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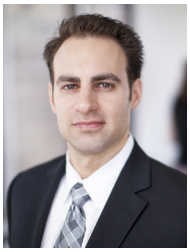
A review of developments in Intellectual Property Law

USPTO Guidance Takes an Expansive View of Patent-Ineligible Subject Matter

By James V. DeGiulio, Ph.D. and Donald L. Zuhn, Jr., Ph.D.



On March 4, in a memorandum issued to the Patent Examining Corps by Deputy Commissioner for Patent Examination Policy Andrew Hirshfeld, the U.S. Patent and Trademark Office ("USPTO") implemented a new procedure for determining the subject matter eligibility of all claims involving laws of nature/natural principles, natural phenomena, and/or natural products under 35 U.S.C. § 101. The memorandum, entitled "*Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*" (the "Guidance Memo")[1], was intended to assist examiners on this issue in view of the Supreme Court's decisions in *Association for Molecular Pathology v. Myriad Genetics, Inc.*[2] and *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[3] On March 19, the USPTO supplemented the Guidance Memo with additional training materials for patent examiners to help implement the Guidance Memo, which took the form of a presentation comprising nearly one hundred slides (the "Training Materials").[4]

It is understandably a monumental challenge to draft any guidance for navigating the Supreme Court's decisions in *Myriad* and *Mayo*. This challenge is further heightened when drafting patent examiner training documents, which require the articulation of objective standards or tests to be applied by examiners during the examination of applications. Some members of the patent community, however, have argued that by issuing the Guidance Memo and Training Materials, the USPTO has gone too far with tests that are unduly inflexible. Opponents of these documents contend that they promote inappropriate bright-line rules and tests that lack support in Supreme Court jurisprudence and at times may even conflict with precedent. The Guidance Memo, it is argued, has expanded the scope of patent-ineligible subject matter beyond the boundaries of *Myriad* and *Mayo*, producing reactions from the patent community that have been resoundingly negative. Some of the more controversial issues from the guidance documents are summarized in this article.

Overbroad Definition of Natural Products

The Guidance Memo and Training Materials provide a definition of "natural products" that is arguably overbroad. The Training Materials paradoxically define the "natural products" judicial exception as encompassing both "naturally occurring products; and ***non-naturally occurring products*** that are not markedly different from naturally occurring

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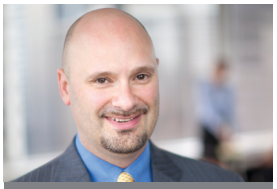

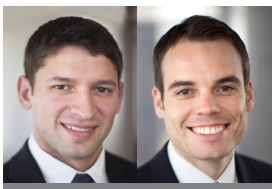

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(continued from page 1)
products."[5] It is hard to imagine that the Supreme Court intended to define "natural products" in such a way that includes "non-natural products," despite qualification.

This expansive definition of "natural products" may amount to a presumption of ineligible subject matter. This presumption is supported in several locations in the guidance documents. First, the Training Materials state that "[a] claim that covers both eligible and ineligible subject matter should be rejected under §101."[6] Since the Guidance Memo mandates that *all claims* that cover *any amount* of ineligible subject matter (no matter how trivial) should be rejected, examiners may be encouraged to presume by default that a claim covers at least *some* ineligible subject matter. This posture is encouraged by the Guidance Memo, which states that "[i]f the claim recites or involves (or *may* recite or involve)" any judicial exception, it should be scrutinized according to the Guidance Memo's analysis.[7] The examiner need not even be sure that a claim involves a natural product or law. The Guidance Memo mandates that if there is "*any doubt* as to whether the claim recites a judicial exception," examiners are required to apply the Guidance Memo's analytical framework.[8] As a result, examiners can presume that nearly any product claim in a biotechnology application involves a judicial exception and should be scrutinized under §101 by default. It is hard to imagine many claims that fail to meet this standard, which unfortunately could subject nearly every claim in the field of biotechnology to the problematic "substantially different" analysis detailed in the Guidance Memo.

