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Enablement: The Federal Circuit Raises the Bar (Again)

As every patent practitioner knows, an enabling disclosure is a requirement of patent validity: the patent specification must contain a written description that enables one skilled in the art to make and use the claimed invention.[1] While the Federal Circuit grapples with the issue of whether the enablement requirement is distinct from the written description requirement,[2] in recent years the Court has suggested that only those embodiments explicitly disclosed in the specification can meet the enablement requirement. Thus, enablement may be required for (1) the full scope of a claimed range;[3] (2) every element of a claimed device;[4] (3) the element on which novelty of the invention is based;[5] and (4) all alternative embodiments.[6] Now, in the recent decision of *In re '318 Patent Infringement Litigation*,[7] the Court appears to be approaching an interpretation of the enablement requirement that requires not only a written description of the invention, but also an actual reduction to practice.

It is a tenet of patent law that actual reduction to practice is not necessary either to file a patent application, or for any resulting patent to be valid. Thus, some patent applicants might be tempted to file a patent application with little or no experimental data, either in an attempt to save costs in the preparation and prosecution of the application or in a race to an early filing date.

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Trade Secret Basics: What Every Business Owner Needs to Know

Many business owners have acquired or developed information assets, otherwise known as "trade secrets," which give them advantages over their competitors. Given the substantial costs and time that are required for developing or acquiring trade secrets, it is critical that a business owner be able to control and prevent others, such as ex-employees or outside consultants, from disclosing the trade secrets to others without permission. While many businesses typically focus on patents and trademarks as the main source of intellectual property protection, businesses should not overlook trade secret protection. Indeed, trade secrets are a distinct form of intellectual property that can provide additional breadth and flexibility to a business's intellectual property portfolio.

Because trade secrets are a distinct form of intellectual property that are not fully covered by federal statutes in the same way that patents, trademarks, and copyrights are, the rules and requirements for trade secrets differ from those laws with which many business owners may be more familiar. This article provides an overview of trade secrets, the legal protections available, and reasonable safeguards for maintainng the secrecy of proprietary trade secret information.

Trade Secrets Defined

Trade secrets are virtually any information that derives independent economic value from not being generally known to the public.[1] Trade secrets extend beyond patent coverage in that the information need not be novel.[2] Trade secrets may include technical and scientific information such as secret manufacturing methods, know-how, formulae, designs, and computer code, as well

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The decision of *In re '318 Patent Infringement Litigation* provides a cautionary tale, particularly to those who practice in the pharmaceutical arts. This case demonstrates that even if the U.S. Patent and Trademark Office issues a patent in the pharmaceutical arts without substantiating data, such a patent can be held invalid as not satisfying the enablement requirement, because the absence of data fails to establish utility. It is therefore important to understand how this decision came about, and what patent applicants can do to avoid such a result.

Background

The facts behind the *In re '318 Patent Infringement Litigation* decision are straightforward. The invention of the patent-in-suit, U.S. Patent No. 4,663,318, related to a method of treating Alzheimer's disease by administration of galanthamine. The application was filed in 1986, more than twenty years before the Federal Circuit's ultimate decision on validity. The specification was just over a single page.

The patent specification stated that, at the time the application was filed, researchers had noted a correlation between Alzheimer's symptoms and a reduced level of acetylcholine in the brain. It further was known that acetylcholine binds to both nicotinic receptors and muscarinic receptors. These receptors are present in both the central nervous system and the peripheral nervous system. In 1986, most researchers focused on the muscarinic receptors in the central nervous system. Galanthamine was known to have anticholinesterase properties, such that it increased the amount of acetylcholine available for binding.

In describing the prior art, the '318 patent specification cited two studies on human patients regarding the effect of galanthamine on plasma cortisol and on plasma ACTH values during anesthesia. The specification also cited four studies on normal animals related to brain wave effects and positive effects on memory achieved by administration of galanthamine. The specification did not draw any inferences from any of these studies regarding potential to treat Alzheimer's disease. The Court stated that those skilled in the art would understand that the studies on humans indicated that galanthamine could cross the blood-brain barrier and have effects within the brain.[8]

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The Federal Circuit is approaching an interpretation of enablement that requires actual reduction to practice.

The specification also cited another prior art reference that described an animal testing model for replicating the effects of Alzheimer's disease by introducing in the animal a brain lesion similar in magnitutde to that seen in early to moderate stage Alzheimer's disease, and characterized by numerous behavioral defects, including the ability to learn and retain new information. The specification observed that "[d]rugs that can normalize these abnormalities [in animals] would have a reasonable expectation of efficacy in Alzheimer's disease."[9]

In the detailed description of the invention, the patent identified different chemical and physical forms in which the galanthamine could be administered for treatment of Alzheimer's disease. It also stated different dosage ranges. There was neither *in vitro* nor *in vivo* data in the patent to support these dosage forms or ranges.

