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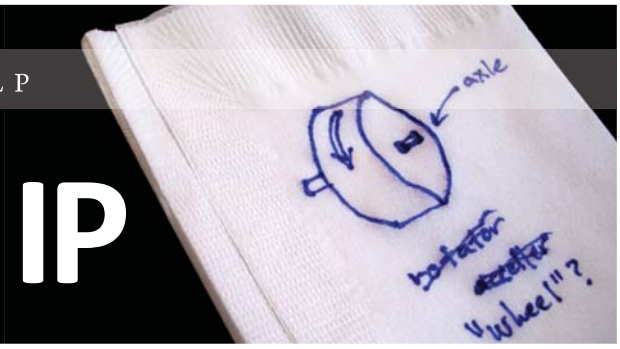

A quarterly newsletter from the Intellectual Property Practice Group at Thompson Coburn LLP

Green Tech Gets the Green Light

By William Holtz, Ph.D.

In December 2009, the United States Patent and Trademark Office (USPTO) implemented a pilot program to accelerate the examination of certain patent applications pertaining to green technologies. These technologies include improving environmental quality, energy conservation, renewable energy resources and reducing greenhouse gas emissions.[1] In a news release announcing the Green Technology Pilot Program, the USPTO stated "The new initiative, coming days before the United Nations Climate Change Conference in Copenhagen, Denmark, will accelerate the development and deployment of green technology, create green jobs, and promote U.S. competitiveness in this vital sector."[2] U.S. Commerce Secretary Gary Locke was quoted as saying "by ensuring that many new products will receive patent protection more quickly, we can encourage our brightest innovators to invest needed resources in developing new technologies and help bring those technologies to market more quickly."

The goal of the Green Technology Pilot Program is to decrease the pendency of previously filed applications. According to the USPTO, it currently takes about 30 months for applications in green technology areas to receive a first office action and 40 months to receive a final decision. The pilot program allows applicants to petition to have their green technology applications examined out of turn, thus reducing the time it takes to obtain a patent by about one year.

Under the pilot program, the USPTO will accept the first 3,000 petitions to make special for non-provisional utility applications filed before December 8, 2009, that have not yet received a first office action.[3] The program does not include applications filed after December 8, 2009, and thus is not necessarily an incentive to file new green technology applications. Petitions to make special under the pilot program must be filed before December 8, 2010. Eligible applications must be ones assigned to an approved art classification.[4] Although the eligible classifications currently do not cover all areas of green technologies, depending on the effectiveness of the pilot program and the resources available, the program may be extended to include more classifications in the future.

Petitions to make special must be accompanied by a request for early publication and an early publication fee if the application has not been published. Eligible applications may contain a maximum of three independent and twenty total claims. Claims may be amended or canceled to meet this requirement. The USPTO has also indicated that for applications cur-

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rently assigned to a non-eligible art classification, it is possible to amend the scope of the claims so that the claimed invention will potentially fall under an eligible classification. The applicant can then suggest to the USPTO that the amended application be assigned an eligible art classification. Also, for applications not yet assigned an art classification, the applicant may suggest that the application be assigned to an eligible classification.[5]

In a January 12, 2010 article, David Kappos, the Under Secretary of Commerce and Director of the United States Patent and Trademark Office, said that after barely a month, several hundred requests to make special had been filed.[6] Kappos was optimistic that after the initial twelve month duration of the pilot program, the success of the program will warrant committing more USPTO resources to "speed U.S. green-tech innovations into the marketplace where they can address climate change and create jobs." In a summary report posted on the USPTO website on February 24, 2010, the office reported that it had received 773 petitions, 117 of which had been granted, and 328 of which were still awaiting a decision.

In short, the scope of the Green Technologies Pilot Program is somewhat narrow because it only applies to pending applications in a limited number of classifications. Inventors of eligible applications may find that the quicker examination period of the pilot program offers them a real advantage in bringing their technologies to the world.

[1] Pilot Program for Green Technologies Including Greenhouse Gas Reduction, 74 Fed. Reg. 64,666 (Dec. 8, 2009), available at http://www.uspto.gov/patents/law/notices/74fr64666.pdf.

