noted that "none of the cited Congressional testimony specifically addresses situations where an applicant sought to overcome the consequences of his own refusal to adhere to the rules of prosecuting a patent application,"<sup>20</sup> and opined that Hyatt "was obligated to respond to the examiner's written description rejection by *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996)."<sup>21</sup> Criticizing Hyatt's offer of "Table 1" in response to the examiner's rejection, the panel majority ruled that his failure to reply adequately was not negligence, as the lower court had found, but rather, a willful refusal to cooperate, "even though [Hyatt] necessarily possessed the information the examiner sought by the time he filed his application."<sup>22</sup> The court continued:

*On these facts*, the district court's exclusion of Hyatt's new evidence must be affirmed.... [I]t is clear from the record that Hyatt willfully refused to provide evidence in his possession in response to a valid action by the examiner. Such a refusal to provide evidence which one possessed was grounds in *Barrett* to exclude the withheld evidence. Similarly, we hold that in light of Hyatt's willful non-cooperation here, the district court did not abuse its discretion by excluding the Hyatt declaration.

....

There is, under *Alton*, only one acceptable response to a written description rejection: showing the examiner where by col-

umn and line number in the specification he may find written description support for each disputed claim limitation.<sup>23</sup>

After rejecting Hyatt's counter-arguments as offering "no acceptable excuse for his failure to properly present his declaration to the PTO,"<sup>24</sup> the court concluded that the district court did not abuse its discretion by excluding the declaration.

In dissent, Judge Moore criticized the majority for engaging in appellate fact-finding in concluding that Hyatt had willfully failed to present his best case to the PTO.<sup>25</sup> She noted that neither the district court judge nor the PTO had made any findings of "willful withholding or intentional suppression."<sup>26</sup> Consequently, "[e]ither the majority is engaging in appellate fact finding or it is determining that breach of its newly created affirmative duty is willful withholding as a matter of law.... Ultimately, the majority's sweeping exclusionary rule is far broader than anything argued by the parties."<sup>27</sup>

Judge Moore characterized the majority's holding as the judicial promulgation of a "sweeping exclusionary rule" that imposes "an affirmative duty" or "obligation" on patent applicants to submit all available evidence to the PTO, effectively preventing the unfettered proffer of new evidence in district court and thereby "tak[ing] away this patent applicant's fundamental right" to a civil action under section 145.<sup>28</sup> She reasoned that the majority opinion made the section 145 proceeding "more of an appeal than the new civil action contemplated and enacted by Congress."<sup>29</sup>

Judge Moore also questioned the majority's reliance on *In re Alton*, noting that while the case stood for shifting the burden of production after an examiner's written-description rejection, the burden shifts for any rejection. If such burden-shifting creates "an affirmative duty," she wrote, then the result is a "per se rule that an applicant is deemed to have willfully withheld anything he possessed during prosecution that was responsive to a rejection regardless of the applicant's actual intent," which she described as a "strict liability approach."<sup>30</sup>

Judge Moore concluded by observing that the majority had blurred the line between an appeal pursuant to section 141 and a civil action under section 145: "The admissibility of new evidence is exactly what distinguishes § 145 from § 141."<sup>31</sup>

After Hyatt moved for a rehearing, the court vacated the panel decision and reinstated Hyatt's appeal for the purpose of rehearing it en banc.<sup>32</sup> Sitting en banc, the court issued a 7-2 decision vacating the summary judgment order and remanding the case to the district court.<sup>33</sup>

The majority opinion, written by Judge Moore, held that the district court had applied the wrong standard for admitting evidence in a section 145 action and thereby

had abused its discretion in determining that Hyatt's negligence affected admissibility.<sup>34</sup> The court held that section 145 permits the entry of any relevant (competent) evidence otherwise admissible under the Federal Rules of Evidence and the Federal Rules of Civil Procedure without regard to why it was not presented during the administrative stage of the proceedings. The court noted that the substantial evidence standard does not apply when new evidence is introduced: "The presence of such new or different evidence makes a factfinder of the district judge,"<sup>35</sup> and "the district court...must make de novo fact findings with respect to factual issues to which the new evidence relates."<sup>36</sup>

Judge Pauline Newman, concurring in part and dissenting in part, went further, asserting that the "statutory plan" of section 145 did not contemplate district court deference to the PTO's fact-findings even in the absence of new evidence. This position is inconsistent with the Supreme Court's dicta in *Dickinson v. Zurko*,<sup>37</sup> and would have effectively overruled the Federal Circuit's holding in *Mazzari v. Rogan*.<sup>38</sup> Probably for that reason, her position was never advanced by Hyatt, although during oral argument some of the Supreme Court justices solicited the view of counsel regarding Judge Newman's position but did not probe their answers.

In a dissenting opinion, Judge Dyk, joined by Judge Gajarsa, opined that section 145 actions should not depart from what the judges regarded as settled administrative law, namely, that new evidence may not be admitted in district court if it could have been introduced and considered during the proceedings before the PTO but for the fact, for example, that the agency's procedures were inadequate to receive and entertain the evidence (such as the direct and cross examination of live witnesses). Judge Dyk was concerned that the majority opinion would encourage the deliberate withholding of evidence from the PTO by patent applicants seeking "a more hospitable forum" in the district court where non-expert judges would be more likely to accept it at face value than PTO examiners and administrative patent judges with superior technical and patent law expertise.<sup>39</sup>

#### IV. The Supreme Court Ruling

The government filed a *cert* petition with the Supreme Court on April 7, 2011, which Hyatt opposed. In supplemental briefs, the parties addressed the Supreme Court's June 9 holding in *Microsoft Corp. v. i4i Limited Partnership*,<sup>40</sup> which confirmed the clear-and-convincing evidence standard for challenging patent validity under 35 U.S.C. § 282 in adversarial court litigation. The Supreme Court granted *certiorari*.

The main issue faced by the Court, stated broadly, was whether in a civil action arising from a government agency decision, relevant, non-cumulative evidence that for whatever reason was not presented (but could have



been presented) during the administrative proceeding must be considered by the court in a de novo judicial review of the administrative decision. The Department of Justice, representing the PTO, argued that the new evidence presented by Hyatt, albeit relevant, was properly excluded because Hyatt's failure to present it at the administrative stage was either willful or negligent. Hyatt argued that section 145 imposes no special, heightened standard of admissibility that would justify such exclusion; rather, he argued, the statute allows the proffer of additional evidence in district court actions and imposes no limitations on the admission of such evidence beyond the provisions of the Federal Rules of Evidence as applied to civil actions under the Federal Rules of Civil Procedure.

The specific issues certified for decision by the Court were framed by two questions set forth in the PTO's cert petition:

1. Whether the plaintiff in a section 145 action may introduce new evidence that could have been presented to the agency in the first instance.
2. Whether, when new evidence is introduced under section 145, the district court may decide de novo the factual questions to which the evidence pertains, without giving deference to the prior decision of the PTO.