During prosecution of the application, the applicant argued that the claimed invention was not obvious over the cited animal studies because those studies related to animals having "normal" brains, and were conducted under circumstances having no relation to Alzheimer's disease, and therefore could not be extrapolated to reach conclusions about the utility of galanthamine as a treatment for Alzheimer's disease. The applicant also stated that experiments were underway using animal models, which were expected to show that treatment with galanthamine was effective in Alzheimer's disease treatment. Although the applicant stated that the results would be provided to the Examiner when available, the application was allowed without this data, and in fact, the experimental results did not become available until after the patent had issued.

In 2001, fourteen years after the '318 patent issued, the assignee, Janssen, received FDA approval for the use of galanthamine for the treatment of mild to moderate Alzheimer's disease. In 2005, several generic drug manufacturers filed abbreviated new drug applications ("ANDAs") related to galanthamine, as well as "Paragraph IV" certifications.[10] Janssen sued each of these generic drug manufacturers for infringement. Following a bench trial, the district court held that, while the claimed invention was neither anticipated nor obvious, the claims were invalid for lack of enablement because: (1) the specification did not demonstrate utility because relevant animal experiments were not finished by the time the patent was allowed, and the specification provided only "minimal disclosure of utility," and (2) the patent did not teach one skilled in art how to use the claimed method because it only "surmised how it could be used" without providing sufficient dosage information.[11]

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The Federal Circuit's Decision: Utility and Enablement Intertwine

The Federal Circuit's majority opinion, written by Judge Dyk, noted the "close relationship" between the utility and enablement requirements.[12] The Court emphasized that, "*[i]f a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement*".[13] The Court also stated that inventions must have "substantial utility" and "specific benefit exist[ing] in currently available form."[14]

The Court stressed "[t]he utility requirement prevents mere ideas from being patented,"[15] noting that a grant of patent protection is not given for "vague intimations of general ideas that may or may not be workable"[16] or for "tossing out the mere germ of an idea."[17] The Court also stated, "[t]he utility requirement also prevents the patenting of a mere research proposal or an invention that is simply an object of research . . . Allowing ideas, research proposals, or objects only of research to be patented has the potential to give priority to the wrong party and to 'confer power to block off whole areas of scientific development, without compensating benefit to the public.'"[18]

The Court noted that "it is clear that testing need not be conducted by the inventor. In addition, human trials are not required for a therapeutic invention to be patentable."[19] The Court never clarified which situation did not require testing by the inventor, instead noting that animal tests or *in vitro* experiments "*may* be sufficient to satisfy the utility requirement".[20]

In this case, however, the '318 patent included neither *in vitro* tests nor animal tests using galanthamine to treat Alzheimer-like conditions. The ongoing experiments discussed during prosecution were not available at the time of the application, and thus could not be used to establish enablement. Nor could utility of the claimed invention be inferred from the prior animal studies cited in the patent and distinguished during prosecution.

The majority rejected the patentee's argument that utility could be established by analytical reasoning, notwithstanding the statement in the MPEP that "arguments or reasoning" may be used to establish utility.[21] The Court noted that the analytical arguments proposed by the patentee during litigation were not described in the specification, and there was no evidence that one skilled in the art could infer utility from the specification.[22,23] And the Court appeared to give weight to the inventor's testimony that at the time of the application, she was not sure that cholinesterase inhibitors (such as galanthamine) would work.[24] The majority therefore held that the specification, doing no more than stating a hypothesis and proposing testing, did not satisfy the enablement requirement because the application did not establish utility.[25]

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The contents of the application, not the merits of the invention, determine utility.

In dissent, Judge Gajarsa pointed out that no one disputed that the inventor's insights were correct and confirmed by later studies.[26] The relevant question, he stated, is whether at the time the application was filed, the patent's written description would have credibly revealed to an ordinarily skilled artisan galanthamine's utility for Alzheimer's disease treatment. Judge Gajarsa believed that the district court had not properly addressed this question.[27]

He pointed out that an inventor may look at the prior art differently than those before her, arrive at a novel and non-obvious insight, and submit a patent application that compiles the prior art findings that led to the insight in such a way as to render obvious in hindsight that which was wholly non-obvious at the time of the application.[28] In the present case, he stated, if the inventor used her unique perspective to examine the prior art and arrive at a novel insight about galanthamine, then the invention may be non-obvious, and if her patent disclosed those selected findings in such a manner that a person of ordinary skill would credit her insight regarding galanthamine's utility, then the invention was enabled.[29] Thus, according to Judge Gajarsa, the district court erred by focusing on the teachings of the prior art, rather than the teachings of the patent.[30]

Judge Gajarsa also criticized the majority's "relentless focus on the need for timely test results" as conflating credible utility in the context of enablement with the notion of 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."[31]

Take-away Tips for Practitioners

- Remember that the contents of the application, not the merits of the invention, determine utility. In this case, the invention itself, *i.e.* the use of galanthamine to treat Alzheimer's disease, was indisputably useful, as shown by the granting of FDA approval, and several parties other than the patentee wanting to introduce

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products to make use of the invention. The issue here, however, was whether the *application* adequately demonstrated utility at the time that the application was filed. The fact that the invention was useful was irrelevant in determining whether utility was established in the patent application to meet the standard of enablement.

