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Review of Developments in Intellectual Property Law

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Where Does the USPTO Go after *Tafas/GSK v. Dudas*?

The Supreme Court has issued a number of recent decisions that have significantly impacted (or which are likely to significantly impact) the practice of patent law, including *Quanta Computer, Inc. v. LG Electronics, Inc.* this year, *KSR Int'l Co. v. Teleflex Inc.* and *MedImmune, Inc. v. Genentech, Inc.* in 2007, and *eBay Inc. v. MercExchange, L.L.C.* in 2006. However, the decision that has had the greatest immediate impact on patent practice – at least as far as patent prosecutors are concerned – came not from the Supreme Court, but rather from the U.S. District Court for the Eastern District of Virginia.

In the consolidated cases of *Tafas v. Dudas* and *Smithkline Beecham Corp. v. Dudas*, Dr. Triantafyllos Tafas and GlaxoSmithKline (GSK) sought to enjoin the U.S. Patent and Trademark Office (USPTO) from enforcing its new continuation and claims rules package.[1] The new continuation and claims rules, which were published on August 21, 2007, and which were scheduled to take effect on November 1, 2007, would have limited the number of continuation applications, claims, and Requests for Continued Examination (RCEs) that patent applicants could file as a matter of right, and would have created a number of other obligations for applicants.

On October 31, 2007, the day before the new continuation and claims rules were set to take effect, Judge James C. Cacheris of the Eastern District of Virginia granted Dr. Tafas' and GSK's motions for a temporary restraining order and preliminary injunction, thereby preventing the USPTO from implementing the new rules. Applying the familiar four-factor test for granting a preliminary injunction, Judge Cacheris was persuaded that Dr. Tafas and GSK would likely prevail on the merits

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Practical Patent Tips: How to Conduct an Effective Inventor Interview

The decision of whether or not to pursue patent protection for an invention depends on a number of factors, including whether or not it is needed to achieve certain business objectives. Assuming that patent protection is desirable to a business, what information does a patent practitioner need in order to evaluate the invention and successfully prepare and prosecute a patent application? This article discusses the typical questions patent practitioners should ask inventors during a preliminary inventor interview in order to obtain information necessary to satisfy legal requirements for the patent application.

The preliminary inventor interview is an important part of the process of preparing a patent application. Patents are important business assets of a company, and require an investment of time and money in order to procure and maintain them. The information obtained during the interview process can have a significant impact on the value of these assets, and on the assessment of whether it is worthwhile or even possible to file for them. The interview process allows the patent attorney or agent to evaluate the invention, as well as to discuss the process involved in patent preparation and prosecution, including timelines, with inventors who may not be patent-savvy.

In particular, the interview allows practitioners to obtain information necessary to satisfy the legal

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with respect to establishing that: (1) the new rules exceeded the USPTO's statutory authority and were contrary to the Patent Act, (2) application of the new rules to pending applications implicated the prohibition on retroactive application of agency regulations, and (3) the standards for submitting an Examination Support Document (ESD) were impermissibly vague. Additionally, in view of the large number of declarants and *amici* that were opposed to the new rules, Judge Cacheris also determined that the public-interest prong of the analysis favored Dr. Tafas and GSK.

On February 8, 2008, after hearing the parties' summary-judgment arguments, Judge Cacheris announced that he was taking the case under advisement and would issue his decision as soon as possible. A little more than seven weeks later (and coincidentally on April Fool's Day), Judge Cacheris finally issued his long-awaited and much-anticipated decision. Finding that "the [continuation and claims] Rules are substantive in nature and exceed the scope of the USPTO's rulemaking authority under 35 U.S.C. § 2(b)(2),"[2] Judge Cacheris granted Dr. Tafas' and GSK's motions for summary judgment and voided the continuation and claims rules as "otherwise not in accordance with law"[3] and "in excess of statutory jurisdiction [and] authority,"[4] and thus, in contravention of the Administrative Procedure Act (APA).