The Court, in a unanimous opinion by Justice Clarence Thomas, decided both questions in the affirmative. Further to the Court's statement in *Dickinson v. Zurko*<sup>41</sup> that a patent applicant may present new evidence to the district court that was not presented to the PTO, "there are no evidentiary restrictions [on a patent applicant's ability to introduce new evidence in a section 145 district court civil action] beyond those already imposed by the Federal Rules of Evidence and the Federal Rules of Civil Procedure."<sup>42</sup> Regarding what standard of review the district court should apply when considering new evidence, the Court held that the district court must make a de novo finding when new evidence is presented on a disputed question of fact, as "it makes little sense for the district court to apply a deferential standard of review to PTO factual findings that are contradicted by the new evidence."<sup>43</sup> The PTO, the Court stated, "cannot account for evidence that it has never seen."<sup>44</sup> Thus, the district court must make its own findings de novo and not act as the "reviewing court" envisioned by the APA.<sup>45</sup> The Court noted that the district court "cannot meaningfully defer to the PTO's factual findings if the PTO considered a different set of facts."<sup>46</sup> The Court concluded that the proper means for the district court to accord respect to decisions of the PTO was through the court's broad discretion over the weight to be given to evidence newly adduced in the section 145 proceedings.<sup>47</sup>

As for what weight to give the new evidence, the Court held that the district court may consider whether

the applicant had an opportunity to present the evidence to the PTO.<sup>48</sup> The Court also held that the principles of administrative exhaustion do not apply in a section 145 proceeding because "by the time a § 145 proceeding occurs, the PTO's process is complete."<sup>49</sup> Section 145 "does not provide for remand to the PTO to consider new evidence, and there is no pressing need for [remand] because a district court, unlike a court of appeals, has the ability and the competence to receive new evidence and to act as a factfinder."<sup>50</sup>

## V. Why Hyatt Is Important

It is fortunate for the patent community that the PTO failed to persuade the Court to adopt a rule that would have saddled district courts with the task of having to decide whether to exclude relevant evidence that was not, but could have been, presented at the agency level. The result sought by the PTO would have hamstrung the business community's ability to rely on the judicial process by foreclosing the right to proffer evidence beyond the administrative record when necessary to refute the factual bases for adverse PTO decisions where it might not have been feasible to introduce the evidence at the administrative stage. Examples include the presentation of live testimony (whether presented by the party or subpoenaed by a third party), survey and statistical evidence, and experimental test results needed, for example, to address alleged inherent disclosures in prior art references.

Any inventor, assignee, or licensee could find itself in the position of having to proffer additional relevant evidence in order to overcome a final adverse ruling at the administrative stage of patent application proceedings. A plenary civil action in district court is intended to provide effective recourse. The admissibility—and excludability—of additional evidence in section 145 actions henceforth will be governed only by the Federal Rules of Evidence, which apply generally to all civil actions under the Federal Rules of Civil Procedure. The district court's threshold acceptance of such evidence will not be affected by the fact that it could have been presented at the administrative stage, regardless of why it was not. There are sound reasons for this:

- The limited scope of judicial review afforded by an appeal to the Federal Circuit makes it highly unlikely that Board decisions based on erroneous fact-findings can be overcome when such findings are supported by substantial evidence.<sup>51</sup>
- Admitting new evidence and then weighing its probative value as opposed to excluding it altogether makes for a full evidentiary record in the district court for subsequent appeal to the Federal Circuit under 28 U.S.C. § 1295(a)(1) and (4)(C), thereby optimizing the prospect of a just result and promoting the uniformity of appellate review.<sup>52</sup>

- The filing of continuing applications or requests for continued examination (RCEs) in lieu of seeking de novo judicial review in district court in order to introduce additional evidence places applicants at an unfair disadvantage when the evidence required, e.g., oral (lay or expert) testimony, cannot be entertained or considered by the PTO or only can be compelled from third parties for which subpoenas are not available in non-contested cases.<sup>53</sup>
- The loss of accrued patent term adjustment (PTA) when a continuing application is filed, and the loss of PTA (for “three-year delay”) accrued prior to appealing to the Board or filing an RCE, would unfairly penalize patent applicants in situations where time is required to obtain and process additional evidence needed to traverse examiners’ rejections. By contrast, a section 145 action affords the applicant as plaintiff the opportunity to adduce more evidence while retaining all PTA accrued prior to Board appeal and adds additional PTA for the entire period between the administrative appeal and the (favorable) court decision.<sup>54</sup> Of course, a section 145 action comes at a steep price to the applicant, who must pay for the entire case, thereby discouraging such recourse when direct appeal to the Federal Circuit would suffice.<sup>55</sup>
- With the certainty provided by *Hyatt* that new evidence submitted in section 145 actions will not be excluded so long as it is relevant and non-cumulative, IP portfolio managers and patent practitioners can exercise sound judgment in making prudent decisions affecting the timing, cost, and extent of generating and presenting evidence that demonstrates the patentability of inventions and the allowability of patent applications without fear of being limited in district court for all intents and purposes to a Federal Circuit-type deferential standard of review of the factual bases of adverse PTO decisions.<sup>56</sup>

In non-contested (ex parte) administrative proceedings, the PTO has long been averse to allowing those aggrieved by its actions to have recourse in district court. That aversion was manifested nine years ago when the agency, through rulemaking, sought to eliminate district court jurisdiction over administrative decisions in ex parte patent reexaminations requested post-November 28, 1999.<sup>57</sup> The rule in question, 37 C.F.R. § 1.303(d), has been criticized<sup>58</sup> as invalid for having been prescribed without statutory authority.<sup>59</sup> The agency’s attitude unfortunately has resurfaced, this time in the Leahy-Smith America Invents Act (AIA). In particular, sections 6(h)(2)(A) and 7(c)(1) of the AIA amend 35 U.S.C. §§ 141 and 306 to bestow immunity from suit upon the PTO *nunc pro tunc* in patent reexaminations, without regard to when the request for reexamination was filed. Patent owners are thereby stripped of their long-standing statutory right

to challenge adverse decisions of the agency in these non-contested (ex parte) cases through a civil action in federal district court.<sup>60</sup>

Likewise, with respect to contested (inter partes) administrative proceedings, the AIA established two new post-patent-grant revocation (claim invalidation) procedures, namely, “inter partes review” under section 6(a) and “post-grant review” under section 6(d). Revised section 319 in chapter 31 and section 329 in new chapter 32, together with 35 U.S.C. § 141, as revised by section 7(c)(1), preclude district court jurisdiction over PTO decisions in those cases as well.<sup>61</sup>

Also troubling is the possibility of future problems arising out of the concurring opinion by Justice Sotomayor, joined by Justice Breyer, which reads in pertinent part:

Consistent with ordinary equity practice and procedure, there may be situations in which a litigant’s conduct before the PTO calls into question the propriety of admitting evidence presented for the first time in a § 145 proceeding before a district court. The most well-known example was presented in *Barrett Co. v. Koppers Co.*, 22 F.2d 395, 396 (C.A. 3 1927), a case in which the Barrett Company, during proceedings before the Patent Office, “expressly refused to disclose and to allow their witnesses to answer questions” essential to establishing the priority of its invention. After the Patent Office ruled against it, the Barrett Company attempted to present in a subsequent R.S. 4915 [the predecessor of 35 U.S.C. § 145] proceeding “the very subject-matter concerning which...witnesses for the [patent] application were asked questions and the Barrett Company forbade them to answer.” *Id.*, at 396. The Third Circuit understandably found the Barrett Company estopped from introducing evidence that it had “purposely” withheld from prior factfinders, lest the company be allowed “to profit by [its] own...wrong doing.” *Id.*, at 397.