- Be defensive. Encourage inventors to provide as much data as possible.
- Understand the inherent risks of providing too little data. Even if data is not required in theory, per the MPEP and case law, as a practical matter a court may require it, even if the PTO does not.
- Do not rely on the knowledge of those skilled in the art at the time of the application. Asserting that those skilled in the art would know how to use the invention could undercut a position of non-obviousness. Claims that are not obvious over the prior art are likely not enabled by that art.
- Be sure to describe in the specification any insights that the inventor has that are not taught or suggested by the prior art.

Endnotes

1. *See* 35 U.S.C. § 112 (2006) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.")
2. *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009), *vacated, reh'g granted,* 2009 WL 2573004 (Fed. Cir., Aug 21, 2009).
3. *AK Steel Corp. v. Sollac Ugine,* 344 F.3d 1234 (Fed. Cir. 2003).
4. *Liebel-Flarsheim Co. v. Medrad, Inc.,* 358 F.3d 898 (Fed. Cir. 2004).
5. *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.,* 501 F.3d 1274 (Fed. Cir. 2007).
6. *Sitrick v. Dreamworks, LLC,* 516 F.3d 993 (Fed. Cir. 2008).
7. *In re '318 Patent Infringement*, 583 F.3d 1317 (Fed. Cir. 2009).
8. *Id.* at 1321.
9. U.S. Patent No. 4,663,318, col. 2, lines 52-54.
10. An Abbreviated New Drug Application ("ANDA") may be filed with the FDA to obtain approval to manufacture, use, or sell a generic version of a previously approved drug. 21 U.S.C. § 355(j) (2006). If the drug is alleged to be covered by one or more patents, then the ANDA must include a so-called "Paragraph IV certification" by the ANDA applicant, stating that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006). The filing of a Paragraph IV certification is defined as an act of infringement for litigation purposes. 35 U.S.C. § 271(e) (2006); *In re '318 Patent Infringement*, 583 F.3d at n.4.
11. 583 F.3d at 1323 (citing 578 F.Supp.2d 711, 723, 735, 736-37 & n. 39. (D. Del. 2008)).
12. 583 F.3d at 1323 (citing *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999)).
13. *Id.* at 1324 (emphasis by the Court).
14. *Id.* (citing *Brenner*, 383 U.S. 519, 534-35 (1966)).
15. *Id.*
16. *Id.* (citing *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).
17. *Id.*
18. *Id.* (citing *Brenner v. Manson*, 383 U.S. at 534).
19. *Id.*
20. *Id.* at 1324-25 (emphasis added).
21. U.S. Patent & Trademark Office, Manual of Patent Examining Procedure (MPEP), § 2107.03 (8th ed., Rev. 7, July 2008).
22. *In re '318 Patent Infringement*, 583 F.3d at 1326.
23. In dissent, Judge Gajarsa stated that the district court erred in failing to undertake the required legal analysis of whether an ordinarily skilled artisan would understand the patent to reveal a credible utility. *Id.* at 1328. The majority responded in footnote 12 that the absence of such analysis is not error where such factual findings would be irrelevant. The majority did not explain why such findings would be "irrelevant," when it relied on the lack of such findings in reaching its own conclusion of non-enablement.
24. *Id.* at 1327.
25. *Id.*
26. *Id.* at 1328.
27. *Id.*
28. *Id.* at 1328-29.
29. *Id.* at 1329.
30. *Id.*
31. *Id.* at 1331 n.1.

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as commercial and financial information such as customer lists, customer requirements, pricing information, and suppliers.[3] Even negative commercial information, such as failed formulations or processes, abandoned technical solutions, and unsuccessful attempts to reach certain markets or customers, can have value as a trade secret.[4]

Patent or copyright protection generally requires public disclosure of information in exchange for a right to exclude the public for a limited time from exploiting that information. Upon expiration of that limited time, the information becomes freely available to the public.[5] In contrast, trade secret protection exists for as long as the owner maintains the secrecy of the information.[6] However, unlike patent or copyright laws, trade secret laws do not provide the owner with any exclusive right to exploit the information.[7] Others may develop the information independently or derive it from reverse engineering of the trade secret owner's product.[8] If a trade secret is readily discernable from the product either by inspection or by reverse engineering, then patent or copyright protection of the information may be more appropriate.[9] If it is possible to maintain the secrecy of the information, trade secret protection may be preferred because it is inexpensive, requires no registration in order to secure the protection, and can potentially last forever.