Citing *Merck & Co., Inc. v. Kessler,*[5] as well as two other Federal Circuit cases that cite *Merck*, Judge Cacheris determined that "[u]nder Federal Circuit precedent . . . Section 2(b)(2) [of the Patent Act] does not vest the USPTO with any general substantive rulemaking power."[6] In *Merck*, the Federal Circuit found that the USPTO's broadest rulemaking power "authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [USPTO]'; it does NOT grant the Commissioner the authority to issue substantive rules."[7] Judge Cacheris also noted that his reading of Section 2(b)(2) was "further supported by the fact that, since 2005, Congress has debated and considered whether it should grant the USPTO substantive rulemaking authority but has declined to do so."[8]

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Judge Cacheris voided the continuation and claims rules as exceeding the USPTO's statutory authority.

Thus, despite the USPTO's attempts to "abolish the substantive-procedural distinction,"[9] Judge Cacheris determined that the relevant case law was clear: "Section 2(b)(2)'s authority is limited to rules governing the 'conduct of proceedings' before the Office, the USPTO does not have the authority to issue substantive rules, and it does not have the authority to make substantive declarations interpreting the Patent Act."[10]

In response to the USPTO's argument that, even if the continuation and claims rules have "collateral substantive consequences," that does not place them beyond the scope of the USPTO's rulemaking authority, Judge Cacheris stated that "any rule that 'affect[s] individual rights and obligations' is substantive."[11] Determining that the rules were "substantive rules that change existing law and alter the rights of applicants such as GSK and Tafas under the Patent Act,"[12] Judge Cacheris found that the new rules had more than mere collateral substantive consequences, and in fact "constitute a drastic departure from the terms of the Patent Act as they are presently understood."[13]

Judge Cacheris concluded his opinion by explaining why the cornerstones of the continuation and claims rules – the 2+1 (2 continuations + 1 RCE) and 5/25 (five independent claims/25 total claims) rules – were substantive rules. With respect to the rule limiting continuations (*i.e.*, Final Rule 78), Judge Cacheris stated that:

> Though Final Rule 78 does not completely prohibit applicants from filing more than two continuation or continuation-in-part applications, because the USPTO intends to deny additional applications in almost all circumstances . . . the "could not have been submitted" standard of the petition and showing requirement effectively imposes a hard limit on additional applications.[14]

Also noting that Final Rule 78 might impact applicants' rights under Sections 102 and 103 and "result in the denial of otherwise meritorious patents,"[15] Judge Cacheris found Final Rule 78 to be substantive.

With respect to the rule limiting RCEs (*i.e.*, Final Rule 114), Judge Cacheris determined that "limiting RCEs based on application family is a clear departure from the plain language of [35 U.S.C. § 132(a)], which states that the USPTO must provide for the continued examination of each application."[16] Because "Congress intended to allow for an unlimited number of RCEs and intended to commit the invocation of the continued examination process to the discretion of the applicant, not the USPTO,"[17] Judge Cacheris found Final Rule 114 to be substantive.

With respect to the new rules creating the 5/25 claims limitations and corresponding Examination Support Documents (ESDs) (*i.e.*, Final Rules 75 and 265), Judge Cacheris noted that 35 U.S.C. § 112 "expressly

permits an applicant to file 'one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention,'"[18] and further noted that "[s]ince 1938, the CCPA has consistently held that the Patent Act does not place any mechanical limits on the number of claims an applicant may file."[19]

According to Judge Cacheris, the rule creating ESDs does not "cure" the above problem, since the ESD rule "go[es] far beyond merely requiring additional information [and instead] changes existing law and alters the rights of applicants under the current statutory scheme by shifting the examination burden away from the USPTO and onto applicants."[20] In support of his finding that the 5/25 and ESD rules were substantive, Judge Cacheris also noted that the Federal Circuit has stated that applicants have no duty to conduct prior art searches, and that 35 U.S.C. § 131 specifically states that the Patent Office "shall cause an examination to be made of the application."

