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## Of Machines & Metamorphoses – Process and Software Claims After *In re Bilski*

Recently, the Federal Circuit published its long-awaited *en banc* opinion in *Bilski*.<sup>1</sup> By abandoning the *State Street*<sup>2</sup> test and embracing a machine-or-transformation test, the Court articulated a potentially significant change in the way that the subject matter eligibility of a claimed process is evaluated. While the Court explicitly maintained that business method and software claims are patent-eligible subject matter, the *Bilski* opinion falls short of establishing clear distinctions between patentable and unpatentable software-based processes.<sup>3</sup> Instead, the *Bilski* opinion raises several questions for future courts to answer regarding the contours and limits of patentable subject matter.

### Background

In *Bilski*, the applicant sought a patent claiming

a method for hedging risk in commodities trading.<sup>4</sup> However, as noted by the Court, the claims included no elements that limited the claims to transactions of actual commodities.<sup>5</sup> Rather, the application specifically disclosed that the transactions recited in the claims could instead involve options, such as the right to buy or sell the commodity at a later time.<sup>6</sup> Further, during prosecution, the applicants admitted that the claims were not limited to operation on a computer.<sup>7</sup>

The Examiner rejected the claims under 35 U.S.C. § 101 based on a conclusion that the claims were “not directed to the technological arts.”<sup>8</sup> On appeal to the Board of Patent Appeals and Interferences, the Board noted that the Examiner erred by relying on an unsupported “technological arts”  
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## Navigating Inventorship in the Chemical Industry

Properly establishing inventorship of a patent is important for a number of reasons. First, if done correctly, inventors are rewarded for disclosing their invention with the grant of a patent, which is a valuable property that may be sold or licensed – valuable of course because of the right to exclude others from making or using the invention claimed in the patent.<sup>1</sup> Additionally, inventors often receive prestige and monetary remuneration from their employer.

However, if inventorship is incorrectly determined, there may be negative repercussions. For instance, a priority claim could be lost. If a provisional application names only inventor A and a utility application on the same invention only names inventors C and D, the utility application cannot claim priority from the provisional application.<sup>2</sup> Furthermore, the validity of the patent may

be suspect. Courts may hold patents unenforceable for failure to correctly name inventors if the named inventors acted in bad faith or with deceptive intent.<sup>3</sup>

Therefore, properly identifying the inventors is crucial. In the chemical industry, however, inventions are often the result of a group effort, and identifying the correct inventors is often very difficult. This article discusses (1) the basic rules governing inventorship, especially joint inventorship, with an emphasis on the chemical industry, (2) how the Federal Circuit has applied these rules, and (3) suggestions regarding the ways that both inventors and employers can protect themselves and their inventions.

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test.<sup>9</sup> Nonetheless, the Board upheld the rejection because the claims were directed to an abstract idea, did not involve a patent-eligible transformation, and did not produce a “useful, concrete and tangible result.”<sup>10</sup>

After an appeal to the Federal Circuit was argued before a three-judge panel, the Court ordered an *en banc* review of the case.<sup>11</sup> Nearly six months after hearing oral arguments, Chief Judge Michel filed the Court’s opinion, affirming the Board’s decision and concluding that the applicant’s claims were not directed to patentable subject matter.<sup>12</sup> Joined by eight other judges, Judge Michel’s opinion declared that the test given in *State Street* was “insufficient to determine whether a claim is patent-eligible under § 101,” and embraced the machine-or-transformation test articulated in *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972).<sup>13</sup>

## The Machine-or-Transformation Test

Under the test set forth in *State Street*, the patent-eligibility of a process could be evaluated by examining whether the process produced “a useful, concrete, and tangible result.”<sup>14</sup> While the Court in *Bilski* recognized that the identification of a useful, concrete, and tangible result could aid in determining whether a claim is drawn to a fundamental principle or a practical application of such a principle, the Court declared that the *State Street* test was inadequate “to determine whether a claim is patent-eligible under § 101.”<sup>15</sup> Relying on the Supreme Court’s decision in *Benson*,<sup>16</sup> the Court returned to the machine-or-transformation test:

The Supreme Court, however, has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is

surely patent-eligible under § 101 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>17</sup>

In returning to the machine-or-transformation test, the Court seemed specifically concerned with processes that could be entirely performed in the human mind.<sup>18</sup> Nonetheless, the Court explicitly rejected the view that the machine-or-transformation test required the process to include physical steps,<sup>19</sup> and declared that the physicality of steps performed by software on a computer

snippets.