The Significant Structural Difference Requirement

Another issue within the Guidance Memo and Training Slides concerns the analysis of whether a claim recites something ***significantly different*** than a judicial exception (e.g., a natural product or law of nature).[9] To establish a significant difference, the Guidance Memo and Training Materials require that the claimed product be structurally different from the product as it exists in nature.[10] With this requirement, the Guidance Memo essentially imparts a new and heightened standard for patent-eligibility.

The origin of this "structural difference" test appears to be rooted in the USPTO's interpretation of *Diamond v. Chakrabarty*[11] and *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[12] However, these cases were focused on the functional—not structural—differences between the claimed products and those existing in nature. In *Chakrabarty*, the Supreme Court noted that an altered bacterium comprised "*markedly different* characteristics from any [bacterium] found in nature, and one having the potential for significant utility."[13] However, *Chakrabarty* did not mention any requirement for *structural* differences between the claimed bacteria and its natural counterpart. And in *Funk Brothers*, although it is true that the Supreme Court found that a mixture of bacteria had the same structure, function, and utility as the same bacteria individually as they existed in nature, the Court's patent eligibility determination focused on differences in function, not structure.[14] Thus, neither *Chakrabarty* nor *Funk Brothers* provides any support for the structural difference test articulated in the Guidance Memo.

The Guidance Memo, it is argued, has expanded the scope of patent-ineligible subject matter beyond the boundaries of *Myriad* and *Mayo,* producing reactions from the patent community that have been resoundingly negative.

The Guidance Memo firmly prioritizes structural differences over functional differences—a departure from the holdings of *Chakrabarty* and *Funk Brothers.* According to the Guidance Memo, "a functional difference is not necessary in order to find a marked difference," but "the presence of a functional difference resulting from the structural difference makes a stronger case that the structural difference is a marked difference."[15] In this way, the Guidance Memo suggests that a claimed product cannot simply be functionally changed or improved to confer patent eligibility—a structural difference is necessary.

To illustrate these principles, the Training Materials analyze the effect of "purification" according to the significant differences test articulated in the Guidance Memo.[16] Examiners are instructed to ignore any purification of the natural product, unless it produces a structural or functional difference in the product.[17] The Training Materials use pasteurization of fruit juice as an example. Pasteurized grapefruit juice is recognized as non-naturally occurring, but it is still considered a "natural product" under the significant differences test because not all pasteurizations alter the structure or function of grapefruit juice.[18] On the other hand, pasteurized pomelo juice is found to be patent-eligible,[19] because in this example the specification describes the pasteurization process as damaging the chemical structure of the components of the juice.[20] Thus, due to this limitation on the effects of pasteurization disclosed in the specification, the claimed pasteurized pomelo juice is structurally, and thus significantly, different from pomelo juice as it exists in nature.

Purification of natural products is a critical innovative process in biology, and thus the USPTO's structural differences distinction makes very little sense scientifically.[21] Generally, the goal of purification is to isolate a natural product from the context of the whole organism while retaining the beneficial function of the product. It is well-recognized in the biotechnology field that even subtle changes to the structure of a molecule can often result in substantial changes to the function of the molecule.[22] If the purified molecule must be structurally different for patent eligibility, this molecule is highly likely to have a different function than the natural product. This would frustrate the purpose of many purifications and discourage such research, particularly since the whole body of knowledge regarding the natural molecule could no longer definitively apply to the (patent-eligible) structurally different molecule.

Considerations for Patent Practice

Although the practical effect of the guidance documents has yet to be realized at the USPTO, there are ways for patent practitioners to anticipate and (theoretically) avoid the pitfalls