As is often the case, the story does not end with a district court's determination. In *Tafas*, the USPTO responded to Judge Cacheris' decision to void the continuation and claims rules by filing a Notice of Appeal with the Federal Circuit. With the USPTO's brief due on July 18th,[21] patent practitioners have spent the past few months speculating as to how the Patent Office will attack Judge Cacheris' ruling. While the limited approach taken by Judge Cacheris in deciding *Tafas* significantly narrowed the scope of the appeal, the USPTO still has several possible arguments to make to the Federal Circuit.

The broadest, and perhaps most simplistic, argument available to the USPTO resides in the assertion that the continuation and claims rules fall within the scope of 35 U.S.C. § 2(b)(2). That is, the USPTO would argue that both the 2+1 rule and the 5/25 rule merely govern the conduct of proceedings in the Office by facilitating and expediting the application process. At its core, this argument could represent an attempt by the USPTO to avoid any discussion of the likely impact of the rules on the rights of applicants, and instead entice the Federal Circuit to engage in a cursory statutory-interpretation exercise.

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Patent practitioners have been speculating as to how the USPTO will attack the ruling in *Tafas*.

This argument is susceptible to attack on several fronts, and is likely to be a non-starter before the Federal Circuit. As noted by Judge Cacheris, such an argument would require the Court to abolish, or at least ignore, the well-established distinction between substantive and procedural rules. Beyond simply asking the Federal Circuit to avoid a well-known principle, this argument requires the Federal Circuit to ignore the clear articulations in *Merck*[22] and *Animal Legal Defense Fund*[23] limiting the rulemaking authority of the USPTO to procedural rules, and thus requiring at least an inquiry into whether the continuation and claims rules are substantive or procedural. Further, a determination that any rule that facilitates or expedites the application process is within the scope of the USPTO's rulemaking authority would effectively authorize rules imposing even the most draconian limitations on applicants.

Alternatively, the USPTO may direct a more tailored attack against Judge Cacheris' decision by arguing that the continuation and claims rules are clearly procedural, or have, at most, collateral substantive consequences. The USPTO's argument on this front will likely be twofold: first, that since the rules do not directly implicate the central requirements of 35 U.S.C. §§ 101, 102, 103, and 112, and instead aim to reduce repetitive filings, the rules are procedural, and any substantive effect is at most collateral, and thus within the scope of the USPTO's rulemaking authority,[24] and second, that Judge Cacheris' articulation of the definition of a substantive rule is overbroad.

If the Federal Circuit accepts Judge Cacheris' characterization of substantive rules, the USPTO's argument that the continuation and claims rules are procedural will likely be unsuccessful. Rather than merely restating a legal precedent and declaring the rules substantive, Judge Cacheris devoted nearly a quarter of his opinion to outlining the significant, multifarious changes to the substantive rights of applications the rules would cause if allowed to go into effect. To succeed on appeal, the USPTO would need to convince the Federal Circuit that the effects described by Judge Cacheris, along with any additional effects described by Dr. Tafas and GSK were at most collateral to the procedures established in continuation and claims rules. However, the sheer degree to which the rules would change and limit the rights of applicants demonstrates that the rules are substantive.

The USPTO's chances of success seemingly increase if the Federal Circuit rejects Judge Cacheris' characterization of substantive rules. In his opinion, Judge Cacheris relied most heavily on *Chrysler Corp.*[25] to support the proposition that any rule that

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"affect[s] individual rights and obligations" is substantive. Notwithstanding the fact that *Chrysler Corp.* remains a valid opinion from the Supreme Court, the language cited by Judge Cacheris is quite broad, encompassing rules that implicate the obligations of individuals acting before an agency. Should the Federal Circuit reject Judge Cacheris' articulation and define substantive rules in a more limited manner, the USPTO may have an improved chance of success on appeal. However, even if the Federal Circuit holds Judge Cacheris' definition of substantive rules to be overbroad, the significant impact on the existing rights of applicants described throughout Judge Cacheris' opinion may render harmless any error associated with an overbroad definition.