*Bilski* leaves at least two open questions for software-based methods: (1) what is a particular machine? and (2) what is a transformation?

was “inapposite to the § 101 analysis.”<sup>20</sup> The Court also declined to issue a wholesale ban on business method and software patents.<sup>21</sup> Instead, the Court indicated that all processes are “subject to the same legal requirements for patentability as applied to any other process or method.”<sup>22</sup>

Despite the *Bilski* opinion’s heavy reliance on the machine-or-transformation test, however, it would appear that the Supreme Court in *Benson* did not view this test as the exclusive measure of the patentability of a process:

It is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a ‘different state or thing.’ We do not hold that no

process patent could ever qualify if it did not meet the requirements of our prior precedents.<sup>23</sup>

Rather, as articulated in *Benson*, the machine-or-transformation test is one method of determining whether a patent claim might impermissibly preclude the use of fundamental principles, abstract intellectual concepts, or natural phenomena.<sup>24</sup> Thus, while the machine-or-transformation test can be used to identify patentable subject matter in some claims, *Benson* indicates that the test is not co-extensive with the limits of patentability. Consequently, beyond simply clarifying the contours of the machine-or-transformation test, it is likely that future cases will articulate additional tests to verify the patentability of claimed subject matter.<sup>25</sup>

## Open Questions

While the Court explicitly preserved the patent-eligibility of software-based process claims,<sup>26</sup> the *Bilski* opinion provides very little guidance regarding how to evaluate such claims. In fact, the Court acknowledges that the facts in *Bilski* are “largely unhelpful in illuminating the distinctions between those software claims that are patent-eligible and those that are not.”<sup>27</sup> Though the machine-or-transformation test appears relatively straightforward for many classes of process claims, the test itself and the *Bilski* opinion leave at least two open questions for software-based methods: (1) what is a particular machine? and (2) what is a transformation?

With regard to machines, a central question for software-based processes is whether a general-purpose computer qualifies as a “particular machine.” While recent non-precedential decisions from the Board of Patent Appeals and Interferences seem to suggest that a general purpose computer is not necessarily sufficiently particular,<sup>28</sup> the Federal Circuit explicitly avoided answering

the question in *Bilski*. Rather, the Court instead opted to “leave to future cases the elaboration of the precise contours of machine implementation, as well as the answers to particular questions, such as whether or when recitation of a computer suffices to tie a process claim to a particular machine.”<sup>29</sup>

Until the courts resolve whether a general purpose computer is sufficiently particular, it may be possible to further insulate a software-based claim from a § 101 rejection by tying the claim to a processor or to computer memory. Further, the *Bilski* opinion makes it clear that the ineligibility of a single claim element does not render the entire claim ineligible.<sup>30</sup> Rather, if one or more elements of a software-based process can be tied to a more specific machine, these elements may immunize the claim as a whole from an ineligibility rejection.

While the Court also declined to articulate a clear definition of what constitutes a transformation, the *Bilski* opinion does provide language that seems to support the eligibility of many software-based processes. In rejecting the claims in *Bilski*, the Court noted that:

Purported transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances. Applicants’ process at most incorporates only such ineligible transformations.... As discussed earlier, the process as claimed encompasses the exchange of only options, which are simply legal rights to purchase some commodity at a given price in a given time period.<sup>31</sup>

The Court also provided an example from

*In re Abele*, 684 F.2d 902, (CCPA 1982) to illustrate that the electronic transformation of data itself into a visual depiction is sufficient to satisfy § 101, for example, and that claims are not required to involve any transformation of an underlying physical object that the data represented.<sup>32</sup> In *Abele*, the Court of Claims and Patent Appeals rejected a broad claim that was generally drawn to the graphical display of data variances, but provided no specifics regarding the type or nature of the data.<sup>33</sup> However, in *Abele*, the Court found that a dependent claim was patent eligible because the data represented

  
It appears that, after *Bilski*, software-based process claims remain viable and potentially valuable features of the patent landscape.

physical, tangible objects.<sup>34</sup>

Given the Court’s apparent concerns regarding patenting of fundamental principles and abstractions, it appears that software-based process claims may be insulated from ineligibility rejections by using data that is representative of a physical, tangible object. While the Court held abstract options and relationships claimed by the *Bilski* applicant were insufficient, the Court’s language seems to suggest that the claims would have been eligible if the data represented a more tangible object.<sup>35</sup> Such transformations of data representing actual assets remain patent-eligible. Further, while not specifically addressed by the Court, the language in *Bilski* seems to support the patent-eligibility of processes involving data that represents stocks, bonds, actual

commodities, inventory, and other entities that can be embodied in a tangible form.