[2] Press Release, United States Patent and Trademark Office, The U.S. Commerce Department's Patent and Trademark Office (USPTO) Will Pilot a Program to Accelerate the Examination of Certain Green Technology Patent Applications (Dec. 7, 2009), http://www.uspto.gov/news/pr/2009/09_33.jsp.

[3] Applications entering the U.S. national stage under 35 U.S.C. § 371 on or after December 8, 2009, may also be eligible to participate in the pilot program if the international application on which the U.S. application is based was filed before December 8, 2009.

[4] A list of the eligible art classifications can be found at 74 Fed. Reg. 64,666, 64,668-69 (Dec. 8, 2009), available at http://www.uspto.gov/patents/law/notices/74fr64666.pdf.

[5] Frequently Asked Questions about the Pilot Program for Green Technologies Including Greenhouse Gas Reduction, http://www.uspto.gov/patents/init_events/faqs_on_green_tech_20091222.pdf (last visited February 10, 2010).

[6] David Kappos, Patents Key to Fighting Climate Change, Law360, January 12, 2010, http://www.law360.com/articles/141988 (Law360 subscribers only).

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Federal Circuit "Messes with Texas" on Motions to Transfer

By Jason M. Schwent

Because of its patent specific local rules and perceived "rocket docket," the Eastern District of Texas is a popular forum for plaintiffs to file patent infringement litigation. Motions to transfer are a fairly common response by patent litigation defendants in that district. It is also fairly common for such motions to be denied. Recent decisions of the Federal Circuit appear to indicate a greater willingness to grant these motions. They also provide direction on several factors cited by the district court judges for justifying their denials of motions to transfer. In 2009, four denials of motions to transfer were appealed from the E.D. Texas to the Federal Circuit and in three of those cases, the Federal Circuit held that clear error had been committed.

One common thread among the cases where the Federal Circuit ordered a transfer was a lack of parties, witnesses, and evidence in the E.D. Texas. Most recently, this lack of connection to the E.D. Texas was critical to Federal Circuit's finding that the denial of a motion to transfer was clear error in *In re Nintendo*.[1] In *Nintendo*, none of the parties were incorporated in Texas, no witnesses were located in Texas, and the parties did not identify any evidence located in Texas. The Federal Circuit discussed that because four witnesses and the majority of the defendants' evidence were located in the Western District of Washington, it was a much more convenient and less costly forum to host the litigation and that it also had a much stronger particularized local interest in the litigation.[2] The Federal Circuit also noted that the district court placed too much weight on the "plaintiff's choice of forum" factor. The Federal Circuit held that the plaintiff's choice to bring the action in the E.D. Texas was due no additional weight during the transfer analysis as plaintiff's choice of forum formed the basis of placing the burden of demonstrating that there was good cause for the transfer on the party seeking transfer.[3]

A common tactic for keeping litigation in the E.D. Texas when witnesses are located throughout the country is to argue that Texas, being centrally located, provides as convenient a location as any other district, thus negating the good cause to transfer. When the Federal Circuit recently addressed this argument in *In re Genentech*, it was not persuaded that the central location of Texas warranted denying transfer.[4] In so finding, the Federal Circuit distinguished the U.S. v. Binder case relied upon by plaintiff because, in *Binder*, there were witnesses in the plaintiff's chosen forum.[5] Turning next to the Fifth Circuit's "100 mile rule,"[6] which looks to the average distance to be travelled for potential witnesses when the proposed transfer venue is more than 100 miles from the plaintiff's choice, the Court believed that the rule should not be rigidly applied.[7] Instead, the Federal Circuit noted that when witnesses must travel a significant distance, especially from a foreign country, requiring them to travel to a different U.S. district did not significantly increase their inconvenience.[8] This is particularly true when there are multiple witnesses located in the proposed transfer forum who would undoubtedly be inconvenienced should the case remain in the E.D. Texas.[9]

Another common argument made during the consideration of motions to transfer is that the location of evidence is of less importance now that discovery and production can be done electronically. Relying on Fifth Circuit law, which requires district courts to consider the location of evidence as part of the motion to transfer analysis, the *Genentech* panel held that minimizing the importance of document location (even where those documents are electronic) was improper because it rendered superfluous the consideration of that prong of the transfer analysis.[10]