that are presented. First, when drafting claims that involve a judicial exception like natural products, the claim drafter must keep in mind that the "significantly different" test applies to *every conceivable embodiment* covered by the claim. Therefore, if there is even a single embodiment that is not significantly different than the natural product, the claim will be found to be ineligible subject matter. This point is confirmed in the pomelo juice example presented in the Training Materials, where juice containing a non-natural preservative is patent-eligible, but juice containing a natural preservative is ineligible.[23] Both preservatives produce the same effect on the juice, yet somehow the use of a non-natural preservative "adds something significant" to the claim, while use of a natural preservative does not. This seemingly trivial distinction may have a substantial impact on the pharmaceutical industry because drug products are often compositions comprising both naturally-derived and non-naturally-derived components.[24] Thus, for naturally-derived products, it may be beneficial to emphasize the source of the differences between the natural and naturally-derived product in the specification. For example, any isolation, purification, or synthesis steps that modify the natural product should be emphasized, perhaps including an explicit definition for these modifying steps. Since any possible embodiment that is not significantly different from the natural product could render the claim patent-ineligible, this strategy may help clarify that the claim does not cover these embodiments. For applications that are currently pending, it may be possible to exclude ineligible embodiments by way of "wherein" clauses or Markush claim listings pertaining to process steps. This technique is seen in Example E of the Guidance Memo,[25] where a claim recites specific limitations in every step of a PCR reaction, rather than claiming a more general term like "amplifying."[26]

Second, a patent drafter may want to consider disclosing in the specification any and all functional differences between claimed products and their natural counterparts. As in the grapefruit juice example, if a patentee can articulate the chemical changes or functional differences introduced by the process of making the claimed product, this may allow even minor structural differences to be considered significantly different. All functional differences should theoretically be disclosed, for the Guidance Memo provides no requirement that the structural differences themselves be directly related to the primary function of the claimed invention. Under this reasoning, any structural difference yielding a functional difference from the natural product should be patent-eligible, even if the functional difference is minor.[27] Example B is illustrative, which finds patentable subject matter in a claimed molecule that is minimally different from the natural molecule in terms of structure (a single methyl group). However, the claimed molecule stimulates hair growth in addition to treating cancer, whereas the natural product molecule only treats cancer.[28] This functional difference is tangential to the claimed molecule's true function as a cancer treatment, yet weighed heavily toward finding the claimed molecule to be significantly different.

Conclusion

The Guidance Memo and Training Materials have provided potent ammunition that examiners, anti-patent advocates, and even district court judges can use to invalidate biotechnology patent claims. The USPTO considers the scope of patentable subject matter for biotechnology applicants to be severely restricted as a result of *Myriad* and *Mayo*, and the scope of "natural product" provided in the Guidance Memo covers nearly every valuable molecule in the field of biotechnology.[29] It should be noted, however, that these guidance materials have no force of law, and will likely find their way to appeal at the Federal Circuit in relatively short order. If history is any guide, most bright line rules like those advocated in the Guidance Memo have been overturned on appeal.[30] Despite the USPTO's attempt to design the tests to be "flexible to accommodate judicial developments and technological advancements,"[31] the resulting *per se* tests advocated in these materials overextend the scope of ineligible subject matter beyond the *Myriad* and *Mayo* decisions and should be revised.

Perhaps more significantly, as a result of criticism from members of the patent community, the USPTO has now begun to solicit public input regarding the guidance materials.[32] The USPTO has promised to provide additional claim examples and workshop training materials after it has received this public feedback.[33] Early input from the USPTO indicates that it intends to develop better examples than those presented in the Guidance Memo, and "update or modify the Guidance as needed."[34]