### A Signal From the USPTO

While the contours of the machine-or-transformation test will be explored by courts in future cases, the United States Patent & Trademark Office has already begun wrestling with the post-*Bilski* landscape. Recently, Deputy Commissioner for Patent Examination Policy, John Love, issued a one-page memorandum to the Patent Examining Corps, outlining the machine-or-transformation test, and identifying two corollaries to the test.<sup>36</sup>

First, the Deputy Commissioner indicated that a field-of-use limitation is insufficient to satisfy the test, and that the machine or transformation “must impose meaningful limits on the method claim’s scope to pass the test.”<sup>37</sup> Second, the memo stated that “reciting a specific machine or a particular transformation of a specific article in an insignificant step...is not sufficient to pass the test.”<sup>38</sup> While the memo identified data gathering and outputting as examples of insignificant steps, it is unclear whether the Deputy Commissioner views data gathering and outputting as fundamentally insignificant steps, or only potentially insignificant depending on details of the claimed process.

### Conclusion

By rejecting the *State Street* test in favor of the machine-or-transformation test, the Federal Circuit’s opinion in *Bilski* has significantly altered the rules used to evaluate whether a process claim is directed to patentable subject matter. While the precise contours of the machine-or-transformation test are left to future cases, it appears that software-based process claims remain viable and potentially valuable features of the patent landscape.

[Editor’s Note: As this article was going continued on p. 4

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to press, the Bilski applicants petitioned the Supreme Court for a writ of certiorari. Please look to future issues of *snippets* for continuing analysis of this case and other developments in intellectual property law.]

## Endnotes

1. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).
2. *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).
3. *In re Bilski*, 545 F.3d at 960 n.23.
4. Claim 1 of the application reads: A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of: (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer; (b) identifying market participants for said commodity having a counter-risk position to said consumers; and (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions. U.S. Patent Application Serial No. 08/833,892, cl. 1.
5. *In re Bilski*, 545 F.3d at 950.
6. *Id.*
7. *Id.*
8. *Ex Parte Bilski*, No. 2002-2257, 2006 WL 5738364 at \*3 (BPAI Sept. 26, 2006).
9. *Id.* at \*41-42.
10. *Id.* at \*42-50.
11. *In re Bilski*, 264 Fed. Appx. 896, 897 (Fed. Cir. 2008).
12. *In re Bilski*, 545 F.3d at 949.
13. *Id.* at 959.
14. *State Street*, 149 F.3d at 1373.
15. *In re Bilski*, 545 F.3d at 959.
16. *Gottschalk v. Benson*, 409 U.S. at 70.
17. *In re Bilski*, 545 F.3d at 954.
18. *Id.* at n.26.
19. *Id.* at 961.
20. *Id.* at n.25.
21. *Id.* at 960 n.23.
22. *Id.* at 960.
23. *Benson*, 409 U.S. at 71.
24. *Id.* at 67-68.
25. The machine-or-transformation test also appears limited in its ability to ensure that a claim does not preclude the use of a fundamental principle. In *Benson*, the Court held that the claimed methods for converting binary coded decimal numbers to pure binary numbers were unpatentable. *Id.* at 71-72. Since the claims had “no substantial practical application except in connection with a digital computer,” the Court noted that allowing the claims would effectively preempt the use of the basic mathematical principle underlying the conversion of BCD numerals to pure binary numerals. *Id.*
26. *In re Bilski*, 545 F.3d at 960 n.23.
27. *Id.*
28. See, e.g., *Ex Parte Langemyr*, 2008 WL 5206740 (BPAI May 28, 2008) and *Ex Parte Wasynczuk*, 2008 WL 2262377 (BPAI June 2, 2008).
29. *In re Bilski*, 545 F.3d at 962.
30. *Id.* at 958.
31. *Id.* at 963-64.
32. *Id.* at 963.
33. *In re Abele*, 684 F.2d at 908-909.
34. *Id.* In *Abele*, the patent-eligible claim was drawn to X-ray attenuation data produced in a two-dimensional field by a computed tomography scanner. *Id.*
35. *In re Bilski*, 545 F.3d at 964-65.
36. John Love, Guidance for Examining Process Claims in view of *In re Bilski*, Jan. 7, 2009; available on the United States Patent and Trademark Office website ([http://www.uspto.gov/web/offices/pac/dapp/opla/documents/bilski\\_guidance\\_memo.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/documents/bilski_guidance_memo.pdf)).
37. *Id.*
38. *Id.*

**Robert J. Irvine III** has significant experience in intellectual property procurement and client counseling in the electronic arts. He has represented Fortune 100 companies and individual inventors in litigation and licensing matters relating to inventions of an electrical nature. Mr. Irvine has an extensive background in telecommunications, with expertise in areas such as digital signal-processing techniques, satellite communication systems, modulation schemes, and coding techniques. He also has a wide range of experience in technologies such as probability theory, information theory, data mining, cryptography, analog and digital circuits, semiconductor structures, network protocols, and financial trading systems.