The Federal Circuit was equally unpersuaded by conduct designed to manufacture a connection to the venue. In *In re Hoffmann-La Roche*, the plaintiff sent some 75,000 pages of documents to its local counsel's offices in the E.D. Texas prior to filing suit.[11] The trial judge found that those documents were "Texas" documents and favored keeping the case in the E.D. Texas. The Federal Circuit saw things differently. According to the Federal Circuit, the transfer of those documents to local counsel's office was clearly a litigation ploy designed to manufacture a connection to the venue that could not defeat an otherwise persuasive motion to transfer.[12]

The case of *In re Volkswagen of America* was the lone case where the denial of transfer was upheld by the Federal Circuit in 2009.[13] In *Volkswagen*, the plaintiff had filed two patent infringement lawsuits in the E.D. Texas against two different sets of defendants on the same patents. A third patent infringement litigation involving those same patents had also previously been transferred to the E.D. Texas. When the defendants in

one action sought transfer to Michigan, the trial judge analyzed the public and private convenience factors and determined that the defendants failed to satisfy their burden of showing that transfer was warranted.[14] Interestingly, the judge's decision on the motion to transfer made no mention of the other litigations pending in the district. In contrast, on appeal, the Federal Circuit made no mention of the public and private convenience factors and instead focused entirely on the other pending litigations in upholding the decision to deny transfer. According to the Federal Circuit, "the existence of multiple lawsuits involving the same issues is a paramount consideration when determining whether a transfer is in the interest of justice."[15]

The Federal Circuit's recent decisions provide some guidelines for presenting or responding to a motion to transfer and the initial selection of a venue. First, it is imperative to determine whether some party, witness, or evidence is located in the venue — even where witnesses and evidence are otherwise distributed throughout the country. Second, transparent litigation tactics are unlikely to keep otherwise transferable cases in the district. Lastly, filing multiple lawsuits against different sets of defendants on the same patents, may provide a basis for keeping litigation in the initial forum.

[1] *In re Nintendo Co., Ltd*, 2009 WL 4842589 (Fed. Cir. December 17, 2009).

[2] *See id.* at *3-4.

[3] *See id.* at *4.

[4] *In re Genentech, Inc.*, 566 F.3d 1338 (Fed. Cir. 2009).

[5] *Id.* at 1344 (distinguishing U.S. v. Binder, 794 F.2d 1195 (7th Cir. 1986) because witnesses in Binder were located in plaintiff's chosen forum).

[6] As enunciated by the Fifth Circuit, the "100-mile rule" is as follows: "When the distance between an existing venue for trial of a matter and a proposed venue under § 1404(a) is more than 100 miles, the factor of inconvenience to witnesses increases in direct relationship to the additional distance to be traveled."

[7] *See id.* ("However, the '100-mile' rule should not be rigidly applied such that it creates the result presented here.").

[8] *See id.*

[9] *See id.* ("In contrast to the foreign witnesses, there are a substantial number of witnesses residing within the transferee venue who would be unnecessarily inconvenienced by having to travel away from home to testify in the Eastern District of Texas.").

[10] *See id.* (holding that "the court's antiquated era argument was essentially rejected in [In re Volkswagen of Am., Inc., [545 F.3d 304, 316 (5th Cir. 2008)(en banc)] because it would render this factor superfluous.")

[11] *In re Hoffmann-La Roche Inc.*, 587 F.3d 1333 (Fed. Cir. 2009).

[12] *Id.* at 1337 ("Thus, the assertion that these documents are 'Texas' documents is a fiction which appears to [sic] have been created to manipulate the propriety of venue.").

[13] *In re Volkswagen of Am., Inc.*, 566 F.3d 1349 (Fed. Cir. 2009).

[14] *Id.* at 1351.

[15] *Id.*

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Jason M. Schwent has extensive experience in litigating complex patent, trademark and copyright matters in administrative proceedings, state and federal courts. He has substantial experience in drafting and reviewing open source and proprietary software licenses, counseling clients regarding media licensing and technology transfer and advising clients about maximizing the protection for their intellectual property assets. Mr. Schwent also has significant experience representing and advising established and emerging technology companies, multi-national manufacturing companies and large Fortune 500 corporations.