Summary of the Law of Trade Secrets

U.S. law protects patents, copyrights, trademarks, and trade secrets. While there is a civil cause of action under federal law for patents, copyrights and trademark infringement, none exists for trade secret misappropriation.[10] The majority of trade secret enforcement occurs through civil suits brought under state law.[11] As of 2009, forty-five states and the District of Columbia had passed trade secret protection laws patterned on the Uniform Trade Secret Act (UTSA).[12] The few exceptions are Massachusetts, New Jersey, New York, North Carolina, and Texas.[13] In those states that have not adopted the UTSA, the courts are generally guided by the Restatement (First) of Torts.[14]

Under the UTSA, a trade secret is defined as "information, including a formula, pattern, compilation, program, device, method, technique, or process, that . . . derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use."[15] To be considered a trade secret, the information must be "the subject of efforts that are reasonable under the circumstances to maintain its secrecy."[16]

A trade secret is "misappropriated" when it is acquired through improper means[17] or where it is disclosed or used without the trade secret owner's consent after having been acquired under circumstances giving rise to an obligation to maintain its secrecy.[18] The term "improper means" includes "theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage through electronic or other means."[19] Misappropriation also occurs when a party discloses or uses information that it acquired by accident or mistake, if the party was given notice that the information was a trade secret of another before the party materially changed its position based on its belief that the information was unprotected.[20]

In addition to a civil action under the UTSA, a trade secret owner may have other causes of action including breach of contract[21] or breach of fiduciary duties owed by employees or officers.[22] If a third party such as a new employer was involved in the misappropriation, an allegation of tortious interference with the trade secret owner's rights may be asserted.[23] Other causes of action exist depending on the manner in which the information was acquired or removed. For instance, misappropriation involving unauthorized access to computer systems may be considered a violation of the federal Computer Fraud and Abuse Act.[24] Also, misappropriation involving physical removal of documents or articles may give rise to an action for return of property.[25] Non-UTSA states may recognize additional causes of action, such as unfair competition, based on the same facts that give rise to a trade secret misappropriation action.[26]

Remedies for trade secret misappropriation include money damages[27] as well as injunctive relief preventing further use by those that misappropriated the trade secret.[28] In UTSA states, if a court finds that the misappropriation was "willful and malicious," the court is authorized to double the amount of money damages[29] and to award attorney fees to the injured party.[30]

Reasonable Precautions to Protect Trade Secrets

> "A trade secret once lost is, of course, lost forever."[31]

The economic importance of taking reasonable precautions to protect trade secrets and other confidential proprietary information cannot be underestimated. Robert Mueller, the former director of the FBI, estimates that economic espionage costs the U.S. $250 billion each year.[32] Indeed, the existence of security precautions is not only required under the UTSA, such precautions suggest that the information has value to the owner, that notice was provided to employees and others that the information is confidential,

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and that unauthorized use or disclosure of the confidential information is improper. To protect against the loss of valuable trade secrets, business owners should employ reasonable safeguards, such as:

(a) classifying documents, such as designating appropriate documents as confidential and proprietary;
(b) controlling visitor access using video surveillance, security cards, and ID badges, and limiting physical access to areas having any confidential information;
(c) securing computer networks by monitoring access to information through log-in procedures, monitoring internet use, minimizing security breaches, and maintaining filing storage programs;
(d) providing confidentiality obligation notices in employee handbooks, and requiring exit interviews for departing employees to emphasize confidentiality obligations and ensure return of all confidential information;
(e) requiring non-disclosure or confidentiality agreements from people having access to confidential information; and/or
(f) avoiding unnecessary distribution or disclosure of information.[33]

Trade secret information should only be disclosed to individuals on a need-to-know basis. An example where trade secrets were misappropriated when individuals had unnecessary access to those trade secrets is the case of Joya Williams and Coca-Cola. Williams was the secretary for Coca-Cola's global brand director at the company's headquarters.[34] She took confidential documents and product samples from Coca-Cola and conspired with two others (who both pleaded guilty) to attempt to sell those trade secrets to Pepsi.[35] The judge in her criminal case sentenced her to eight years in prison—more than requested by the prosecutors.[36] The Joya Williams case provides a clear example of why business owners should only disclose their trade secrets to those who need the information to carry out their duties.