Endnotes

1 The Guidance Memo, March 4, 2014, *available at* http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf [last accessed April 10, 2014].
2 133 S. Ct. 2107 (2013).
3 132 S. Ct. 1289 (2012).
4 USPTO, Evaluating Subject Matter Eligibility Under 35 USC § 101: March 2014 Update, March 19, 2014, *available at* http://www.uspto.gov/patents/law/exam/myriad-mayo_slides_20140319.pdf (the "Training Materials") [last accessed April 10, 2014].
5 Training Materials at Slide 25.
6 Training Materials at Slide 12.
7 Training Materials at Slide 30; Guidance Memo at p. 8.
8 Training Materials at Slide 30; Guidance Memo at p. 3.
9 Guidance Memo at p. 3-4.
10 *See, e.g.,* Training Materials at Slides 48-56.
11 447 U.S. 303 (1980).
12 333 U.S. 127 (1948).
13 Id. at 2116-17.
14 333 U.S. at 131.
15 Guidance Memo at p.8.
16 Training Materials at Slides 43 (purified chemical from strawberry), 38 (genetically modified bacteria), 45 (metal alloy), 55 (glazed gunpowder), and 69 (fruit juice and a natural preservative).
17 Training Materials at Slides 42 and 46.
18 Training Materials at Slide 25.
19 Training Materials at Slides 75-78.
20 Training Materials at Slide 77.
21 *See In re Bergy*, 596 F.2d 952 (CCPA 1979) ("In summary, soil contains a complex jungle of microorganisms. It is only by the discovery and skills of the microbiologist that biologically pure cultures of microorganisms come into existence.").
22 Another example are primer pairs, which are likely unpatentable under the Guidance Memo's analysis (see Example E and Slide 53 of the Training Materials). If the patentee must change the primers enough to introduce "marked structural differences" between the primers and naturally occurring nucleic acids, the primers will no longer function. If the patentee merely introduces a minor change in the sequence of the primer, such that it still functions to bind the target DNA, this may turn out to be too small of a change to meet the "significantly different" standard.
23 Training Materials at Slides 67-78.
24 *See* Brinckerhoff, C., A First Look At The USPTO 101 Training Slides, Pharma Patents Weblog, March 24, 2014, *available at* http://www.pharmapatentsblog.com/2014/03/24/a-first-look-at-the-uspto-101-training-slides/ [last accessed April 20, 2014].
25 Guidance Memo at p. 11-13.
26 This approach should also help satisfy the machine-or-transformation test articulated in Factor (e) of the Guidance. Slide 63 of the Training Materials suggests that merely specifying the type of machine (e.g. a bench-top or high-speed flow cytometer) could be enough to satisfy this factor weighing toward patent eligibility.
27 However, in *Myriad*, while evaluating the chemical changes in the claimed isolated DNA, the Court stated that "Myriad's claims…[do not] rely in any way on the chemical changes that result from the isolation of a particular section of DNA." 133 S. Ct. 2107, 2118. This may be since there were no changes to the actual structure of the DNA (e.g. the DNA sequence), only the covalent bonds between nucleic acids.
28 Guidance Memo at p. 7-9 (Example B).
29 Also see Guidance Memo at p. 3: [C]hemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature . . . regardless of whether particular words (e.g., "isolated", "recombinant", or "synthetic") are recited in the claim.
30 Noonan, K., Thoughts on the USPTO's Patent Eligibility Guidelines (and What to Do About Them), PatentDocs Weblog, March 18, 2014, *available at* http://www.patentdocs.org/2014/03/thoughts-on-the-usptos-patent-eligibility-guidelines-and-what-to-do-about-them.html [last accessed April 10, 2014].
31 Training Materials at Slide 33.
32 See, e.g., http://www.uspto.gov/patents/announce/myriad-mayo.jsp.
33 Training Materials at Slide 88.
34 Zuhn, D., USPTO Tries to Address Public Misunderstandings Regarding Myriad-Mayo Guidance, PatentDocs Weblog, March 18, 2014, *available at* http://www.patentdocs.org/2014/04/uspto-tries-to-address-public-misunderstandings-regarding-myriad-mayo-guidance.html [last accessed April 20, 2014], also see http://www.uspto.gov/patents/announce/myriad-mayo.jsp.

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Patent Exhaustion Doctrine Continues to Energize the Courts

By Patrick G. Gattari and Chad A. Kamler

The past year has been unusually active for the "first sale" doctrine. Also known as patent exhaustion, the doctrine is based upon the premise that a patent holder is entitled to only one royalty for its sale of a patented article. Therefore, once the patent holder has received consideration for an unconditional sale of a patented article, the holder "surrenders all rights to any future use or sale of it."[1] The underlying rationale is that the consideration bargained for as part of the sale represents the benefit that the patent laws were meant to bestow on the patent holder.[2]