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Lowering the Bar for Filing Declaratory Judgment Actions

Triggering Declaratory Judgment Jurisdiction

By Pamela M. Miller

The recent Federal Circuit decision in Acceleron continues to lower the threshold for declaratory judgment jurisdiction, particularly when an accused infringer is targeted by a patent holding company.[1]

It is common for a patent owner to send a letter to an accused infringer requesting that it stop an alleged infringing activity. Although these types of letters can result in the patent owner and the accused infringer reaching an agreement without litigation, sending such a letter is not without risk. Such letters may provide the accused infringer the right to file a declaratory judgment action seeking a judgment that the patent is invalid, unenforceable, or not infringed. These declaratory judgment actions are often considered to be unfavorable to the patent owner because they enable the accused infringer to choose the forum of the litigation and may give the plaintiff the privilege of putting on its case first. For these reasons, such letters were usually drafted in a manner that would make it unlikely that the letter could be the basis for a declaratory judgment action.

The declaratory judgment playing field changed in 2007 with the Supreme Court's decision in MedImmune, which rejected the Federal Circuit's long-standing test for determining whether an accused infringer has the right to file a declaratory judgment action.[2] The old Federal Circuit test involved determining whether the accused infringer had a reasonable apprehension of imminent suit being brought by the patent owner. In *MedImmune*, the Supreme Court ruled that a broader "all circumstances" test should be used to determine whether, under the facts alleged, "there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[3] The Court found declaratory judgment jurisdiction where the declaratory plaintiff was effectively coerced into paying royalties under a licensing agreement, noting that a patent licensee need not breach a license agreement to create a reasonable apprehension of suit before it can seek declaratory judgment.[4] Unlike the Federal Circuit's previous test, a patent holder may no longer avoid a declaratory judgment action by controlling its action so as to fall short of creating in the accused infringer a reasonable apprehension of imminent suit. After MedImmune, something less could suffice to confer declaratory judgment jurisdiction. The Federal Circuit has been attempting to determine how low the bar has been set.[5] As the Federal Circuit noted in *Acceleron*, "a lowered bar does not mean no bar at all."[6]

Following the Supreme Court's guidance in *MedImmune*, the Federal Circuit in *Acceleron* reversed the district court's dismissal for lack of declaratory judgment jurisdiction.[7] Acceleron, a patent holding company, acquired a patent only months before it sent a demand letter to Hewlett-Packard ("HP") "call[ing] attention" to the patent as relevant to HP's product line.[8] Acceleron requested HP to respond within two weeks, provided HP agree that any information exchanged would not be used for litigation and that no declaratory judgment jurisdiction existed.[9] HP responded to Acceleron's letter by agreeing to not file an action for a set period of time only if Acceleron similarly agreed. Acceleron refused and again imposed another deadline, noting this time that there was no basis for declaratory judgment jurisdiction.[10] HP filed a declaratory judgment action that was dismissed by the district court.[11]

On appeal, the Federal Circuit viewed the facts objectively under the totality of the circumstances to find that the implicit assertion of Acceleron's patent rights in its demand letters was sufficient to establish declaratory judgment jurisdiction when coupled with Acceleron's conduct.[12] The court concluded that Acceleron's actions could reasonably be inferred as demonstrating an intent to enforce those patent rights.[13] The lack of any express or explicit assertion of infringement by Acceleron in its communications with HP was not fatal for the establishment of jurisdiction. Significant to the court's decision was Acceleron's status as a patent holding company, *i.e.* a non-practicing entity that solely licenses its patents. As the Federal Circuit noted, "without enforcement [Acceleron] receives no benefits from its patents."[14] Also significant was the fact that Acceleron identified its patent to and imposed deadlines upon HP.[15]

The bar seems to have been significantly lowered as Acceleron made no claim of infringement and demanded no license or royalty agreement from HP. Although mere knowledge of a patent owned by another or the perception that a patent poses a risk of infringement is not enough, it is an open question after *Acceleron* what action a patent owner may take without triggering declaratory judgment jurisdiction.