....

Because there is no suggestion here that [Hyatt’s] failure to present the evidence in question to the PTO was anything other than the product of negligence or a lack of foresight, I agree that [Hyatt] was entitled to present his additional evidence to the District Court. But I do not understand today’s decision to foreclose a district court’s authority, consistent with “the ordinary course of equity

practice and procedure,” *ante*, at 1700 (quoting *Butterworth*, 112 U.S., at 61, 5 S. Ct. 25), to exclude evidence “deliberately suppressed” from the PTO or otherwise withheld in bad faith. For the reasons set out by the Court, see *ante*, at 1700-1701, an applicant has little to gain by such tactics; such cases will therefore be rare. In keeping with longstanding historical practice, however, I understand courts to retain their ordinary authority to exclude evidence from a § 145 proceeding when its admission would be inconsistent with regular equity practice and procedure.<sup>62</sup>

When would the admission of new evidence in a section 145 proceeding be “inconsistent with regular equity practice and procedure”? It would not be an unreasonable stretch of the imagination to suppose that the PTO will try to exploit the above-quoted language by inquiring of patent applicants during the prosecution stage whether all of the evidence available to the applicant that supports the traversal of a rejection has been submitted. Could the failure to respond or to identify any such evidence that was available at the time be used by the PTO to estop the applicant in subsequent prosecution or to support an inference later on that evidence newly presented in a section 145 action that could in theory have been presented (although perhaps at great expense) during the examination stage had been “deliberately suppressed” or “otherwise withheld from the PTO in bad faith” rather than for cost savings? That an applicant would, for no good reason, engage in “deliberate suppression” of or “withhold in bad faith” existing or procurable evidence supportive of patentability in the administrative proceeding is too counterintuitive, illogical, unrealistic, and improbable to warrant serious concern. Even in a case like that of *Hyatt*, whose pre-GATT application might benefit from prolongation of its pendency, such withholding would seem far-fetched given the loss of royalty income that would ensue, not to mention the likelihood of obsolescence of the invention by the time the patent was granted.

Despite the virtual impossibility of such a speculative scenario, it creates a tension between the PTO’s goal in limiting the bases for section 145 civil actions, on the one hand, and the exercise of sound professional judgment on the part of patent practitioners in foregoing “data dumps” of evidence of patentability<sup>63</sup> in the PTO beyond what is necessary and prudent, on the other. In such circumstances, one would be well advised to respond to the PTO’s inquiry by stating that, in the professional opinion and judgment of the applicant’s representative, the evidence presented is considered sufficient to address the rejection and that the applicant reserves the right to present additional supporting evidence as may be appropriate in the event a subsequent de novo judicial review proceeding becomes necessary.

It remains to be seen whether the PTO, emboldened by the perception of indifference on the subject within the patent community,<sup>64</sup> could thwart the prophylactic benefit of such a response through rulemaking statutorily authorized by some future “technical” amendment or “tweak” of the AIA or by persuading Congress to statutorily limit the evidentiary scope of section 145 or to eliminate the section entirely, thereby achieving a devastating inroad toward what would appear to be the PTO’s objective of abolishing once and for all the right of de novo judicial review of its decisions.

## VI. Conclusion

What is the take-away from *Hyatt*? The Supreme Court rejected an argument by the PTO that, if accepted, would have harmed the interests of the inventive and business communities by distorting and frustrating the constitutional purpose of the patent system, which is and has always been “[t]o promote the Progress of...useful Arts.”<sup>65</sup> For many years the PTO has tried to preclude patent applicants and their assignees and licensees from fully exercising their right to seek plenary, district-court review of adverse PTO decisions. In the long run, what the PTO sought would have created uncertainty in the minds of inventors and entrepreneurs, who must be able to rely on settled business expectations grounded on a stable patent system that justifies and encourages the efficient investment of risk capital in developing and fostering the creation, legitimate protection, and enjoyment of quiet title to technological innovations.

Fortunately, the Supreme Court unanimously endorsed the long-standing principle of full de novo judicial review of PTO decisions by means of a civil action against the agency. Unfortunately, however, the outcome urged unsuccessfully by the PTO in *Hyatt* may yet loom over the inventive community through future legislation and rule-making. Indeed, this has happened already in the area of administrative post-grant review procedures under the AIA, for which the patent community will pay dearly.<sup>66</sup>

## Endnotes

1. 566 U.S. \_\_\_, 132 S. Ct. 1690 (2012) (Thomas, J.) (concurring opinion by Sotomayor and Breyer, JJ.).
2. *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010) (en banc).
3. “De novo judicial review”—as opposed to appellate judicial review—is defined in Black’s Law Dictionary 924 (9th ed. West Group 2009), as “[a] court’s nondeferential review of an administrative decision, usually through a review of the administrative record plus any additional evidence the parties present.” The phrase is a convenient shorthand but somewhat misleading, inasmuch as a court does not “review” a tribunal’s decision on an evidentiary record after the record has been supplemented by new evidence. It suggests a tension between “review” and the prefatory words “de novo.” At the risk of putting too fine a point on it, the present author suggests that one might instead consider thinking of it in terms of “judicial adjudication” of an administrative decision. The de novo judicial review sought in *Hyatt* was thus a recourse aimed at an adjudication in district court, in contrast to direct recourse to the Federal Circuit which



would have entailed an appellate review requiring deference to the agency's fact-findings on a record fixed at the administrative stage—provided the evidence in the record was “substantial”—with no opportunity to introduce rebuttal evidence aimed at refuting those findings.