The third – and perhaps most compelling – argument that the USPTO could raise also arises from Judge Cacheris' definition of substantive rules. Rather than focusing on the definition as it applies to the 2+1 and 5/25 rules, the USPTO may instead argue that Judge Cacheris' definition effectively divests the USPTO of any rulemaking authority. Indeed, it is difficult to imagine any meaningful rule that does not somehow affect an obligation of an applicant. Even the most basic formatting or filing formalities establish obligations for applicants, and eliminating the ability of the USPTO to promulgate fair, procedural rules that could improve the application process would effectively preclude the USPTO from addressing almost all current problems.

It is too early to tell how the Federal Circuit may respond to such an argument from the USPTO. While the USPTO clearly needs to have the ability to promulgate basic, procedural rules that foster an efficient and orderly application process, it is unlikely that the simple rulemaking needs of the USPTO justify the severe departures from the patent laws embodied in the continuation and claims rules.

For the most recent information regarding the *Tafas/GSK* case, *snippets* readers are encouraged to visit the Patent Docs weblog (http://www.patentdocs.net).

Endnotes

1. *See* Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably-Indistinct Claims and Examination of Claims in Patent Applications; Final Rule, 72 Fed. Reg. 46,716 (2007).
2. *Tafas v. Dudas*, 541 F. Supp. 2d 805, 811 (E.D. Va. 2008).
3. *Id.*
4. *Id.*
5. 80 F.3d 1543, 1550 (Fed. Cir. 1996).
6. *Tafas,* 541 F. Supp. 2d at 811
7. *Merck & Co., Inc.,* 80 F.3d at 1549-50 (emphasis in original).
8. *Tafas,* 541 F. Supp. 2d at 812.
9. *Id.* at 813.
10. *Id.*
11. *Id.* at 814.
12. *Id.*
13. *Id.*
14. *Id.*
15. *Id.* at 815.
16. *Id.*
17. *Id.* at 814.
18. *Id.* at 816.
19. *Id.*
20. *Id.*
21. Due to printing deadlines, the authors submitted this article before the USPTO filed its opening brief. The USPTO's opening brief should be available at the time this article is published.
22. *Merck & Co., Inc.*, 80 F.3d at 1550
23. *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991).
24. *See In Re Van Ornum*, 686 F.2d 937, 945 (C.C.P.A. 1982).
25. *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979)

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Computer-Implemented Claim Limitations and 35 U.S.C. § 112, paragraph 6

Patent attorneys have learned to be particularly cautious when drafting claims with means-plus-function limitations. Such limitations are subject to 35 U.S.C. § 112, paragraph 6, which states as follows:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Computer-implemented "means" limitations

Contrary to the expectations of many who are unfamiliar with U.S. patent law, means-plus-function limitations do not cover every conceivable means for performing the recited function; rather, they are statutorily limited to the corresponding structure disclosed in the specification and equivalents thereof.[1] Further, as the *quid pro quo* for the convenience of employing § 112, paragraph 6, the specification must disclose sufficient structure that corresponds to (is clearly linked or associated with) the function recited in the "means" element.[2]

Failure to disclose sufficient corresponding structure may result in the claim being held invalid as indefinite under § 112, paragraph 2. For example, in *Default Proof Credit Card Sys. v. Home Depot U.S.A., Inc.*,[3] the U.S. Court of Appeals for the Federal Circuit (hereafter "the Federal Circuit") concluded that the specification of the asserted patent disclosed no structure corresponding to a "means for dispensing" claim element and, on that basis, invalidated the claims containing that "means."[4]

Patent practitioners should also be aware of the unique requirements for disclosing corresponding structure for a "means" element that recites functions carried out by a computer. Recent case law from the Federal Circuit has made it clear that, for such computer-implemented "means," the specification must disclose more than a microprocessor or other computer hardware, and more than a general reference to software or appropriate programming as the corresponding structure. In order to be sufficient, the corresponding structure disclosed in the specification must also include a specific algorithm for carrying out the recited function.