Confidentiality agreements may be useful in protecting trade secrets, though courts often require that such agreements only restrict the use of information that is actually confidential.[37] Non-competition agreements may also be useful so long as the restrictions are reasonably limited in time, scope and geography.[38] A court is unlikely to enforce a non-competition agreement without time or geographic restrictions because the court is likely to find that the agreement is overly broad in its efforts to protect the interests of the employer.[39] However, the permissible scope of a confidentiality or non-competition agreement will vary among the different states and courts. For example, one court enforced a non-competition agreement that contained no territorial restrictions,[40] while another court refused to enforce such an agreement because it was overly broad.[41]

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While courts have deemed a number of precautionary procedures as adequate, there is generally no requirement that the procedures result in absolute secrecy of the information.[42] The particular circumstances will typically dictate what constitutes reasonable precautions.[43] As one extreme example, one court held that a trade secret owner was not required to put a temporary roof over an unfinished manufacturing plant to guard the manufacturing trade secrets from aerial reconnaissance.[44]

Conclusion

With these basics in mind, business owners should consider undertaking a review of their trade secret information as well as their security precautions for protecting against the loss of such information. Business owners should also consider consulting with an attorney to determine what information may be considered a trade secret, and to develop a trade secret policy as part of the business's overall intellectual property strategy.

Importantly, business owners should pay particular attention to employees and others who have access to the business's trade secrets, in order to ensure that such individuals are aware of their confidentiality obligations, and do not, without permission, use or disclose the business's trade secrets.

Endnotes

1. *See, e.g., Hoffmann-La Roche Inc. v. Yoder*, 950 F. Supp. 1348, 1357 (S.D. Ohio 1997) ("As numerous courts have recognized . . . there is no specific subject matter criterion for a trade secret. As long as the definitional elements are met, virtually any type of information can be a trade secret.").
2. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974) ("Novelty, in the patent law sense, is not required for a trade secret."); *See also Cataphote Corp. v. Hudson*, 422 F.2d 1290, 1293 (5th Cir. 1970) ("As distinguished from a patent, a trade secret need not be essentially new, novel or unique."), *Capital Asset Research Corp. v. Finnegan*, 160 F.3d 683, 686 (11th Cir. 1998).
3. *See, e.g., Ackerman v. Kimball Int'l, Inc.*, 634 N.E.2d 778, 783 (Ind. Ct. App. 1994) (noting that there was evidence to establish that defendant's "customer lists, supplier list and pricing data are protectable trade secrets").
4. *See, e.g., Morton v. Rank Am., Inc.*, 812 F. Supp. 1062, 1073 (C.D. Cal. 1993) ("Certain 'negative' research may also result in the creation of protectable information.") (citing *Courtesy Temporary Serv., Inc. v. Camacho*, 222 Cal. App. 3d 1278, 1287 (Ct. App. 1990) (describing "negative" trade secrets as "information that has commercial

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value from a negative viewpoint, for example the results of lengthy and expensive research which proves that a certain process will *not* work [and which] could be of great value to a competitor")).

5. *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945) ("By the patent laws Congress has given to the inventor opportunity to secure the material rewards for his invention for a limited time, on condition that he make full disclosure for the benefit of the public of the manner of making and using the invention, and that upon the expiration of the patent the public be left free to use the invention.").

6. *Cataphote*, 422 F.2d at 1293 ("The patent is totally exclusionary for the period for which granted. The trade secret is protected only so long as competitors fail to duplicate it by legitimate, independent research. The trade secret is protected by being kept secret. The patent is protected after being spread on the public records for all to see.") (internal citations omitted).

7. *See id.*

8. *See id.*

9. *See Kewanee Oil*, 416 U.S. at 476 ("A trade secret law, however, does not offer protection against discovery by fair and honest means, such as by independent invention, accidental disclosure, or by so-called reverse engineering, that is by starting with the known product and working backward to divine the process which aided in its development or manufacture.").

10. *Rohm & Haas Co. v. Adco Chem. Co.*, 689 F.2d 424, 428–29 (3d Cir. 1982) ("A trade secret claim in the federal courts is governed not by federal common law but by state law.").

11. One exception is the Economic Espionage Act of 1996, 18 U.S.C. §§ 1831–39 (2006), which provides for criminal penalties for trade secret misappropriation.

12. Nat'l Conference of Comm'rs on Unif. State Laws, A Few Facts About The Uniform Trade Secrets Act, http://www.nccusl.org/Update/uniformact_factsheets/uniformacts-fs-utsa.asp (last visited Jan. 13, 2010).

13. *Cf. id.*

14. Marina Lao, *Federalizing Trade Secrets Law in an Information Economy*, 59 Ohio St. L.J. 1633, 1650 n.99 (1998) ("The other . . . non-UTSA states [except Massachusetts] have no statutory trade secrets law and continue to rely on the principles set forth in section 757 of the Restatement (First) of Torts for guidance.").