Patent owners, in general, and those that do not practice the patent, in particular, should be aware that sending a letter informing someone of their patent even without alleging infringement or demanding license fees may be considered by a court to be sufficiently threatening to the recipient to trigger declaratory judgment jurisdiction.

[1] *See Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358 (Fed. Cir. 2009).

[2] *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

[3] *Id.* at 127 (quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)).

[4] *See id.* at 130-37.

[5] *See, e.g., Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d. 871 (Fed. Cir. 2008); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007); *San-Disk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007).

[6] *Acceleron*, 587 F.3d at 1362.

[7] *See id.* at 1361-64.

[8] *Id.* at 1360.

[9] *Id.*

[10] *Id.* at 1360-61.

[11] *Id.* at 1361 (*citing Hewlett-Packard Co. v. Acceleron, LLC,* 601 F. Supp.2d 581 (D. Del. 2009)).

[12] *Id.* at 1363-64.

[13] *Id.* at 1363.

[14] *Id.* at 1364.

[15] *Id.* at 1362-63.

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Are Test Results Required to Show the Utility of an Incredible Pharmaceutical Invention?

By Steven M. Ritchey and Charles P. Romano Ph.D.

To obtain a patent on an invention, the claimed invention must have utility and the patent specification must, among other things, enable a person of ordinary skill in the art to make and use the invention without undue experimentation. The relationship of the utility and enablement requirements is well-established, since it is impossible to teach the use of an invention that is useless or inoperable.[1] Thus, a patent specification that fails to convey an assertion of "credible utility" is invalid for a lack of enablement. Credible utility was the focus of *In re '318 Patent Infringement Litigation*, a case in which a three-judge panel of the Federal Circuit Court of Appeals affirmed a trial court decision that a patent on an operable and otherwise enabled invention was invalid for a lack of enablement because the specification lacked credible utility at the time the patent application was filed.[2]

At issue in the *'318 Litigation* were claims directed to methods of treating Alzheimer's disease with galantamine. In this case, there was no dispute as to the operability of the claimed methods of treating Alzheimer's. In fact, the drug was ultimately approved by the Food and Drug Administration for use in treating Alzheimer's. The patent is little more than a page in length and contained a brief analysis of various prior art references, a brief description of drug administration methods and doses, and a brief description of a published "test that provides a good animal model for Alzheimer's disease in humans." Absent from the patent were any working examples of the claimed methods. Working examples, even when conducted in cultured cells or other test systems, have long been deemed sufficient evidence of utility when there is a reasonable correlation between a compound's activity and the claimed therapeutic use.[3]

In reaching its decision that the '318 patent claims were not enabled, the Federal Circuit seemed to regard as significant the fact that the specification did not disclose any *in vitro* experiments with living organisms or animal tests. Although animal testing results showing galantamine was effective for treating Alzheimer's disease were eventually obtained by the inventor, they "required several months and considerable effort by researchers," and were not available until about two months after the patent issued.[4] The court's majority continued to expound upon the importance of test results stating "[t]ypically, patent applications claiming new methods of treatment are supported by test results" and "[w]e have held that results from animal tests or in vitro experiments may be sufficient to satisfy the utility requirement."[5] Further, the majority noted that "'[w]e perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the [pharmaceutical] compound in question' in order for a patent to issue."[6]

As mentioned above, test results were obtained shortly after the patent issued but the trial court ruled that the results could not be used to establish credible utility necessary for enablement because they were not available at the time the application was filed. The majority of the appellate court looked to *In re Brana* to support the affirmance of the trial court's decision, which apparently they believed stands for the proposition that post-filing results are not to be considered when evaluating enablement.[7] Judge Gajarsa, in his dissent, disputed the majority's characterization of In re Brana and asserted that the Brana panel found post-filing test results to be acceptable for supporting a finding of utility.[8]

The majority then addressed the plaintiff's argument that utility may be established without testing the proposed treatment in the claimed environment or a sufficiently similar predictive environment — in this case by analytic reasoning. Although the majority noted that the U.S. Patent and Trademark Office's Manual of Patent Examining Procedure allows for arguments or reasoning to establish an invention's therapeutic utility, it also pointed out that those guidelines were not binding on the court. The majority further noted that there were no cases in which analysis was the sole basis for establishing utility. Nonetheless, the court considered the plaintiff's testimonial evidence of the various "insights" that could be gleaned from the prior art summarized in the specification. The majority was unpersuaded because the insights weren't expressly disclosed in the specification and there "was no evidence that someone skilled in the art would infer galantamine's utility from the specification, even if such inferences could substitute for an explicit description of utility."[9] In summary, the court held that "the patent specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis."