The basis for these decisions is the notion that when "the disclosed structure is a computer programmed to carry out an algorithm, the disclosed structure cannot be a general purpose computer, but rather must be a special purpose computer programmed to perform the disclosed algorithm."[5] Thus, the structure corresponding to a computer-implemented "means" must include a specific algorithm that transforms a "general purpose computer" into a "special purpose computer."

Failure to disclose a specific algorithm for a computer-implemented means-plus-function limitation in a claim may result in the claim being held invalid if it is enforced in litigation. Federal Circuit case law provides two recent examples. In *Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech.*,[6] a claim to a gaming machine recited a "control means" that performed three specified functions. However, the only structure disclosed in the specification as corresponding to the three functions was a "microprocessor" with "appropriate programming." In the Court's view, the reference to "appropriate programming"[7] was not a disclosure of any

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Failure to disclose a specific algorithm for a computer-implemented means-plus-function limitation in a claim may result in the claim being held invalid.

Computer-Implemented Claim Limitations and 35 U.S.C. § 112, paragraph 6

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algorithm at all. As a result, there was insufficient disclosure of structure corresponding to the "control means," and the claim was held invalid as being indefinite under § 112, paragraph 2.[8]

The Federal Circuit specifically rejected the patentee's argument that the disclosure of a microprocessor with "appropriate programming" should be sufficient because one of ordinary skill in the art could build the claimed device based on the disclosure in the specification. The Federal Circuit distinguished between disclosure that is sufficient for enablement under § 112, paragraph 1 and disclosure that is sufficient under § 112, paragraph 6. Even though a disclosure may enable a person of ordinary skill in the art to make and use the device, a § 112, paragraph 6 disclosure serves the very different purpose of limiting the scope of the claim.[9] For a computer-implemented "means," a microprocessor with "appropriate programming" is insufficient structure under § 112, paragraph 6, because the structure amounts to a general purpose computer that is not limited to a special purpose computer programmed to perform a specific algorithm.[10]

In *Finisar Corp. v. DirecTV Group, Inc.*,[11] the Federal Circuit similarly held a claim with a computer-implemented "means" to be invalid as being indefinite under § 112, paragraph 2. In that case, the specification referred to "software" that performed the function recited by the "means."[12] However, the Court reasoned that "[s]imply reciting 'software' without providing some detail about the means to accomplish the function is not enough."[13]

Step-plus-function limitations

Although the Federal Circuit has not yet addressed the issue directly, the case law regarding disclosure of a specific algorithm may also be relevant to method claims that recite one or more computer-implemented steps, if such steps are construed as being subject to 35 U.S.C. § 112, paragraph 6. Although means-plus-function language is more familiar, § 112, paragraph 6 also states that an element in a claim for a combination may be expressed as a *step* for performing a specified function. Thus, a step in a method claim can be a "step-plus-function" limitation that is subject to § 112, paragraph 6.

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If a step recites a function, but does not recite any "acts" that describe how the function is accomplished, the step may be construed as a step-plus-function limitation subject to § 112, paragraph 6.

There are few precedents regarding step-plus-function limitations. In *O.I. Corp. v. Tekmar Corp.*,[14] the Federal Circuit held that § 112, paragraph 6 can be applied to method claims because the statute provides that "[a]n element in a claim for a combination may be expressed as a means or *step* for performing a specified function *without* the recital of structure, material, or *acts* in support thereof."[15] The Court interpreted the "steps" to refer to the elements of a process and the "acts" to refer to the implementation of such steps.[16] However, the Court urged that § 112, paragraph 6 "is implicated only when steps *plus function* without acts are present."[17]