15. Uniform Trade Secrets Act § 1(4)(i) (amended 1985).

16. *Id.* § 1(4)(ii).

17. *Id.* § 1(2)(ii)(A).

18. *Id.* § 1(2)(ii)(B)(II).

19. *Id.* § 1(1).

20. *Id.* § 1(2)(ii)(C).

21. *See, e.g., Hertz v. Luzenac Group*, 576 F.3d 1103, 1115–16 (10th Cir. 2009) (recognizing "a claim for breach of contract regarding an employee who was bound to confidentiality").

22. *See, e.g., Sw. Stainless, LP v. Sappington*, 582 F.3d 1176, 1187–90 (10th Cir. 2009) (affirming district court decision that former employee owed fiduciary duty to former employer, even though information did not rise to level of trade secret).

23. *Id.* at 1188–90 (affirming district court decision that former employee breached fiduciary duty owed to former employer).

24. Counterfeit Access Device and Computer Fraud and Abuse Act of 1984, 18 U.S.C. § 1030 (2006); Computer Fraud and Abuse Act of 1986, 18 U.S.C. § 1030 (2006).

25. *See., e.g. Penalty Kick Mgmt. Ltd. v. Coca Cola Co.*, 318 F.3d 1284, 1297–98 & n.12 (11th Cir. 2003).

26. *See, e.g., Prescott v. Morton Int'l, Inc.*, 769 F. Supp. 404, 407 (D. Mass. 1990) ("The Consumer Protection Act . . . provides a cause of action for persons engaged in trade or commerce against another such person who engages in an unfair method of competition or in an unfair or deceptive act or practice . . . [and] has been applied by Massachusetts courts to misappropriation of trade secrets.").

27. Uniform Trade Secrets Act, § 3(a).

28. *Id.* § 2.

29. *Id.* § 3(b).

30. *Id.* § 4.

31. *FMC Corp. v. Taiwan Tainan Giant Indus. Co.*, 730 F.2d 61, 63 (2d Cir. 1984).

32. Robert S. Mueller, Director, Fed. Bureau of Investigation, Protecting the U.S. Economy in a Global Age (Oct. 16, 2003), http://www.fbi.gov/pressrel/speeches/director101603.htm.

33. *See generally Zemco Mfg., Inc. v. Navistar Int'l Transp. Corp.*, 759 N.E.2d 239, 246-49 (Ind. Ct. App. 2001); *Schalk v. State*, 823 S.W.2d 633, 637 (Tex. Crim. App. 1991).

34. *Ex-Secretary Gets 8-Year Term in Coca-Cola Secrets Case*, N.Y. Times, May 24, 2007, at C3.

35. *Id.*

36. *Id.*

37. *See, e.g., Tax Track Sys. Corp. v. New Investor World, Inc.*, 478 F.3d 783, 787 (7th Cir. 2007) ("An Illinois court, in whose place we sit, will enforce [confidentiality] agreements only when the information sought to be protected is actually confidential and reasonable efforts were made to keep it confidential.").

38. *See, e.g., Vt. Microsys., Inc. v. Autodesk, Inc.*, 88 F.3d 142, 150 (2d Cir. 1996) ("Noncompetition agreements generally are construed narrowly by courts, and must contain time, geographic and/or industry limitations.").

39. *See, e.g., Thomas v. Best Mfg. Corp.*, 218 S.E.2d 68, 70 (Ga. 1975) ("[A]ttempting to extend the restriction beyond the employer's business in perpetuity . . . without geographic restriction reaches beyond the scope permitted in Georgia in terms of time, territory, and activities protected.").

40. *Mixing Equip. Co. v. Phila. Gear, Inc.*, 436 F.2d 1308, 1310, 1314 (3d Cir. 1971) ("We further find that the [one year] covenant was sufficiently limited as to time and that the absence of a geographical limitation does not render the covenant unreasonable.").

41. *Taquino v. Teledyne Monarch Rubber*, 893 F.2d 1488, 1498 (5th Cir. 1990) ("A restrictive covenant which contains no territorial limitation is unreasonable as written, and cannot be enforced in accordance with its terms.").

42. *See, e.g., Wyeth v. Natural Biologics, Inc.*, 395 F.3d 897, 900 (8th Cir. 2005) ("Absolute secrecy is not required by [the Minnesota] UTSA.").

43. Uniform Trade Secrets Act, *supra* note 16, § 1(4)(ii).

44. *E.I. duPont deNemours & Co. v. Christopher*, 431 F.2d 1012, 1016 (5th Cir. 1970).