4. Although other types of civil actions against the PTO were not addressed in *Hyatt*, the Court's holding in the case affects the admissibility of evidence in contexts other than patent applications, namely, under 35 U.S.C. § 32 (decisions in disciplinary proceedings), 35 U.S.C. § 154(b)(4)(A) (decisions on patent term adjustments), 35 U.S.C. § 156 (decisions on patent term extensions), and 15 U.S.C. § 1071(b)(3) (decisions in trademark registration applications).
5. Pub. L. No. 103-465, Dec. 8, 1994, amending 35 U.S.C. §§ 104, 111, 154, and 271. Under the URAA, U.S. patents issued on applications filed before June 8, 1995 have terms of 17 years from the grant date without regard to the filing date of any antecedent application. Patents issuing on applications filed thereafter have terms of 20 years from the filing date of the earliest U.S. non-provisional application to which priority has been claimed under 35 U.S.C. § 120. *See* 35 U.S.C. § 154(a)(2). Had *Hyatt* forfeited his right to a 17-year patent term from the grant date by filing a continuing application, he would not have been able to obtain a patent of any value.
6. *See supra* note 5.
7. No. 03-0901(HHK), 2005 WL 5569663 (D.D.C. Sept. 30, 2005).
8. *Hyatt's* declaration was treated by the district court essentially as a document whose contents constituted additional evidence. On the other hand, one could say that the actual purpose of the declaration was to point out where the evidence required under section 112 to support the rejected claims already existed in the specification of the patent application which was part of the administrative record and hence was not new evidence at all. Viewed as such, the declaration was more in the nature of an argument that *Hyatt* (or his attorney had he had one at the time) could have presented in the “Remarks” section of his response to the examiner's rejection rather than in a subsequent declaration, or even in an appeal brief in the Federal Circuit had he chosen that route. This point was not discussed by the parties to any significant extent during the appellate review of the district court's granting of summary judgment in the wake of the exclusion of *Hyatt's* declaration.
9. *Hyatt v. Doll*, 576 F.3d 1246 (Fed. Cir. 2009).
10. *Id.* at 1247-79.
11. *Id.* at 1253.
12. *Id.* at 1261.
13. *Id.* at 1266.
14. 22 F.2d 395 (3d Cir. 1927).
15. *Hyatt v. Doll*, 576 F.3d at 1262-63 (quoting *Barrett*, 22 F.2d at 397).
16. *Id.* at 1267.
17. *Id.* at 1269 n.22.
18. 401 U.S. 402 (1971).
19. *Hyatt v. Doll*, 576 F.3d at 1270.
20. *Id.* at 1272.
21. *Id.* at 1274.
22. *Id.* at 1274-75.
23. *Id.* at 1275, 1278 (footnotes omitted).
24. *Id.* at 1277.
25. *Id.* at 1279-90.
26. *Id.* at 1279.
27. *Id.*
28. *Id.*
29. *Id.* at 1279-80.
30. *Id.* at 1287.
31. *Id.* at 1289.
32. *Hyatt v. Kappos*, 366 F. App'x 170 (Fed. Cir. 2010).
33. *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010).
34. *Id.* at 1338.
35. *Id.* at 1333 (quoting *Dickinson v. Zurko*, 527 U.S. 150, 164 (1999)).
36. *Id.* at 1336.
37. 527 U.S. 150 (1999).
38. 323 F.3d 1000 (Fed. Cir. 2003).
39. *Hyatt v. Kappos*, 625 F.3d at 1342-44.
40. 564 U.S. \_\_\_, 131 S. Ct. 2238 (2011).
41. 527 U.S. at 164.
42. *Kappos v. Hyatt*, 132 S. Ct. at 1694.
43. *Id.* at 1694, 1696.
44. *Id.* at 1696.
45. *Id.*
46. *Id.* at 1700; *cf. Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. at \_\_\_, 131 S. Ct. at 2251 (noting that “if the PTO did not have all material facts before it, its considered judgment may lose significant force”).
47. *Kappos v. Hyatt*, 132 S. Ct. at 1700.
48. *Id.* at 1694.
49. *Id.* at 1696-97 (citing *McKart v. United States*, 395 U.S. 185, 193-94 (1969)).
50. *Id.* at 1697.
51. It is difficult—and in many cases quite futile—to advocate Federal Circuit reversal of PTO decisions by attacking the agency's fact-findings when they are supported by substantial evidence in the administrative record which cannot be altered or supplemented at the appellate review stage. This is illustrated time and time again in the case law, most recently, for example, in *In re Hyon*, 679 F.3d 1363 (Fed. Cir. 2012), and *In re Breiner*, No. 2011-1387, 2012 WL 1631021 (Fed. Cir. May 10, 2012) (nonprecedential).
52. *See supra* Part IV.
53. By characterizing a particular administrative proceeding as contested or non-contested, can the PTO, through its own rulemaking, determine or limit the availability of an Article III court's 35 U.S.C. § 24 subpoena power and other discovery devices under 35 U.S.C. § 23? *See infra* note 57. Given that 35 U.S.C. §§ 23 and 24 remain unchanged by the AIA, and that the ability or inability to obtain discovery affects a party's right to adduce evidence in support of the merits of its case, the PTO thus has acquired a subtle form of *substantive* rulemaking authority which Congress may not have intended the agency to have. *See Cordis Corp. v. Kappos*, Civil Action No. 1:12-cv-75, filed Jan. 26, 2012 (E.D. Va.).
54. 35 U.S.C. § 154(b)(1)(C)(iii).
55. 35 U.S.C. § 145, last sentence.
56. *See supra* Part IV.
57. 37 C.F.R. § 1.303(d) (2003) (“For an ex parte reexamination proceeding filed on or after November 29, 1999,...no remedy by civil action under 35 U.S.C. 145 is available.”). The rule when prescribed was (in the present author's opinion) ultra vires and hence invalid. *See* Charles E. Miller & Daniel P. Archibald, *Interpretive Agency-Rulemaking vs. Statutory District Court Review-Jurisdiction in Ex Parte Patent Reexaminations*, 92 J. Pat. & Trademark Off. Soc'y 498, 502 n.7 (2010). In a case of first impression, *Teles AG v. Kappos*, \_\_ F. Supp. 2d \_\_\_, 2012 WL 695610 (D.D.C. 2012) (Howell, J.), the district court addressed the question as to whether 35 U.S.C. § 306 confers pre-AIA district-court jurisdiction under 35 U.S.C. § 145 of PTO decisions in post-November 28, 1999 ex

parte reexaminations (thereby providing discovery mechanisms under the Federal Rules of Civil Procedure that are not available in direct appellate review in the Federal Circuit). The court did not address the validity vel non of 37 C.F.R. § 1.303(d), *Teles*, 2012 WL 695610, at \*7 n.8, notwithstanding that the rule flies in the face of the express language of 35 U.S.C. § 306 in effect at the time (“The patent owner involved in a[n ex parte] reexamination proceeding...may seek court review under the provisions of sections 141 to 145 of this title, with respect to any decision [of the Board] adverse to the patentability of any...claim of the patent.”), *Teles*, 2012 WL 695610, at \*2 (emphasis added) (quoting 35 U.S.C. § 306 (2006)). An appeal of the district court’s March 5, 2012 ruling was filed in the Federal Circuit on April 3, 2012.