Later, in *Masco Corp. v. United States*,[18] the Federal Circuit held that the language "steps for" may be required to trigger a presumption that § 112, paragraph 6 applies, analogous to the presumption triggered by the word "means."[19] However, "where a method claim does not contain the term 'step[s] for,' a limitation of that claim can be construed as a step-plus-function limitation by showing that the limitation contains no act."[20] To explain the distinction between the "function" of a claim element and "acts," the Court cited Judge Rader's concurrence in *Seal-Flex, Inc. v. Athletic Track*.[21] In Judge Rader's view, the "function" of a step corresponds to *what* that step accomplishes in relationship to the other claim elements and to the claim as a whole, whereas "acts" correspond to *how* the function is accomplished.[22]

Whether a step in a method claim is likely to be construed as a step-plus-function limitation turns on (i) what function is identified for the step, and (ii) whether any of the language in the step would be considered acts that describe how the function is performed. If a step recites a function, but does not recite any "acts" that describe how the function is accomplished, the step may be construed as a step-plus-function limitation subject to § 112, paragraph 6. However, as acknowledged in Judge Rader's concurrence in *Seal-Flex*, it can be difficult to distinguish between an act and a function because both acts and functions are often stated in verbs ending in 'ing'.[23] Judge Rader offered the following example: "if the method claim element at issue in this case had merely recited 'the step of spreading an adhesive tack coating,' it would not have been clear solely from this hypothetical claim language whether 'spreading' was a function or an act."[24]

For a step-plus-function claim limitation, courts look to the specification for a description of the corresponding acts that are necessary to perform the recited function.[25] For the case of a computer-implemented "step" for performing a specified function, the corresponding acts would presumably be part of the specific algorithm that the case law

would require for a computer-implemented "means" for performing the same function. Thus, disclosure of a specific algorithm for carrying out a computer-implemented function may be necessary to support a limitation that is subject to § 112, paragraph 6, regardless of whether the limitation is drafted as a "means" or as a "step" for performing the function.

Patent Application Drafting Tips

Given the recent Federal Circuit decisions in *Aristocrat* and *Finisar*, patent practitioners should carefully consider the potential pitfalls of drafting computer-implemented limitations in means-plus-function or step-plus-function form. If such language is used, then the practitioner should make sure that the specification discloses a specific algorithm for performing the recited function. A listing of source code or a highly detailed description of the algorithm used to achieve the recited function is not required to satisfy § 112, paragraph 6.[26] Instead, a patentee may express the required algorithm in any understandable terms, such as a mathematical formula, in prose, as a flow chart, or in any other manner that provides sufficient structure.[27] Whatever form of expression is used, however, the disclosure must do more than merely restate the function recited in the claim.[28]

Endnotes

1. *See J&M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1367 (Fed, Cir. 2001).
2. *See Default Proof Credit Card Sys. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed. Cir. 2005).
3. 412 F.3d 1291, 1298 (Fed. Cir. 2005).
4. *See Id.* at 1302-03.
5. *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999).
6. 521 F.3d 1328 (Fed. Cir. 2008).
7. *See Id.* at 1334.
8. *See Id.* at 1337-38.
9. *See Id.* at 1336.
10. *See Id.*
11. 523 F.3d 1323 (Fed. Cir. 2008).
12. *See Id.* at 1340.
13. *Id.* at 1340-41.
14. 115 F.3d 1576 (Fed. Cir. 1997).
15. *Id.* at 1582 (emphasis added).
16. *See Id.* at 1582-83.
17. *Id.* at 1583 (emphasis in original).
18. 303 F.3d 1316 (Fed. Cir. 2002).
19. *See Id.* at 1326.
20. *Id.* at 1327.
21. 172 F.3d 836 (Fed. Cir. 1999).
22. *See Masco*, 303 F.3d at 1327; *Seal-Flex*, 172 F.3d at 849-50.
23. *Seal-Flex*, 172 F.3d at 849-50
24. *Id.* at 849.
25. *See Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1259 (Fed. Cir. 1999).
26. *See Aristocrat*, 521 F.3d at 1338.
27. *See Finisar*, 523 F.3d at 1340.
28. *See Id.*

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requirements for patent protection such as the written description, enablement, and best mode requirements under the Patent Statute, specifically 35 U.S.C. § 112. Practitioners need to learn about the invention in order to draft claims and fully describe the invention in the specification, including alternative embodiments and optional components.