The first sale doctrine seems straightforward when patented articles are involved, which explains why the recent court decisions in this area involved patented methods. These decisions all apply the Supreme Court's 2008 decision in *Quanta Computer v. LG Electronics*, which held that patented methods are exhausted by the sale of articles when the use of the articles embodies the patented methods.[3] In *Quanta*, Intel secured a license from LG Electronics (LGE) authorizing Intel to manufacture and sell integrated circuits that were designed to perform LGE's patented methods for managing computer memory and data bus traffic. The license agreement between Intel and LGE specifically disclaimed any license to third parties to practice the patented methods by combining licensed products with other non-licensed components. In a separate "Master Services Agreement," Intel agreed to inform its customers in writing that Intel's license did not extend to combinations of the patented circuits with non-Intel products. Quanta Computer later purchased the integrated circuits from Intel and combined them with non-Intel products to build computers that practiced the patented methods. LGE sued Quanta for infringing its method patents and Quanta raised the defense of exhaustion based on the license agreement.

The US Supreme Court held that the doctrine of patent exhaustion applied to LGE's patents, and ruled for Quanta. The Court recognized that a "patented method may not be sold in the same way as an article or device," but that methods can be embodied by a product, and a sale of such a product will exhaust the patented method.[4] The Court noted that method claims could otherwise be used to "shield practically any patented item from exhaustion" by claiming what the article does, as well as the article itself.[5] The Court found that Intel's sale of the integrated circuits to Quanta, authorized by LGE, exhausted the method claims because the circuits had "no reasonable non[-]infringing use and included all the inventive aspects of the patented methods."[6] Even though the license agreement specifically disclaimed any license to third parties to practice the patents by combining licensed products with non-licensed products, the Court found that the disclaimer was only related to the question of whether Quanta had an implied license, and that the disclaimer was not relevant to the question of patent exhaustion. The Court also found that the Master Services Agreement was not sufficient to limit the license.

> **Patent holders who attempt to place a value on their patent without understanding its enforceability will do so at their own peril.**

The Federal Circuit in *Keurig, Inc. v. Sturm Foods, Inc.* was presented with a similar set of facts as the Court in *Quanta* to the extent that the sales of products in *Keurig* were not conditioned on any particular use.[7] Keurig's patents covered both its single-serve coffee brewers, as well as methods of brewing coffee using single-serving brewing cartridges.[8] Sturm sold brewing cartridges to consumers, and Keurig sued Sturm for induced and contributory infringement based on the theory that the consumers used Sturm's cartridges in conjunction with the brewers to infringe Keurig's patented brewing method. Sturm argued that the cartridges themselves were not covered by any patents and that the sales of the brewers exhausted exclusionary rights to the patented brewing methods performed by the consumers.

Keurig argued that its brewers were capable of several non-infringing uses and, therefore, its brewers alone did not "substantially embody" the asserted method claims, which would be required for a finding of exhaustion under *Quanta*. The Federal Circuit found, however, that even though Keurig's brewers had reasonable non-infringing uses, Keurig sold the brewers without any conditions. Therefore, the method patents were exhausted by each respective sale to a consumer, and Sturm could not be liable for contributory or induced infringement. The Court also reaffirmed that patents are exhausted as a whole, and not on a claim-by-claim basis.[9]

Another recent Federal Circuit decision, *LifeScan Scotland, Ltd. v. Shasta Technologies, LLC*, stands as another warning that *any* unconditional transfer of a product may exhaust a related patent.[10] Lifescan encouraged health care providers to provide its patented blood glucose meters to patients free-of-charge, with the expectation (but not the requirement) that patients would, in the future, purchase test strips intended for use with the meters.[11] Shasta sold test strips to consumers that were designed for use with Lifescan's patented blood glucose meters. Lifescan sued Shasta for indirect infringement, alleging that end users of Shasta's test strips would be direct infringers of its patented method for using the meter.

Lifescan's first argument against the application of patent exhaustion was that it gave the meters away, which precluded exhaustion. The Federal Circuit rejected this argument and ruled that "in the case of an authorized and unconditional transfer of title, the absence of consideration is no barrier to the application of patent exhaustion principles."[12]

The Court also rejected Lifescan's argument that because the meters required test strips to practice the patented method, the meter alone did not "substantially embody" the patented method.[13] The Court found that, like the sale of the articles that were sold in *Quanta* and *Keurig*, the conveyance of the meters in

Lifescan was unconditional. Therefore, the patent's restrictions could not be imposed upon the end user.