58. See Charles E. Miller & Daniel P. Archibald, *supra* note 57, at 502 n.7.
59. Prior to the AIA, the PTO’s rulemaking authority was strictly set forth in 35 U.S.C. § 2(b)(2). *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008), *aff’d in part and vacated in part sub nom. Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir.), *vacated en banc*, 328 F. App’x 658 (Fed. Cir.), *appeal dismissed sub nom. Tafas v. Kappos*, 586 F.3d 1369 (Fed. Cir. 2009). See Charles E. Miller & Daniel P. Archibald, *supra* note 57, at 501 n.3.
60. A more detailed treatment of this aspect of the AIA is contained in a soon-to-be-published article by Charles E. Miller & Daniel P. Archibald, tentatively titled *Beware the Suppression of District-Court Jurisdiction of Administrative Patent-Validity Determinations Under the America Invents Act: A Critical Analysis of a Legislative Black Swan in an Age of Preconceived Notions and Special-Interest Lobbying*. Preprints are available from the present author upon request.
61. See *supra* note 60.
62. *Kappos v. Hyatt*, 132 S. Ct. at 1701-02 (Sotomayor, J., concurring) (second and third brackets and alterations in first paragraph in original).
63. Such an attitude is not inconsistent with the *ratio decidendi* of the holding in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc). A patent applicant’s behavior in withholding evidence *supportive* of patentability in order to avoid unduly burdening the application record would be of no relevance to the duty of disclosure under 37 C.F.R. § 1.56 because it could not be a basis for imputing to the applicant the *mens rea* required to prove inequitable conduct.
64. Some have posited that the filing of only a few hundred section 145 civil actions since the 1952 Patent Act came into effect, and of numerous such suits under the predecessor statutes, evinces a degree of desuetude relative to direct appeals to the Federal Circuit. From this they argued that such de novo judicial review of PTO decisions no longer serves its purpose, thereby warranting the abolition of section 145 (not to mention the trademark (Lanham Act) counterpart, 15 U.S.C. § 1071(b)). Such an attitude gives one pause, to say the least. On that basis, why not abolish the sections of other titles of the United States Code that are supposedly underutilized?
65. U.S. Const. art. I, § 8, cl. 8.
66. See *supra* note 60.

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# So What'cha Want? The Need for Clarity in Copyright Infringement Cases Based on Digital Sampling

By Robert Potter, Andrew Gerber, and Olivia Harris

## I. Introduction

With rather unfortunate timing, hip-hop and R&B label TufAmerica sued the rap group the Beastie Boys (as well as the band's record label, among other music publishing entities) on May 3, 2012,<sup>1</sup> the day before Adam "MCA" Yauch, one of the group's three members, died of cancer at age 47.

In its complaint, TufAmerica—the exclusive licensee of the copyrights in the recordings of "Say What" and "Drop the Bomb" by funk band Trouble Funk—claims that at least four Beastie Boys recordings incorporate unauthorized samples from these two Trouble Funk recordings. Notably, in all four instances, TufAmerica admits that "[the Beastie Boys recording] effectively concealed to the casual listener the fact that the [Trouble Funk] sample was part of [the recording]" and that "[o]nly after conducting a careful audio analysis...was TufAmerica able to determine that [the Beastie Boys recording] incorporates the [Trouble Funk] [s]ample."<sup>2</sup>

Assuming these allegations are true, and while the Beastie Boys have not filed an answer as this goes to press, the band may well argue that because the samples are "concealed to the casual listener," the parties' works, as a whole, are not substantially similar and that the Trouble Funk samples are, in any event, *de minimis*. If either of these defenses is raised, this case will present a much-anticipated opportunity for the courts to address whether these defenses are availing—or even available—in the context of digital sampling.

## II. Substantial Similarity and the *De Minimis* Use Defense

Under U.S. copyright law, in order for the copying of a copyrighted work to be actionable, the copyrighted work and the allegedly infringing work must be substantially similar.<sup>3</sup> There is no bright-line test for substantial similarity. Over time, courts have developed varying tests for determining whether two works are substantially similar.<sup>4</sup>

The *de minimis* defense is commonly asserted against alleged substantial similarity in this context. The defense "insulates from liability those who cause insignificant violations of the rights of others."<sup>5</sup> As with substantial similarity, there is no bright-line test for determining a *de minimis* use, but the Second Circuit, in *Ringgold v. Black Entertainment Television, Inc.*,<sup>6</sup> articulated three ways in which the defense can be applied:

1. "First, *de minimis* in the copyright context can mean what it means in most legal contexts: a tech-

nical violation of a right so trivial that the law will not impose legal consequences."<sup>7</sup>

2. "Second, *de minimis* can mean that copying has occurred to such a trivial extent as to fall below the quantitative threshold of substantial similarity, which is always a required element of actionable copying."<sup>8</sup>
3. "Third, *de minimis* might be considered relevant to the defense of fair use."<sup>9</sup>

Courts in copyright cases often make a threshold analysis of substantial similarity and potential *de minimis* use in order to determine *prima facie* infringement liability. Once infringement has been established, courts then assess any affirmative defenses, including fair use, within which, as noted in *Ringgold*, *de minimis* use also can be a relevant factor.

In cases involving alleged digital sampling, however, the Sixth Circuit held in *Bridgeport Music, Inc., et al. v. Dimension Films, et al.*,<sup>10</sup> that the court need not engage in a substantial similarity or *de minimis* analysis to decide whether copyright infringement has occurred. Rather, the Sixth Circuit found, digital sampling is infringement *per se*.<sup>11</sup> Although *Bridgeport* has been heavily criticized,<sup>12</sup> it remains an unavoidable precedent for artists seeking to use digital samples—even very short ones, and even if the resulting work is not substantially similar to the sampled work—and thus merits close analysis.

## III. *Bridgeport Music, Inc. v. Dimension Films*

In *Bridgeport*, a two-second digital sample of three musical notes from George Clinton and the Funkadelics' recording of "Get Off Your Ass and Jam" were used in the song "100 Miles and Runnin'" by rap group NWA. The sample was a very short snippet of a guitar track that NWA had cut and looped in such a way that, according to the district court, it was no longer recognizable as originating from the underlying sound recording. The district court found that "no reasonable juror, even one familiar with the works of George Clinton, would recognize the source of the sampling without having been told of its source," and it held that the use was *de minimis* because it did not "rise to the level of a legally cognizable appropriation."<sup>13</sup> Accordingly, the court granted summary judgment to NWA.