Before the interview, it is helpful for the inventors to provide the patent practitioner with copies of all available relevant materials. These materials may include an invention disclosure, drawings, and prior art. For mechanical and software cases, drawings and flowcharts may be involved. For chemical inventions, experimental and structural detail concerning compounds may be needed.

What is the invention?

The main purpose of the interview is to aid the patent practitioner in gathering all information about the invention necessary to satisfy the written description and enablement requirements of 35 U.S.C. § 112. In addition, U.S. practice is unique in requiring that the best way (also known as "best mode") known by the inventors for carrying out the invention, including any preferred materials, be disclosed in the application. To learn what the invention is all about, and to identify the best mode, the patent practitioner will often ask a series of leading questions about the invention, including the background of the invention and how it came about.

In addition, the patent practitioner needs to know the advantages of the invention, problems that the invention solves, and features of the invention that are commercially important. The patent practitioner also needs to know what the various embodiments of the invention are, whether alternatives exist, and what the core features and optional features are. For pharmaceutical inventions, are there alternative synthetic routes for making a compound? Alternative ways to formulate and administer the compound? Is the compound itself known? Are there other uses for the compound? This information is necessary in order to gauge what additional information is needed for the application, and what types of claims will best protect the invention.

What prior art exists?

To be patentable, the Patent Statute requires that an invention be useful (35 U.S.C. § 101), novel (35 U.S.C. § 102), and non-obvious to one skilled in the art at the time the invention was made (35 U.S.C. § 103). To determine whether the invention is novel and non-obvious, the patent practitioner should ask the inventors about prior art of which they are aware, how they became aware of the prior art, and whether they have copies of the prior art in their possession.

Prior art can exist in a variety of forms, including patents, published patent applications, scientific articles, advertisements, commercial products/services, offers for sale, presentations, trade-show displays, third-party information, grant proposals, *etc*. Prior art may be created by some act of the inventors, such as prior publication or offer for sale. The patent practitioner should be interested in identifying all potential prior art, including all related publications and related filed patent applications. Updated *curriculum vitae* often contain comprehensive lists of patents and papers by the inventors, and may be helpful to the patent practitioner in identifying potential prior art.

Information regarding prior art is important because it allows the patent practitioner to determine whether the inventors are familiar with the prior art, and whether or not a prior-art search is needed. Furthermore, once the patent practitioner has information about the

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prior art, the patent practitioner should be interested in learning how the invention differs from the prior art, in order to determine what scope of claims can be pursued.

Finally, U.S. patent law imposes an ongoing requirement on all persons, including the inventors, involved in the preparation and prosecution of the application to disclose relevant information to the USPTO material to patentability of the invention. Failure to disclose relevant art of which the inventor is aware during prosecution of an application may be a basis for finding the patent unenforceable during litigation.

Are there any potential statutory bar dates?

The public disclosure of an invention before a patent application is filed is considered prior art and, depending on the nature of the disclosure, as well as on what information was actually disclosed and when, the prior disclosure may have important ramifications on whether or not patent protection is available in the U.S. and abroad. The patent practitioner needs to know about any existing bar dates, and should therefore identify all bar dates and circumstances during the interview process.

Bar dates are triggered in two ways: actions that have already taken place and actions that are about to occur. For example, the inventors may have already given a talk at a scientific conference, including publishing an abstract, thereby publicly disclosing the invention. These types of prior disclosures can bar the inventors' ability to obtain patent protection in most foreign countries, which require that an application be filed before public disclosure of the invention. The U.S. is more lenient, offering a one-year grace period, triggered from the date of the disclosure, to file for patent protection. Thus, depending on how much time has lapsed from the date of public disclosure, it may still be possible to file for patent protection in the U.S.

Alternatively, the inventors may, for example, have plans to engage in commercial activity in the near future in which they will offer price quotes, make offers for sale, display the invention at trade shows, *etc.* Planned future disclosures may set a definitive filing date for foreign patent applications in order to ensure that patent protection is sought in advance of any public disclosure.