In yet another exhaustion case where the patent owner unsuccessfully attempted to maintain exclusivity to its patented methods, the District Court in *Helferich Patent Licensing, LLC, v. New York Times Co.* considered agreements that attempted to license only apparatus-type "handset" claims of Helferich Patent Licensing's ("HPL's") patents to cellphone manufacturers.[14] HPL tried to protect the "content" claims of the patents by carefully reserving its rights to those claims in the license agreements. HPL's "handset" claims covered cell phones with the capability of receiving hyperlinks for downloading the associated content, and the "content" claims covered methods for sending the hyperlinks to cell phones.[15] HPL brought an action against The New York Times ("the Times") for infringing the "content" claims when the Times sent text messages to the licensed handsets with hyperlinks to the newspaper's content. HPL argued that the Times' actions were outside the scope of the license executed by the cellphone manufacturers because those manufacturers were licensed only to practice the handset claims. The Times argued that HPL's license exhausted all claims of the licensed patents, including the "content" claims.

The Court found that the handset devices "at least partially practice, and therefore, sufficiently embody," the content claims of the patents, meaning that the licensed sale of the cell phones had exhausted all of the related claims, not just the "handset" claims.[16] The Court noted that the doctrine of patent exhaustion was meant to "avoid double recovery by a patentee," implying that patent rights were not meant to be used to exact royalties from a manufacturer's sale of a handset to a consumer, and then also used again to exact royalties from a content provider when the consumer uses the phone to access a hyperlink provided by a content provider such as the Times.[17] "There would be little value to the handset manufacturers (or their end users) to have purchased licenses to [the] patents to receive content from a third-party content provider if the content provider, like Defendants, could not send the message to the licensed handset device without infringing the patents."[18]

These recent decisions highlight a number of important issues in licenses associated with sales of patented products: (1) patents are exhausted as a whole, and not on a claim-by-claim basis, (2) authorized sales of products embodying a method patent cause the patent to be exhausted with respect to that product, and (3) patent holders lose control of patented inventions after an authorized conveyance, regardless of the consideration received. Patent holders who attempt to place a value on their patent without understanding its enforceability will do so at their own peril. When licensing patents that contain both product and method claims, care must be taken to ensure that the license is truly limiting without running into the exhaustion doctrine.

Endnotes

1 Robert A. Matthews, Jr., 2 Annotated Patent Digest § 11:30 (2014).
2 *See Keurig, Inc. v. Sturm Foods, Inc.,* 732 F.3d 1370, 1373 (Fed. Cir. 2013).
3 553 U.S. 617 (2008).
4 *Id.* at 628.
5 *Id.* at 629–30.
6 *Id.* at 638.
7 732 F.3d 1370 (Fed. Cir. 2013).
8 *Id.* at 1371.
9 *Id.* at 1374; *see also Helferich Patent Licensing, LLC v. New York Times Co.*, No. 10-CV-4387, 2013 WL 4401378 at *7–8 (N.D. Ill. Aug. 14, 2013), order clarified on reconsideration, No. 10-CV-4387, 2013 WL 6354209 (N.D. Ill. Dec. 4, 2013) (reasoning that allowing patentees to license patents on a claim-by-claim basis would introduce uncertainty and would effectively allow the patentee to create "hundreds of patents out of a single patent").
10 734 F.3d 1361 (Fed. Cir. 2013).
11 *Id.* at 1365.
12 *Id.* at 1374.
13 *See id.* at 1365.
14 No. 10-CV-4387, 2013 WL 4401378 (N.D. Ill. Aug. 14, 2013) *order clarified on reconsideration*, No. 10-CV-4387, 2013 WL 6354209 (N.D. Ill. Dec. 4, 2013).
15 By clicking a hyperlink, a user can be directed to web-hosted content.
16 *Id.* at *6 (citing *Quanta*, 553 U.S. at 635).
17 *Id.* at *8.
18 *Id.* at *6.