The Sixth Circuit reversed, finding that *any* sampling of a sound recording, however small, constitutes copyright infringement *per se*. The court rejected categorically the application of a *de minimis* defense or even a substan-



tial-similarity analysis in the digital sampling context.<sup>14</sup> Instead, the court found that “even when a small part of a sound recording is sampled, the part taken is something of value.”<sup>15</sup> Accordingly, one must “[g]et a license or do not sample.”<sup>16</sup>

In reaching this conclusion, the Sixth Circuit relied upon section 114 of the Copyright Act, which states, in part, that the exclusive rights granted to copyright holders under section 106 of the Act “do not extend to the making or duplication of another sound recording that consists *entirely* of an independent fixation of other sounds, even though such sounds imitate or simulate those in the copyrighted sound recording.”<sup>17</sup> According to the *Bridgeport* court, “[t]his means that the world at large is free to imitate or simulate the creative work fixed in the recording so long as an actual copy of the recording itself is not made.”<sup>18</sup> From this noncontroversial conclusion the court then made the questionable leap of logic that because “you cannot pirate the whole sound recording,” you therefore cannot “‘lift’ or ‘sample’ something less than the whole.”<sup>19</sup>

In other words, the court concluded, because “a sound recording owner has the exclusive right to ‘sample’ his own recording,”<sup>20</sup> sampling by anyone else is essentially *per se* infringement.<sup>21</sup> The court thereby abdicated its responsibility to assess substantial similarity and effectively rejected even the possibility of a successful *de minimis* defense in connection with digital sampling.

#### IV. Questioning *Bridgeport*

*Bridgeport*’s holding, and its apparent blanket prohibition against unlicensed sampling, has been questioned in two subsequent decisions.

In *Saregama India Ltd. v. Mosley, et al.*,<sup>22</sup> defendants Timothy Mosley, producer of the sound recording “Put You on the Game,” and others involved with the sound recording and with the album on which it appears, argued that regardless of whether they actually sampled the plaintiff’s sound recording, the defendants’ sound recording was not substantially similar. The court found that “the only portion of [the plaintiff’s sound recording] found in [the defendants’ sound recording] is an approximately one-second snippet of a female vocal performance” and that it was “highly unlikely that the average lay observer could discern the source of the one-second snippet without prior warning.”<sup>23</sup> Because the court found no substantial similarity, it granted summary judgment to the defendants.

The *Saregama* court explicitly rejected the Sixth Circuit’s holding in *Bridgeport* that “any sampling of a sound recording constitutes infringement, no matter how small the sampled snippet,” stating that “the Sixth Circuit’s decision to carve out an exception for sound recordings has not been followed in this Circuit.”<sup>24</sup> The court went on to explain that “[the] Eleventh Circuit imposes a ‘substan-

tial similarity’ requirement as a constituent element of *all* infringement claims.”<sup>25</sup>

In *EMI Records Ltd. v. Premise Media Corp. L.P.*,<sup>26</sup> a New York state court case dealing with common-law copyright infringement, the plaintiffs relied on *Bridgeport* in arguing against the defendants’ *de minimis* use defense. The trial court expressly rejected *Bridgeport*’s holding that a *de minimis* exception is not available for sampling sound recordings, and it ultimately found that the defendants’ use of the plaintiffs’ sound recording was fair use because, among other reasons, the use involved criticism of the plaintiffs’ work, and it entailed using only a small portion.

Both the *Saregama* and *EMI Records* court cited David Nimmer’s criticism of *Bridgeport* in *Nimmer on Copyright*. In Nimmer’s view, “the practice of digitally sampling prior music to use in a new composition should not be subject to any special analysis: to the extent that the resulting product is substantially similar to the sampled original, liability should result. Yet against that conclusion comes an unprecedented [opinion] in *Bridgeport* [... The Sixth Circuit adopted a bright-line rule at odds with the balance of jurisprudence...by adopting [the] argument that ‘no substantial similarity or *de minimis* inquiry should be undertaken at all when the defendant has not disputed that it digitally sampled a copyrighted sound recording.’”<sup>27</sup> Nimmer opines that *Bridgeport*’s interpretation of section 114 is fundamentally incorrect and does not comport with Congressional intent:

[The] sentence [from Section 114 quoted in *Bridgeport*] immunizes the maker of a sound-alike recording; if *no* sounds are recaptured, the newcomer is categorically exempt from liability to the owner of the sound recording. From that proposition, the [*Bridgeport*] panel summarily reasons that if *some* sounds are recaptured, the newcomer’s liability is complete. But it is submitted that that conclusion rests on a logical fallacy. By validating entire sound-alike recordings, the quoted sentence contains no implication that partial sound duplications are to be treated any differently from what is required by the traditional standards of copyright law—which, for decades prior to adoption of the 1976 Act and unceasingly in the decades since, has included the requirement of substantial similarity.... Indeed, had *Bridgeport* [] consulted Section 114’s legislative history instead of dismissing that history as irrelevant, it would have discovered that Congress explicitly noted in that context that “infringement takes place whenever all or any *substantial por-*

tion of the actual sounds that go to make up a copyrighted sound recording are reproduced in phonorecords by repressing, transcribing, recapturing off the air, or any other method....” That excerpt debunks the [*Bridgeport*] court’s imputation that Congress, when adopting Section 114, intended to dispense with traditional notions of substantial similarity.<sup>28</sup>

## V. Conclusion

As digital sampling has become standard not just among hip-hop artists but across the music industry generally, there is a critical need for greater clarity as to what does or does not constitute infringement. The *TufAmerica* case presents an opportunity for some needed judicial guidance to artists and music publishers, at least in the Second Circuit. In the meantime, *Bridgeport* remains good law within the Sixth Circuit. Whether the other circuits move toward or away from *Bridgeport*, and whether there will ever be a uniform approach to digital sampling cases, remains to be seen.


## Endnotes

1. *TufAmerica, Inc. v. Diamond, et al.*, 12 CV 3529 (AJN) (S.D.N.Y. 2012).
2. *TufAmerica*, May 3, 2012 Complaint (Docket No. 1), ¶¶ 24-25, 38-39, 51-52, 63-64.
3. See, e.g., *Newton v. Diamond*, 388 F.3d 1189, 1193 (9th Cir. 2004) (“[E]ven where the fact of copying is conceded, no legal consequences will follow from that fact unless the copying is substantial.”) (internal citations omitted); *Ringgold v. Black Entertainment Television, Inc.*, 126 F.3d 70, 74 (2d Cir. 1997) (“[S]ubstantial similarity...is always a required element of actionable copying.”); David Nimmer, *Nimmer on Copyright*, § 13.03 (“[S]ubstantial similarity between the plaintiff’s and defendant’s works is an essential element of actionable copying.”) (internal quotation omitted).
4. See, e.g., Nimmer, *supra* note 3, § 13.03 (identifying, among others, the “abstractions test,” the “total concept and feel” test, and the “iterative test” for assessing substantial similarity).
5. *Ringgold*, 126 F.3d at 74.
6. 126 F.3d 70, 74 (2d Cir. 1997).
7. *Id.* at 74.
8. *Id.*
9. *Id.* at 75.
10. 410 F.3d 792 (6th Cir. 2005).
11. *Bridgeport Music, Inc., et al. v. Dimension Films, et al.*, 410 F.3d 792, 801 (6th Cir. 2005) (“Get a license or do not sample.”).
12. See Nimmer, *supra* note 3, § 13.03 (arguing that the holding in *Bridgeport* “rests on a logical fallacy”).
13. *Bridgeport*, 410 F.3d at 797-98 (internal quotation and citation omitted).