What is the business purpose for filing the application?

Patent filings are typically driven by specific business purposes; therefore, it is important for the patent practitioner to learn about these purposes, and to determine how the invention fits in, particularly if the business owner is considering expanding into other markets or offering licenses in other markets. This information would be helpful to the patent practitioner in determining whether to include claims that are directed to the new market or licensing opportunity, as well as in querying the inventors for additional information to satisfy § 112 requirements for the alternative uses.

For instance, if the business owner's core business is directed to developing compounds as human pharmaceuticals for treating HIV infections, and the business is considering expanding the market for veterinary use, in addition to claims directed to the core use, namely generic chemical structure, specific structures, compositions including the compound, compositional ranges, methods of therapeutic use, and methods of making, and any additional technical features, the filing and prosecution of claims specifically directed to a veterinary composition and method of use may be advisable.

Who are the inventors?

One of the most difficult tasks for patent practitioners in dealing with inventions is identifying who the inventors are.[1] Inventorship determinations are made with reference to the claims, and thus may need to be revisited during prosecution each time claims are added, amended, and/or cancelled. An invention disclosure that lists all of the people involved in developing the invention is helpful. However, the invention disclosure should not be used as a basis for concluding that all of those people are, in fact, inventors in the eyes of the law.

Once the patent practitioner has the necessary information regarding the invention, including how the invention can be distinguished over the prior art, the patent practitioner will typically draft claims to cover the invention, and then use these claims as the basis to interview the inventors about their role in and contribution to the claimed invention, in order to identify the proper inventors. Failure to list the proper inventors in a U.S. patent can be a basis for finding the patent invalid or unenforceable. In some circumstances, it may be possible to correct inventorship if the error occurred without deceptive intent. For more information on determining inventorship, see *snippets* Volume 1, Issue 2, "Drafting a Technology Game Plan, Part 3: Proper Inventorship Determinations," available at http://www.mbhb.com/snippets.

Are there any contractual obligations related to the invention?

The existence of agreements relating to rights to the invention and contractual obligations may present challenges with respect to ownership of the invention, as well as the ability to file the application. For instance, inventions funded by government money, such as by Small Business Innovation

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Research (SBIR) and Small Business Technology Transfer (STTR) grants have notice and invention-disclosure requirements, along with reporting requirements relating to commercialization of the invention. Failure to comply with these obligations in a timely manner may affect ownership of the invention, and entitle the U.S. Government to take title to the invention under the Bayh-Dole Act.[2]

Other contractual agreements, such as non-disclosure agreements, joint development agreements, license agreements, options, assignments, and material-transfer agreements should be reviewed. Some of the agreements may include confidentiality clauses that restrict the ability to disclose or use third-party confidential information. These restrictions may, in turn, prevent inclusion in the application of information that is needed to satisfy all the requirements of 35 U.S.C. § 112 which, as a consequence, may preclude the filing of the application. Finally, some of the agreements may have given rights to third parties; this should also be investigated to avoid, as one example, an improper assertion of small-entity status.

Conclusion and follow-up activities

Once the initial meeting concludes between the patent practitioner and the inventor(s), and an inventorship determination has been made, the creation of a table listing actions, people designated for carrying out each action, and deadline dates for completing each action is often helpful in facilitating the preparation and filing of the application.

Endnotes

1. *See Sewall v. Walters*, 21 F.3d 411, 417 (Fed. Cir. 1994).
2. 35 U.S.C. §§ 200-212.

Emily Miao, Ph.D., has broad experience in all aspects of foreign and domestic intellectual property practice, including patent and trademark procurement and portfolio management; client counseling on validity, infringement, freedom-to-operate, and patent strategy matters; due diligence reviews; and licensing/secrecy agreements. She is now blogging at http://www.resourcenation.com, one of the premier sites for entrepreneurs and start-up businesses

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We mourn the loss of our partner and friend

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