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MBHB to Exhibit at 2014 BIO International Convention in San Diego

MBHB will be participating as an exhibitor at the 2014 BIO International Convention ("BIO") set for June 23-26 in San Diego. We invite you to visit us at Booth #1337 in the exhibit hall to meet our attorneys, learn more about our services and enter our raffle. Billed as the largest global event for the biotechnology industry, 2014 BIO is organized by the Biotechnology Industry Organization. The organization represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. MBHB is also a proud sponsor of the North Carolina Pavilion at 2014 BIO (Booth #1727).

2014 BIO covers the wide spectrum of life science innovations and application areas. Drug discovery, biomanufacturing, genomics, biofuels, nanotechnology, and cell therapy are just a few of the industries represented. Thousands of leaders from over 65 countries are expected to attend 2014 BIO. The key elements of the event are education, networking, BIO Business Forum partnering and the 1,700 companies showcasing the latest technologies, products and services in the BIO Exhibition. View complete details at http://convention.bio.org.

"Patent Trolls" in the Crosshairs—But How Will Patent Reform Legislation Impact the Rest of Us

By Andrew W. Williams, Ph.D.

Both Congress and the White House have been actively pursuing patent litigation reform in an attempt to combat the perceived "patent troll" problem.[1] Of course, any legislation will impact all patent holders, even though most will not consider themselves to be patent trolls. The disconnect occurs because so-called "trolls" are being equated with all non-practicing entities ("NPEs")[2], even though this includes a large number of entities to which that derogatory term was never meant to apply. After all, an NPE is simply a patent holder that does not commercialize the claimed innovation. Therefore, entities such as universities, research institutions, start-up companies, and even sole inventors, can be considered NPEs. But rather than discourage such institutions from possessing intellectual property, the US patent system actually encourages it.

For example, under this system, the property rights associated with patents are readily transferrable without any working requirement, meaning that a patent holder does not need to actually practice the invention. This system helps to ensure that society benefits from the innovations because the original inventor is often not in the best position to commercialize the invention. Therefore, rather than "hindering" innovation, as the detractors decry, the current system is meant to encourage it.

The problem with the current legislative efforts is that Congress is setting out to curb "patent troll" activity without first deriving a workable definition. Instead, members of Congress use the old Justice Stewart line, "I know it when I see it."[3] Rather than defining what a troll is, Congress has defined various traits or behaviors that trolls are thought to exhibit, seeking to minimize or eliminate the ability of patent holders to engage in these activities. However, it is often difficult to distinguish between abusive assertion tactics and the legitimate licensing efforts of patent holders. Indeed, the proposed legislation will impact all patent holders, not just the so-called "trolls." The result is that most of the legislative proposals are not narrowly tailored, but rather are blunt instruments that will likely impact all patent holders. Accordingly, it is important that all patent holders pay attention to the proposed legislation and be aware of how to respond to any changes should they become law. This article will highlight some of the more significant proposals, how they might impact legitimate patent assertion, and what new actions might be required.

Bad-Faith Demand Letters

Interestingly, one of the first "traits" that "patent trolls" are thought to exhibit does not even necessarily implicate patent litigation. In fact, regulating the sending of bad-faith demand letters does not necessarily fall within the scope of the patent statute. As a result, reforms meant to address this behavior are coming not only from the Congressional Judiciary committees, which have jurisdiction over the patent system, but are coming from other sources as well.

The problem with the current legislative efforts is that Congress is setting out to curb "patent troll" activity without first deriving a workable definition.

For example, Sen. Claire McCaskill introduced a bill targeting abusive demand letters[4], and it was referred to the Senate Committee of Commerce, Science, and Transportation. Instead of changing the patent statute, this bill directs the Federal Trade Commission to promulgate rules to regulate the sending of demand letters.[5] Moreover, some states are contemplating similar bills aimed at curbing these practices as well, which will make abusive demand letters an unfair or deceptive business practice at the state level.[6] This follows the actions of some states' Attorneys General that have been targeting "trolls" under existing consumer protection laws.