[irvine@mbhb.com](mailto:irvine@mbhb.com)

**Benjamin R. Huber** prepares and prosecutes patent applications, conducts legal research, and provides technological advice in support of validity, infringement and patentability analyses, patent application preparation and prosecution, and litigation matters in the electrical engineering field.

[huber@mbhb.com](mailto:huber@mbhb.com)

# Navigating Inventorship in the Chemical Industry

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## Inventorship Basics

Inventorship is a question of law,<sup>4</sup> that depends on the content of the patent claims, *i.e.*, only the people that contribute to the subject matter encompassed by the claims are actually inventors; contributing to subject matter that is disclosed in the application but is not encompassed by the claims does not make one an inventor. There are two fundamental aspects of inventorship: conception and reduction to practice. Of the two, conception is the “touchstone of inventorship” and it is the “critical question.”<sup>5</sup>

Conception is “the completion of the mental part of the invention.”<sup>6</sup> It is also “the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”<sup>7</sup> “[A]n inventor need not show that his invention will work for conception to be complete. He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice.”<sup>8</sup> The inventor may consider and adopt ideas and materials derived from other sources, such as a suggestion from an employee, or a hired consultant, so long as the inventor maintains intellectual domination of the work, from making the invention to the successful testing of the invention.<sup>9</sup>

In the chemical industry, conception of a chemical compound requires “knowledge of both the specific chemical structure of the compound and an operative method of making it.”<sup>10</sup> There is no conception of a chemical compound based solely on its biological activity.<sup>11</sup> For example, without more, the idea to make a compound that treats a particular disease or condition is not conception.

While there is a requirement that the inventor be the one to conceive the invention, “there is no requirement that the inventor be the

one to reduce the invention to practice so long as the reduction to practice was done on his behalf.”<sup>12</sup> An invention can be reduced to practice in two ways, and either is acceptable. First, there is actual reduction to practice, where the inventive concept is in some physical form and is demonstrated to work for its intended purpose.<sup>13</sup> In the chemical industry, the synthesis and testing of a small molecule would be an example of an actual reduction to practice.<sup>14</sup> The second way to reduce an invention to practice is constructive reduction to practice, by filing a patent application.<sup>15</sup>



**Contributing to only one claim in a patent is enough to be considered an inventor.**

In some rare instances, simultaneous conception and reduction to practice exists. This requires actual reduction to practice and occurs when the inventor cannot establish conception until he or she has reduced the invention to practice through a successful experiment.<sup>16</sup> Simultaneous conception and reduction to practice usually occurs in “gene” patents.<sup>17</sup> In most situations, however, inventorship depends on conception. Nevertheless, more than one person can conceive an invention.

## Types of Inventors

Inventorship can be either sole or joint. Sole inventorship occurs when one person conceived all of the inventive features (*e.g.*, the solution to the problem, means to the end), regardless of the routine follow-up by others. In chemical fields, however, most inventions are the result of a group effort, leading to joint inventorship. Joint inventorship occurs when two or more inventors

collaborate in conception to achieve an end. Inventors may apply for a patent jointly even if: they did not physically work together or at the same time, each inventor did not make the same type or amount of contribution, or each inventor did not make a contribution to the subject matter of every claim of the patent.<sup>18</sup> Contributing to only one claim in the patent is enough to be considered an inventor for that patent.<sup>19</sup>

For joint inventorship, the efforts could be small by one inventor and large by the other; no minimum contribution is required.<sup>20</sup> The invention also could be conceived in stages via organized research and development efforts.

One notable aspect of joint inventorship is that the joint inventors each own an undivided share of the patent.<sup>21</sup> Therefore, if a patent contains 50 claims, and inventor A invented 48 of the claims and inventor B invented 2 of the claims, inventor B can still license or use all of the claimed subject matter.

However, not all people who have a connection with an invention can be correctly named as inventors. For instance, a person is not an inventor if he or she merely suggests an idea of research or a desired result.<sup>22</sup> Also, someone whose contributions are not encompassed by the claims is not an inventor. As noted above, contributing to the reduction to practice of an invention is not enough to be considered an inventor. Others who are not inventors include those who adopted the invention from another<sup>23</sup> or contributed to the invention after conception.<sup>24</sup> Therefore, determining correct inventorship can be complicated and time-consuming.