14. *Id.* at 798 (finding that “no substantial similarity or *de minimis* inquiry should be undertaken at all when the defendant has not disputed that it digitally sampled a copyrighted sound recording”).
15. *Id.* at 801-02.
16. *Id.* at 801.
17. 17 U.S.C. § 114(b) (emphasis added).
18. *Bridgeport*, 410 F.3d at 800.
19. *Id.*
20. *Id.* at 801.
21. Notably, while the Sixth Circuit in *Bridgeport* court did not engage in a fair use analysis, it expressly noted that the district court was free to engage in such an analysis on remand. 410 F.3d at 805. This is at odds with its holding that the *de minimis* use doctrine does not apply in cases of digital sampling, as *de minimis* usage may in fact be relevant to a fair use defense. See, e.g., *Ringgold*, 126 F.3d at 75. As *Bridgeport* appears ultimately to have settled, the district court never had a chance to engage in a fair use analysis or to otherwise address this point.
22. 687 F. Supp. 2d 1325 (S.D. Fla. 2009).
23. *Id.* at 1338.
24. *Id.*
25. *Id.* at 1338-39.
26. 2008 WL 5027245, 89 U.S.P.Q.2d 1593 (N.Y. Sup. Aug. 08, 2008).
27. Nimmer, *supra* note 3, § 13.03.
28. *Id.*

**Robert N. Potter, Andrew Gerber, and Olivia Harris are associates in the Trademark and Copyright Group in the New York office of Kilpatrick Townsend & Stockton LLP.**

NEW YORK STATE BAR ASSOCIATION




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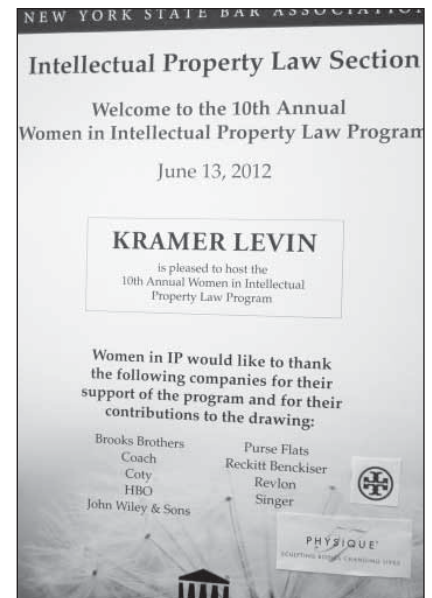
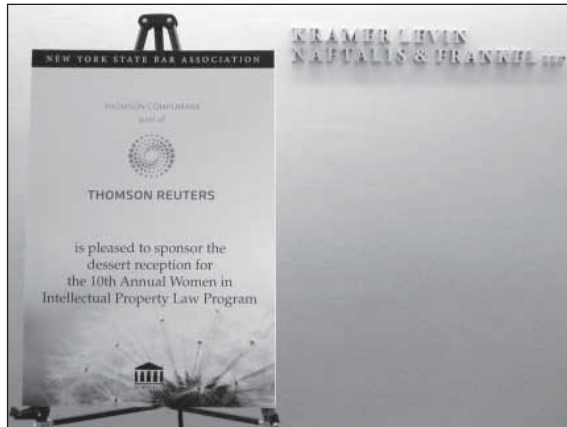
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# Section Activities

## Women in IP



June 13, 2012 was another special day in the New York State Bar's IP Section's calendar as the Section held its annual Women in IP event. The program was ably led by the IP Section's Diversity Initiative Committee chair, Joyce Creidy of Thomson Reuters, and program co-chair Suzanne M. White of Coach Inc. This year was particularly significant, as it marked the tenth anniversary of this annual event.

This year's three-hour event was hosted at Kramer Levin Naftalis & Frankel LLP. The event kicked off with inspiring welcoming remarks by Ms. Creidy, who stressed the importance for women of continuing to build and foster relationships through networking. The Section's new Chair, Kelly M. Slavitt, Deputy General Counsel & Legal Director for North America & Food at Reckitt Benckiser, said she was particularly proud that this event continues to attract more than one hundred attendees every year. She praised the co-chairs for putting together yet again another spectacular panel, thanked the sponsors, and presented Joyce with a surprise gift for her contributions to this event over the past ten years.







**SCENES FROM THE  
10TH ANNUAL  
WOMEN IN IP EVENT  
JUNE 13, 2012**



The first speaker, Erica Klein, partner at Kramer Levin Naftalis & Frankel, explored different definitions of success and how success translated into meaning for different women. The second panelist, Valyncia Simmons, partner at Baker Williams Matthiesen LLP, shared how her different work experiences ultimately led her to her career in law. Although she started off as a public finance lawyer, she quickly realized that her passion lay in IP. Understanding firm dynamics and being open to helping out where help was needed was key in launching her in the field of trademark litigation.

Ashima Aggarwal of John Wiley & Sons encouraged everyone to constantly update their CVs to ensure that one remained aware of one's strengths and weaknesses. The final speaker of the evening, Nadine Flynn, Vice President, Associate General Counsel and Chief Trademark Counsel of Colgate-Palmolive Company, shared her experiences and discussed how important it is to provide candid and constructive feedback to colleagues in order to be a good manager.

The evening came to a close with a reception and raffle featuring lovely gift baskets from Brooks Brothers, Coach, Coty, HBO, John Wiley & Sons, Purse Flats, Reckitt Benckiser, Revlon, and Singer. All winners went home happy!



# Trade Winds

**Trade Winds** offers Section members a way to keep up on the comings and goings of their colleagues and upcoming events of interest. Has there been a change in your practice? Any recent or forthcoming articles or lecture presentations? Won any awards recently? Please e-mail submissions to Jonathan Bloom at [jonathan.bloom@weil.com](mailto:jonathan.bloom@weil.com).

## Welcome New Members:

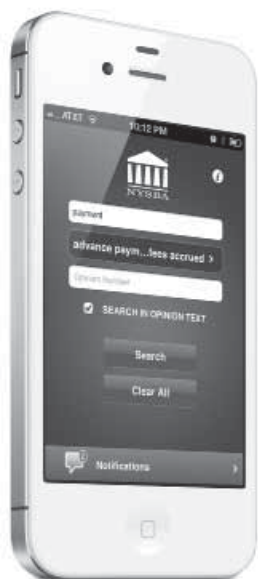
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# MEMBERSHIP APPLICATION

## New York State Bar Association

### INTELLECTUAL PROPERTY LAW SECTION

Membership in the New York State Bar Association's Intellectual Property Law Section is a valuable way to:

- enhance professional skills;
- keep up-to-date with important developments in the legal profession;
- join colleagues in exciting Section events.