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Rule Changes to European Patent Practice

On April 1, 2010, the European Patent Office will institute new rules under its "Raising the Bar" program.[1] These new rules implement a significant number of changes, all of which cannot be discussed in this article. Thus, we will focus on three changes that we believe to be of great importance.[2] For a complete summary of all of the rule changes, please visit the European Patent Office's Web site.[3]

Changes in the Deadline for Filing Divisional Applications – Rule 36(1) European Patent Convention ("EPC")

Current Rule

Rule 36(1) EPC currently reads as follows:

> The applicant may file a divisional application relating to any pending earlier European patent application.

Under the current Rule 36(1) EPC, a divisional application may be filed at any time before the European Patent is granted. Under the current rule, practitioners could continuously argue for virtually the same invention in multiple divisional filings as a "second bite at the apple" because of the absence of the equivalent of the U.S. terminal disclaimer in EPO practice.

New Rule

The amended Rule 36(1) EPC, effective April 1, 2010, will read as follows:

> (1) The applicant may file a divisional application relating to any pending earlier European patent application, provided that:
>
> (a) the divisional application is filed before the expiry of a time limit of twenty-four months from the Examining Division's first communication in respect of the earliest application for which a communication has been issued, or
>
> (b) the divisional application is filed before the expiry of a time limit of twenty-four months from any communication in which the Examining Division has objected that the earlier application does not meet the requirements of Article 82, provided it was raising that specific objection for the first time.

With regard to when a divisional application can be filed, there will be two requirements that must be met: (i) the application to be divided (the "parent" application on which the divisional is based) must be pending, and (ii) at least one of the two periods mentioned below must not yet have expired:

> (a) the period for voluntary division under Rule 36(1)(a) EPC, or
>
> (b) the period for mandatory division under Rule 36(1)(b) EPC, where applicable.

Additionally, the amended version of Rule 36(1) EPC will apply only to European divisional applications filed after its entry into force, *i.e.*, on or after April 1, 2010. If the time limits provided for in amended Rule 36(1) EPC have expired before that date, a divisional application may still be filed before the expiration of a six-month grace period, on October 1, 2010.

If the relevant time limits are still running on April 1, 2010, they will continue to do so for not less than six months. In other words, *for any applications pending on April 1, 2010, where either (1) a first communication from the examining division has been issued, or (2) a non-unity objection has been (subsequently) raised, the time limit will not expire before October 1, 2010.* Additionally, a transitional period for the amended Rule 36(1)(b) EPC is in place for situations where the twenty-four month period has already expired, or expires before October 1, 2010.

What the Change Means

The changes to Rule 36(1) implement a shortened time limit for filing *all* divisional applications claiming priority to a parent. The new time limit begins upon issuance of the first communication in the parent application or upon the subsequent issuance of a non-unity objection in an examination report. However, this amended rule is not triggered by the Search Opinion.

Practitioners will still be allowed to file divisional applications that claim priority to earlier divisional applications; however, the deadline for filing all divisional applications will still be twenty-four (24) months from the issuance of the first unity of invention objection. We emphasize that this deadline is *non-extendable*. The only way to file a divisional application after the expiration of the twenty-four (24) month time period afforded in Rule 36(1) is if the European Patent Office issues a new unity objection. While this may happen, we anticipate that it will happen infrequently. One strategy to address this shortened time limit in subsequently-filed divisional applications is to request accelerated prosecution. Doing so should allow earlier insight into any potential non-unity issues that may lie ahead, and should afford the applicant the maximum amount of time to file any necessary divisional application(s).

Practical Impact

Initially, applicants should review all of their pending European applications before the new rule changes are implemented on April 1, 2010, and decide whether any divisional applications must be filed before the expiration of the six-month grace period on October 1, 2010. Additionally, applicants may be

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forced to file several divisional applications in a short time, which could result in significant expense. The rule changes will also curtail the applicant's ability to use divisional applications in a manner analogous to continuation practice in the U.S. Finally, overall application drafting will likely be impacted. More narrowly focused applications may be more desirable, as such an application could decrease the likelihood that the EPO would issue a unity of invention objection.

Mandatory Response to an EPO-Issued Search Opinion – Rule 161 EPC

Current Rule

Rule 161 EPC currently reads as follows:

> Without prejudice to Rule 137, paragraphs 2 to 4, the application may be amended once, within one month from a communication informing the applicant accordingly. The application as amended shall serve as the basis for any supplementary search which has to be performed under Article 153, paragraph 7.

Under current Rule 161 EPC, applicants are not required to reply to the objections raised in Written Opinions of the International Search Authority or International Preliminary Examination Report issued by the EPO.