## Inventorship Scenarios

A classic inventorship situation arises in the [continued on p. 6](#)

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chemical industry when a team of chemists is working on a project and everyone contributes. When a patent application is filed, who is an inventor? In short, as stated above, inventorship is based on conception. However, difficulties arise when parsing the contributions of the various team members. In order to determine inventorship, one must consider, among other issues: who contributed to the conception of the invention, whose contributions are being claimed, who acted at the behest of others, whose work was really directed toward reduction to practice and not conception, whether any unusual problems were encountered when making the compounds (which may imply incomplete conception), how much effort was required to make the compounds, and who attended meetings where strategy was discussed. In light of the above, it is useful to review how the Federal Circuit has applied the rules discussed above.

## Scenario 1 – “I have an idea, but not an invention”

C has D and E study *in vivo* absorption of an iron formulation. D and E then conducted additional studies and told C that certain inorganic compounds appear to interfere with iron absorption and that new formulations may be better. C filed a patent application on the new formulations naming himself as the sole inventor. C’s employer made a large profit from the patent. D and E found out about the patent and sued, claiming they were the inventors. The result: the Federal Circuit agreed with D and E, and awarded \$45 million in damages because C did not conceive the invention.<sup>25</sup>

## Scenario 2 – Using Another’s Invention

A invented a polymer. B invented a method of using the polymer to fracture subterranean formulations, thereby facilitating oil and gas removal. B filed a patent application, claiming only the method. A did not know

about the method; should A have been named as an inventor? The Federal Circuit said A should not have been named as an inventor because the claims of the patent did not cover A’s invention, the polymer itself, and A had no knowledge of the method or how the polymer would be used (i.e., no conception).<sup>26</sup>

## Scenario 3 – Conception of Chemical Compounds

F and G were post-doctoral research assistants, working for H. F invented an improved method of making taxotere analogs. G finished his post-doctoral research and went to

The logo for 'snippets' features the word in a lowercase, sans-serif font. The letter 'i' is stylized with a square bracket-like shape around its dot.

First and foremost, companies should make all reasonable efforts to ensure that the correct set of inventors is listed on every patent application.

work at a private company that also worked on taxotere analogs. G and others invented new taxotere analogs at the private company, using F’s method, and they claimed the analogs in a patent. H found out about G’s patents and sued to have F and H added as inventors and to have G’s collaborators at the private company removed from the list of inventors. The Federal Circuit held that G and the collaborators were the inventors of the analogs they created and that F and H were not inventors.<sup>27</sup> The court explained that F and H did not conceive the claimed compounds, only a method of making such compounds.<sup>28</sup> As discussed above, conception of a chemical compound requires knowledge of how to make the compound and the chemical structure of the compound.

## Scenario 4 – Improper Appropriation

Companies A and B considered working together. A had expertise in insulin compounds. B owned technology directed to drug delivery. Scientists from A met several times with scientists from B but did not record exactly what they discussed. B filed a patent application directed to methods of using A’s insulin, but naming only B’s inventors. B’s patent issued and A sued, seeking to have its employees added as co-inventors. The Federal Circuit concluded that A’s employees were not inventors because A could not demonstrate “by clear and convincing evidence” that A’s employees disclosed a limitation contained in the claims (i.e., A could not demonstrate conception).<sup>29</sup>

## What Should Inventors Do?

So what should inventors do to ensure that they receive proper credit for their inventions? First, evidence corroborating conception is very important. Inventors should keep good records, detailing the compounds that they believe should be made, drawing structures, and being as specific as possible. Inventors should record their ideas immediately and communicate these ideas to other team members. In addition, inventors should regularly have their records witnessed by someone that understands them.

## What Should Companies Do?

Likewise, what should companies do to ensure that inventorship is proper? First and foremost, companies should make all reasonable efforts to ensure that the correct set of inventors is listed on every patent application, according to the inventorship-determination principles described above, with assistance, of course, from their own in-house and/or outside counsel. Second, where meetings with representatives of other companies are concerned, it is important to keep detailed records of what is disclosed and discussed.

And although these points pertain more to ownership than inventorship, since inventorship is a legal determination, it is also prudent practice to (1) get assignments from inventors as soon as provisional applications are finalized, and again after non-provisional applications are filed and (2) confirm that employment agreements cover ownership of intellectual property, for both regular employees and experts.

### Conclusion

The above examples demonstrate how the Federal Circuit applies the rules when determining inventorship, and illustrate the serious repercussions that can occur when inventorship is incorrectly determined. In light of these repercussions, we have provided suggestions regarding the ways that both inventors and employers can protect themselves and their inventions.