#### OPPORTUNITIES FOR EDUCATION

The Intellectual Property Law Section offers both the experienced and novice practitioner excellent opportunities to enhance their practical and legal knowledge and expertise. Through Section activities, including conferences on intellectual property (an annual Winter event), members may examine vital legal developments in intellectual property law. The Section's Web site provides current information regarding Section events and offers "members only" access to current issues of *Bright Ideas* and current Committee bulletins providing updates on intellectual property law. The Section sponsors continuing legal education (CLE) credit-bearing programs for Section members at reduced rates. Recent programs offered by the Section related to computer software and biotechnology protection, conducting intellectual property audits, and practical considerations in trade secret law. Now, with Mandatory Continuing Legal Education (MCLE) requirements, Intellectual Property Law Section membership is more valuable than ever before! The Section also sponsors joint programs with Law Schools including an annual writing contest for law students wherein the winning articles appear in an issue of *Bright Ideas*.

#### OPPORTUNITIES FOR PROFESSIONAL DEVELOPMENT

Intellectual Property Law Section committees address unique issues facing attorneys, the profession and the public. The Section offers opportunities to serve on committees such as Copyright Law; Diversity Initiative; Ethics; Greentech; International IP Law; Internet & Technology Law; Legislative/Amicus; Litigation; Patent Law; Pro Bono and Public Interest; Trademark Law; Trade Secrets; Transactional Law; and Young Lawyers.

Committees allow you to network with other attorneys from across the state and give you the opportunity to research issues and influence the laws that can affect your practice. Committees are also an outstanding way to achieve professional development and recognition. Law students are automatically members of the Young Lawyers Committee. Section members may join more than one committee.

#### A VOICE IN THE ASSOCIATION

The Intellectual Property Law Section takes positions on major professional issues that affect practitioners and advocates those positions within the New York State Bar Association, the legislature, and the public.

**See page 24 to become a member of the Intellectual Property Law Section**



## COMMITTEE ASSIGNMENT REQUEST

Please designate, from the list below, those committees in which you wish to participate. For a list of Committee Chairs and their e-mail addresses, please refer to page 25 of this issue.

- |  |   |
|--|---|
| <input type="checkbox"/> Copyright Law (IPS1100)                           | <input type="checkbox"/> Litigation (IPS2500)                   |
| <input type="checkbox"/> Diversity Initiative (IPS2400)                    | <input type="checkbox"/> Patent Law (IPS1300)                   |
| <input type="checkbox"/> Ethics (IPS2600)                                  | <input type="checkbox"/> Pro Bono and Public Interest (IPS2700) |
| <input type="checkbox"/> Greentech (IPS2800)                               | <input type="checkbox"/> Trademark Law (IPS1600)                |
| <input type="checkbox"/> International Intellectual Property Law (IPS2200) | <input type="checkbox"/> Trade Secrets (IPS1500)                |
| <input type="checkbox"/> Internet and Technology Law (IPS1800)             | <input type="checkbox"/> Transactional Law (IPS1400)            |
| <input type="checkbox"/> Legislative/ Amicus (IPS2300)                     | <input type="checkbox"/> Young Lawyers (IPS1700)                |

Please e-mail your committee selection(s) to Stephanie Bugos at: [sbugos@nysba.org](mailto:sbugos@nysba.org)

\* \* \*

To be eligible for membership in the Intellectual Property Law Section, you first **must** be a member of the NYSBA.

- ☐ As a member of the NYSBA, I enclose my payment of \$30 for Intellectual Property Law Section dues.  
(Law student rate: \$15)
- ☐ I wish to become a member of the NYSBA and the Intellectual Property Law Section. I enclose both an Association and Section application with my payment.
- ☐ Please send me a NYSBA application. No payment is enclosed.

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**ANNOUNCING THE**  
**Intellectual Property Law Section's**  
**ANNUAL LAW STUDENT WRITING COMPETITION**

To be presented at the **Annual Meeting of the Intellectual Property Law Section, January 2013, New York, NY** to the authors of the best publishable papers on subjects relating to the protection of intellectual property **not published elsewhere, scheduled for publication, or awarded another prize.**

**First Prize: \$2,000**

**Second Prize: \$1,000**

**COMPETITION RULES ARE AS FOLLOWS:**

To be eligible for consideration, the paper must be written solely by students in full-time attendance at a law school (day or evening program) located in New York State or by students in full-time attendance at an out-of-state law school who are members of the Intellectual Property Law Section. (Non-members wishing to join the IP Section may do so at [www.nysba.org/Join](http://www.nysba.org/Join). First join NYSBA, then select the Intellectual Property Law Section.)

The deadline for submission of papers is December 7, 2012. An electronic copy must be submitted by e-mail to [IntellectualProperty@nysba.org](mailto:IntellectualProperty@nysba.org) prior to 5:00 p.m. on December 7. An additional hard copy may also be submitted (postmarked by December 7) but is not required.

Papers will be judged by the Section and must meet the following criteria or points will be deducted: no longer than 35 pages, double-spaced (footnotes must be single-spaced); 12-point font; and a cover page indicating the submitter's name, law school and expected year of graduation, mailing address, e-mail address, telephone number, and employment information (if applicable). Papers should exhibit thorough and accurate legal research, logical thought process with clarity of expression and a well-grounded conclusion.

Winning papers may be published in the Section's publication *Bright Ideas*. Reasonable expenses will be reimbursed to the author of the winning paper for attendance at the Annual Meeting to receive the Award.

The judges reserve the right to: not consider any papers submitted late or with incomplete information, not publish papers, and/or determine that no entries are prizeworthy or publishable.

**Entries by e-mail and hard copy (optional) to: E-mail: [IntellectualProperty@nysba.org](mailto:IntellectualProperty@nysba.org)**  
**Mail: Stephanie Bugos, NYSBA, One Elk Street, Albany, NY 12207.** Comments and/or questions may be directed to the Chair of the Section's Young Lawyers Committee: Natasha Azava, Law Offices of Peter Thall, 110 West End Avenue, Suite 7K, New York, NY 10023, (212) 245-6221, [nazava@thallentlaw.com](mailto:nazava@thallentlaw.com).

**Winners of the 2011 Annual Law Student Writing Competition**

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Columbia Law School

Second Place  
**Meredith Hatic**  
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Anyone wishing to submit an article, announcement, practice tip, etc., for publication in an upcoming issue of *Bright Ideas* is encouraged to do so. Articles should be works of original authorship on any topic relating to intellectual property. Submissions may be of any length.

Submissions should preferably be sent by e-mail to Jonathan Bloom, Editor-in-Chief, at the address indicated on this page. Submissions for the Winter 2012 issue must be received by October 1, 2012.

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ISSN 1530-3934 (print) ISSN 1933-8392 (online)

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