New Rule

The amended Rule 161 EPC, effective April 1, 2010, will read as follows:

> (1) If the European Patent Office has acted as the International Searching Authority and, where a demand under Article 31 PCT was filed, also as the International Preliminary Examining Authority for a Euro-PCT application, it shall give the applicant the opportunity to comment on the written opinion of the International Searching Authority or the International Preliminary Examination Report and, where appropriate, invite him to correct any deficiencies noted in the written opinion or in the International Preliminary Examination Report and to amend the description, claims and drawings within a period of one month from the respective communication. If the applicant does not comply with or comment on an invitation in accordance with the first sentence, the application shall be deemed to be withdrawn.
>
> (2) Where the European Patent Office draws up a supplementary European search report on a Euro-PCT application, the application may be amended once within a period of one month from a communication informing the applicant accordingly. The application as amended shall serve as the basis for the supplementary European search.

(Emphasis added).

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For a complete summary of the rule changes, please visit http://www.epo.org/.

What the Change Means

The change in Rule 161 EPC *only* applies to European applications and PCT applications entering the European national phase in which the search report is published on or after April 1, 2010. The new rule requires applicants to correct any deficiencies as noted in the issued Written Opinion of the International Search Authority or International Preliminary Examination Report. Additionally, any amendment to the claims, description and/or drawings must also be filed within one (1) month from the issuance of the EPO's Opinion. This should expedite prosecution by requiring applicants to respond to the objections made in the Written Opinion or the International Preliminary Examination Report.

Practical Impact

Electing the EPO as the International Search Authority should expedite prosecution. Conversely, it may be more prudent to elect a non-EPO search authority if delayed prosecution is more desirable. Doing so will (1) allow applicants more time to develop their invention, and (2) avoid the one (1) month response deadline. In contrast to the Rule 36 changes, however, this Rule change does seem to be extendable for a fee.

Amending the Application – Rule 137 EPC

Current Rule

As with Rule 161 above, Rule 137 EPC deals with amending the European application to only searchable subject matter as originally filed. Rule 137 EPC currently reads as follows:

> (1) Before receiving the European search report, the applicant may not amend the description, claims or drawings of a European patent application unless otherwise provided.
>
> (2) After receipt of the European search report, the applicant may, of his own volition, amend the description, claims and drawings.
>
> (3) After receipt of the first communication from the Examining Division, the applicant may, of his own volition,

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amend once the description, claims and drawings, provided that the amendment is filed at the same time as the reply to the communication. No further amendment may be made without the consent of the Examining Division.

(4) Amended claims may not relate to unsearched subject-matter which does not combine with the originally claimed invention or group of inventions to form a single general inventive concept.

Currently, Rule 137 EPC allows for related subject matter in amended claims to be searched anew by the Examining Division even if it was not part of the original search report.

New Rule

As of April 1, 2010, Rule 137 EPC will read:

(1) Before receiving the European search report, the applicant may not amend the description, claims or drawings of a European patent application unless otherwise provided.

(2) Together with any comments, corrections or amendments made in response to communications by the European Patent Office under Rule 70a, paragraph 1 or 2, or Rule 161, paragraph 1, the applicant may amend the description, claims and drawings of his own volition.

(3) No further amendment may be made without the consent of the Examining Division.

(4) When filing any amendments referred to in paragraphs 1 to 3, the applicant shall identify them and indicate the basis for them in the application as filed. If the Examining Division notes a failure to meet either requirement, it may request the correction of this deficiency within a period of one month.

(5) Amended claims may not relate to unsearched subject-matter which does not combine with the originally claimed invention or group of inventions to form a single general inventive concept. Nor may they relate to subject-matter not searched in accordance with Rule 62a or Rule 63.

What the Change Means

Amended Rule 137 EPC defines all potential amendments to be made in an application as being limited to only the subject matter of the original search report. This prospective change alleviates the burden placed on the Examining Division to go back and search broadly on previously presented and unsearched subject matter.

Practical Impact

Support for claim amendments will need to be explicitly identified by reference to the application as filed. This will likely cause drafters to either (1) more narrowly focus their applications, or (2) include extra embodiments and support in the PCT application. If patent protection on any unsearched subject matter is desired, then a divisional application must be filed.

Conclusion

The new and amended EPC rules will greatly affect the decisions of inventors and their representative agents and attorneys. Consideration should be paid to the new rules discussed here, as well as the host of other changes that take effect on April 1, 2010.

Endnotes

1. European Patent Organisation, Annual Report 2007, available at http://www.epo.org/about-us/office/annual-reports/2007/focus.html.
2. While the authors address several of the upcoming rule changes in EPO practice, the authors are not European Patent Attorneys. For a more complete analysis, we recommend contacting a licensed European Patent Attorney. We wish to thank Cyra Nargolwalla and Bertrand Cochet, of the Cabinet Plasseraud law firm in France, for their help in reviewing this article.
3. Revision of the Guidelines for Examination – Draft Version. European Patent Office Website, available at http://www.epo.org/patents/law/legal-texts/guidelines-2010.html.

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