### Endnotes

1. See 35 U.S.C. § 271(a) (2006) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent.”).
2. See 35 U.S.C. § 120 (2006) (“An application for patent for an invention . . . which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application.”).
3. See *Board of Education ex rel. Board of Trustees of Florida State University v. American Bioscience Inc.*, 333 F.3d 1330, 1344 (Fed. Cir. 2003).
4. *Sewall v. Waters*, 21 F.3d 411, 415 (Fed. Cir. 1994).
5. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998).
6. *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1227–28 (Fed. Cir. 1994) (citation omitted).
7. *Id.* at 1228 (citation omitted).
8. *Id.* (citations omitted).
9. See *Morse v. Porter*, 155 U.S.P.Q. 280, 283 (BPAI 1965).
10. *Burroughs Wellcome Co.*, 40 F.3d at 1229 (citation omitted).
11. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991).
12. *In re DeBaun*, 687 F.2d 459, 463 (C.C.P.A. 1982).
13. See *Eaton v. Evans*, 204 F.3d 1094, 1097–98 (Fed. Cir. 2000).
14. See *Burroughs Wellcome Co.*, 40 F.3d at 1229 (citation omitted).
15. *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998).
16. *Amgen*, 927 F.2d at 1206.
17. See *Id.* (“[W]hen an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.”).
18. 35 U.S.C. § 116 (2006).
19. See *Ethicon*, 135 F.3d at 1460.
20. See 35 U.S.C. § 116.
21. *Ethicon*, 135 F.3d at 1465.
22. See *Univ. of Colorado Foundation, Inc. v. American Cyanamid Co.*, 342 F.3d 1298, 1308–09 (Fed. Cir. 2003).
23. See 35 U.S.C. § 102(f) (2006) (“A person shall be entitled to a patent unless . . . he did not himself invent the subject matter sought to be patented . . .”).
24. *Ethicon*, 135 F.3d at 1460.
25. See *Univ. of Colorado Foundation*, 342 F.3d at 1308–12.
26. See *BJ Services Co. v. Halliburton Energy Services, Inc.*, 338 F.3d 1368, 1373 (Fed. Cir. 2003).
27. See *Board of Educ. ex rel. Board of Trustees of Florida State Univ.*, 333 F.3d at 1341.
28. See *Id.* The Federal Circuit also noted, in dicta, that if G had conceived the structures of the claimed compounds, but could not make them without F’s method, then F might be a co-inventor. *Id.* at 1342.
29. See *Eli Lilly and Co. v. Aradigm Corp.*, 376 F.3d 1352, 1370 (Fed. Cir. 2004).

**Bradley W. Crawford** has extensive experience in patent application preparation and prosecution, with an emphasis in synthetic organic chemistry as well as medicinal chemistry. Before joining MBHB, Mr. Crawford drafted patent applications at Abbott Laboratories, where he also worked as a medicinal chemist. He is listed as a co-inventor on three U.S. patents.

[crawford@mbhb.com](mailto:crawford@mbhb.com)

**Sydney R. Kokjohn** prepares and prosecutes patent applications, conducts legal research, and provides technological advice in support of validity, infringement and patentability analyses, patent application preparation and prosecution, and litigation matters in the chemical engineering field.

[kokjohn@mbhb.com](mailto:kokjohn@mbhb.com)

## News from the USPTO

This article focuses specifically on issues that may be of interest to agents and attorneys who are registered to practice before the U.S. Patent and Trademark Office (USPTO). The topics below relate to patent prosecution in the U.S., and include recent proposed and final rule changes, as well as the USPTO's e-Commerce initiatives.

### **EFS-Web Digital Certificate Expiration and Automatic Renewal**

For many agents and attorneys, the USPTO's web-based Electronic Filing System (EFS-Web) provides a desirable alternative to last-minute trips to the nearest branch of the U.S. Post Office. In order to use EFS-Web, attorneys and agents that have a USPTO registration number must fill out an application for a digital certificate and submit it to the USPTO's Electronic Business Center (EBC). The EBC will then send to the practitioner by e-mail a unique electronic authorization code and reference number that the practitioner can use to ultimately receive a unique digital certificate.

Each time a practitioner uses EFS-Web, he or she must use their unique digital certificate to sign in. However, digital certificates will expire if users fail to take steps to maintain them. A practitioner who attempts to log in to EFS-Web using an expired digital certificate will be unable to do so. In order to help prevent this from happening, the EBC has published a list of four tips to help minimize the time required to fix or prevent any of the common expiration problems associated with digital certificates:

1. Practitioners should create and download their digital certificate within 120 days of receiving an authorization code and reference number from the EBC. After 120 days, the authorization code and reference number will expire and will need to be replaced.
2. Practitioners should create a set of digital certificate self-recovery codes immediately after downloading the digital certificate. Recovery codes can be created online at <https://sas.uspto.gov/ptosas/>. These codes, which should be saved in a secure location, allow for the immediate recovery of a digital certificate if any problem occurs with the certificate. Without these self-recovery codes, the only recovery option available to practitioners is to contact the EBC Helpdesk and ask their staff to recover the certificate. The USPTO advises that EBC-assisted recovery is likely to take at least several business days to complete.
3. Active digital certificates are periodically automatically renewed, providing indefinite access to EFS-Web. This renewal occurs as a result of digital certificate use. Therefore, it is important that certificates be used regularly, at least once every 90 days.
4. If a digital certificate is copied for use on multiple computers, it is important to document the location of each copy. Because of the automatic-renewal protocol, only the copy of the certificate in use at the time of renewal will be valid; all other copies will be rendered invalid. If there is a problem with one copy of a certificate, the EBC suggests trying the following steps: (a) review the modification dates of all copies of the digital certificate; (b) determine which copy is the most current; and (c) replace all outdated copies with a copy of the most-recently-modified certificate.

Specific questions about EFS-Web or any other aspect of the USPTO's e-Commerce initiatives can be directed to the EBC Customer Service Center, which can be contacted by phone at 866-217-9197 (toll-free) or 571-272-4100, or by e-mail at [ebc@uspto.gov](mailto:ebc@uspto.gov).

The logo for 'snippets' is displayed in a red, lowercase, sans-serif font. The letter 'i' in 'snippets' has a small square above it, resembling a cursor or a highlight.

For many agents and attorneys, the USPTO's web-based Electronic Filing System (EFS-Web) provides a desirable alternative to last-minute trips to the nearest branch of the U.S. Post Office.



## **Annual Practitioner Fees & Correspondence Address**

This past fall, the USPTO enacted a new rule that creates an annual maintenance fee for all registered practitioners.<sup>1</sup> The fee is required of all agents and attorneys in order to maintain “active status” and to practice before the USPTO, and is set at \$118.00.<sup>2</sup> Alternatively, a practitioner can elect to be put on “voluntary inactive status,” which carries an annual fee of \$25.00.<sup>3</sup> However, anyone that opts to be put on voluntary inactive status may not practice before the USPTO on patent-related matters. Further, anyone who is on voluntary inactive status and subsequently wishes to be placed back on active status must pay a restoration fee of \$50, in addition to the balance of the “active status” fee.<sup>4</sup> The consequence of non-payment of either type of these annual fees is that the practitioner is placed on administrative suspension. While practitioners on administrative suspension can be placed back on active status if the suspension was due to a mistake (in good faith), the USPTO will charge additional fees for delinquent payment (\$50), or for reinstatement from inactive status (\$100).<sup>5</sup> These fees are in addition to the fee for active status or voluntary inactive status.

The Office plans to notify registered agents and attorneys about this annual fee using the contact information that the USPTO has in its records for each practitioner. This means that any out-of-date mailing address on the Office’s Patent Agent/Attorney Roster should be updated with the USPTO using a Change of Address form.<sup>6,7</sup> Once completed, the Change of Address form should be mailed to: Mail Stop OED, Director, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia, 22313-1450. Later this year, the USPTO plans to launch an online registration system that will be used to keep attorney and agent contact information accurate, as well as provide

notification of other important notices and communications.

## **Changes to Appeals Rules Delayed**

The USPTO had planned to introduce changes to the rules relating to Practice before the Board of Patent Appeals and Interferences in Ex Parte Appeals (appeal rules) in December of 2008. However, prior to the date on which the modified appeal rules were to take effect, the USPTO announced that the changes would be delayed in order to allow for further regulatory review.<sup>8</sup> With that announcement, the USPTO indicated that, during the interim period of further review, it would accept appeal briefs in formats that comply with either the existing rules or the formatting rules as outlined in the delayed, revised rules.

While these interim procedures appear to demonstrate flexibility on the part of the USPTO, filing appeal briefs under the existing rules is likely the best option for several reasons. For one, the additional time needed to become acquainted with the requirements of the revised formatting rules is likely to translate into increased professional fees relating to appeal-brief preparation. Further, there may be no benefit derived from the time and effort in proactively familiarizing oneself with a revised rule that may not ever take effect, or may not take effect in its current form. While there are additional reasons for filing appeal briefs under the existing rules, there seems to be little to no foreseeable benefit to filing appeal briefs according to the proposed revised version of the appeal rules.

## **e-Filing of Sequence Listings**

Since the launch of EFS-Web in the fall of 2006, applicants have had the option of e-filing sequence listings as text files only, rather than filing sequence listings in both paper and computer-readable copies. The text-files-only option eliminates the need to

submit sequence listings on separate electronic media, and avoids potential additional fees for excess application pages, currently set at \$270.00 for large-entity applicants, and \$135.00 for small-entity applicants per 50 pages after the first 100.