In addition to *In re Brana*, Judge Gajarsa addressed what he perceived to be the majority's improper fusion of credible utility in the context of enablement with reduction to practice, which was not at issue: "Such a conflation risks the introduction of an actual reduction-to-practice requirement into patent law, contrary to more than a century of settled precedent."[10]

The full impact of *In re '318 Patent Infringement Litigation* remains to be seen. Ultimately, it may have limited applicability to other situations because of its particular facts — the case involved an unusually short specification with no working examples and the inventor made statements during prosecution and litigation that perhaps could have been more precisely worded, which the majority seemed to consider important.[11] That said, it seems there are generally applicable lessons to take away from *In re '318 Patent Infringement Litigation* for both patentees and challengers of an issued patent. First, although additional evidence to support the scientific credibility of an asserted utility may be submitted to the Patent Office during prosecution of the application to counter other inconsistent evidence of record or current scientific knowledge,[12] a court may not be able to consider such evidence and may be limited to considering what is disclosed in the patent application itself.[13] Therefore, if an invention is groundbreaking or contrary to current scientific knowledge (e.g., an invention claiming to diagnose, treat, or cure a disease or condition known to be to difficult to treat such as a cancer or Alzheimer's disease) it is probably advisable to include disclosure in the application sufficient to counter what contemporary knowledge might otherwise suggest. Second, for such "incredible" inventions, the importance of including working examples showing a reasonable correlation between a compound's activity and the claimed therapeutic results has been highlighted. Although the majority did not expressly hold that working examples were required, the lack of them appeared to be a major factor that led to their decision. Third, in situations where it is not possible to provide a working example, patent applicants may wish to expressly articulate the novel and non-obvious insights they gained from the prior art that led to their claimed invention rather than possibly being required to argue those insights may be inferred from the patent specification. As suggested, the majority doubted whether an inference of utility "could substitute for an explicit description of utility."[14]

[1] *See In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995); *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989).

[2] *In re '318 Patent Infringement Litigation*, 583 F.3d 1317 (Fed. Cir. 2009).

[3] *See In re Brana* at 1565-66.

[4] *In re '318 Patent Infringement Litigation* at 1322.

[5] *Id.* at 1324-25.

[6] *Id.* at 1325 (*quoting Cross v. Iizuka*, 753 F.2d 1040, 1051 (Fed. Cir. 1985)).

[7] *See Id.* at 1325 (*citing In re Brana* at 1566).

[8] *Id.* at 1330 n.1 (*citing In re Brana* at 1567) ("The majority's claim that 'unlike the present case, the testing [in *Brana*] was submitted to the PTO during prosecution' is misleading. The appeal in Brana was taken from the Board of Patent Appeals . . . . And thus the Brana panel could not have intended to provide for a distinction between the test results offered to support the credible utility of an otherwise enabling disclosure pre- and post-patent issuance.").

[9] *Id.* at 1326.

[10] *Id.* at 1331.

[11] *See Id.* at 1322, 1327 ("[The inventor] responded to an obviousness rejection by explaining that, because the brains of the animals in the studies cited in the specification were 'normal' (rather than having 'physiological changes' similar to Alzheimer's disease), the studies were conducted under 'circumstances having no relevance to Alzheimer's disease,' and that it thus would be 'baseless' to predict from such studies that galantamine would be useful to treat Alzheimer's disease."); ("[W]hen I submitted this patent, I certainly wasn't sure, and a lot of other people weren't sure that cholinesterase inhibitors[, a category of agents that includes galantamine,] would ever work.").

[12] Manual of Patent Examining Procedure § 2107.02.

[13] *See In re '318 Patent Infringement Litigation* at 1325, 1326.

[14] *Id.* at 1326.

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