Section XIII of the EFS-Web Legal Framework<sup>9</sup> authorizes the filing of a sequence listing as a text file, provided the file is ASCII compliant. When submitting a sequence listing text file by EFS-Web, 37 C.F.R. § 1.52(e)(5) requires an incorporation-by-reference of the material in the text file through amendment of the specification. The incorporation-by-reference needs to be made in a separate specification paragraph and must include the name of the text file, the date of its creation, and the size of the text file in bytes. This paragraph should be inserted immediately before the Background of the Invention.<sup>10</sup>

Pursuant to 37 C.F.R. § 1.821, a patent application which discloses nucleotide and/or amino-acid sequences must contain both “a paper copy” of the sequence listing and a computer-readable form (CRF) of the sequence listing.<sup>11</sup> As long as the sequence-listing text file submitted via EFS-Web is an ASCII-compliant text file, it will serve as both the paper copy and the CRF as required by the sequence-listing rules. Because the single text file fulfills both requirements, the statement indicating that the paper copy and CRF copy of the sequence listing are identical is no longer necessary.<sup>12</sup>

When filing a sequence listing in response to a Notice to Comply or Notice of Missing Parts, the submission must include a statement indicating that the sequence listing does not include any information beyond the originally-filed application. As with the filing of a sequence listing with an original application, the statement indicating that the

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# News from the USPTO

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paper copy and CRF copy of the sequence listing are identical is not required.

Sequence-listing text files submitted by EFS-Web have a size limit of 100 megabytes. Because of this limit, sequence-listing files larger than 100 megabytes are more simply submitted to the USPTO as a text file on CD-R via Express Mail under 37 C.F.R. § 1.10 on the same date of the corresponding EFS-Web filing. This will ensure that the electronic copy, submitted on CD-R will be considered part of the original application.

EFS-Web can also be used to submit sequence-listing files in international applications with the U.S. Receiving Office of the Patent Cooperation Treaty (PCT).<sup>13</sup> The filing procedures for PCT applications are essentially identical to those for U.S. applications. However, one noteworthy difference relates to the associated fees. As noted above, the USPTO does not charge excess-page fees for compliant sequence listings submitted by EFS-Web only. However, the PCT does charge a fee for submitting a sequence listing as a text file only by EFS-Web (or on any electronic media). The fee is equivalent to the fee for 400 excess pages (currently \$5,600.00). Thus, filing sequence listings in the PCT only as electronic text files makes economic sense only if the sequence listing is over 400 pages in length. For sequence listings that are less than 400 pages, a better alternative is to submit the sequence listing as PDF pages as part of the application, while also including the text file of the sequence listing. In this situation, the filer should also submit the statement that the CRF copy and the paper copy of the sequence listing are identical in content.

Current news relating to USPTO rule changes, notices, and procedures can be found at Patent Docs (<http://www.patentdocs.org>),

which covers important developments in patent law generally, with a particular focus on issues relating to biotechnology, chemistry, and pharmaceuticals.

## Endnotes

1. 73 Fed. Reg. 67750.
2. 37 C.F.R. § 1.21(a)(7)(i).
3. 37 C.F.R. § 1.21(a)(7)(ii).
4. 37 C.F.R. § 1.21(a)(7)(iii).
5. 37 C.F.R. §§ 1.21(a)(9)(i), (ii).
6. The Change of Address for Registered Patent Attorneys and Agents form is available at this URL: <http://www.uspto.gov/web/offices/dcom/olia/oed/addchangefrm.pdf>.
7. Under 37 C.F.R. § 11.11(a), registered agents and attorneys are required to update contact information within 30 days of any change in that information.
8. 73 Fed. Reg. 74972.
9. The EFS-Web Legal Framework can be accessed at this URL: <http://www.uspto.gov/ebc/portal/efs/legal.htm>.
10. 37 C.F.R. § 1.77(b)(5).
11. 37 C.F.R. §§ 1.821(c), (e).
12. 37 C.F.R. § 1.821(f).
13. Sections XVII and XVIII of the Legal Framework.

**Dr. Christopher P. Singer's** practice consists primarily of patent preparation and prosecution in the biotechnology, chemical, and pharmaceutical arts in the U.S. as well as in foreign countries. Dr. Singer has experience counseling clients in the areas of patentability analyses and the rendering of opinions concerning patent validity, infringement, and freedom-to-operate.

[singer@mbhb.com](mailto:singer@mbhb.com)



**McDonnell Boehnen  
Hulbert & Berghoff LLP**

300 South Wacker Drive  
Chicago, Illinois 60606-6709

312 913 0001 phone  
312 913 0002 fax  
www.mbhb.com  
snippets@mbhb.com

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