Because these various proposals impact pre-litigation activity, they may be the only deterrent against "patent trolls" who have no intention of ever filing suit. These provisions would provide relief against the "shake-down" of companies and individuals, which may result in quick settlements as a way to avoid costly litigation. The difficulty with any attempt to regulate the sending of demand letters, however, is that the First Amendment rights of patent holders need to be accounted for. The sending of such letters, without more, should not create a judicial cause of action. More importantly, legislators need to take care, because the sending of such demand letters is an essential part of our patent system, allowing patent holders to put alleged infringers on notice and, ideally, facilitating licensing activity between the parties.

Patent owners will therefore not only need to pay close attention to which version of demand-letter legislation is enacted by Congress, they will also need to be mindful of the requirements of the states in which they send such letters. In some cases, the penalty for an insufficient demand letter is limited to preventing an allegation of willfulness. However, it is possible that by not including certain information in the demand letter, such as the factual allegations related to any perceived infringement, the patent holder could be subject to state or federal consumer protection laws. As an extreme measure, it might become a prudent practice for a patent holder faced with such concerns to pre-emptively file an infringement complaint before sending a demand letter. Of course, the reason behind the demand letter would dictate whether filing the infringement complaint would be warranted, but such action could negate allegations from the accused infringer that the litigation threat was falsely made.

Transparency of Patent Ownership

Another characteristic trait of prototypic "patent trolls" is that that they are shell

companies with little to no assets other than the asserted patent. Accused infringers complain because they do not know who the real party-in-interest is that stands to benefit. A potentially more significant problem, however, is that such shell companies will have minimal discovery burdens, and therefore reduced litigation costs, and they are not likely to be subject to infringement counterclaims from the accused infringer. Moreover, shell companies with no assets would essentially be judgment proof against any attorney fee-shifting if the accused infringer prevails at trial.

As a result, there has been strong interest in increasing the transparency of patent ownership. For example, the White House has proposed an initiative to ensure that patent ownership records are updated regularly.[7] The proposed rules promulgated by the US Patent and Trademark Office to enact this initiative would make the ultimate penalty for failing to comply the abandonment of the application.[8] The legislative proposals are less draconian. Remedies for non-compliance range from the inability to recover attorney fees or increased damages based on willfulness, to being responsible for the reasonable fees incurred by an alleged infringer to discover the ultimate parent entity. As a result, it would behoove any patent owner to confirm that all assignments have been properly recorded at the first sign of any potential infringing activity. Moreover, it would be prudent to conduct the proper due diligence related to assignment recordation before taking any interest in a patent, because the ability to recover fees for some period of time may already have been forfeited.

Changes to Patent Infringement Actions

Congress is also looking to mandate changes to how the judiciary handles patent lawsuits. Anti-"troll" advocates point to the relative ease with which a patent holder can file an infringement lawsuit, as well as the substantial costs associated with patent discovery, as reasons for the rise in "patent-troll" activity. For example, unscrupulous patent holders can make vague accusations at the initiation of a case and treat the subsequent litigation as a fishing expedition. Congress is considering amending or eliminating Form 18, which limits the requirements of a patent complaint to little more than notice pleading of the patent at issue, a statement of jurisdiction, and an identification of the alleged infringing product or activity. Congress would instead heighten the pleading requirements to require details often not provided until later during litigation. However, this could have the unfortunate consequence of encouraging accused infringers to challenge the sufficiency of the pleadings without ever addressing the merits of the case. This could side-track the proceedings with pre-litigation ancillary hearings that elevate form over substance. As a result, patent holders would be advised to conduct a more detailed pre-litigation analysis, and be prepared to include as much information as possible in the complaint (potentially including claim charts).

It is very possible that we will see abusive-patent-litigation legislation sometime this year. And, regardless of what version passes, there will likely be unintended consequences for the legitimate assertion of patents.

"Trolls" are also thought to request excessive amounts of discovery while having minimal discovery costs themselves. As a result, Congress is proposing limiting initial discovery to documents required for claim construction. In addition to interfering with the ability of the judiciary to manage their cases, this approach is likely to protract all patent litigation. Smaller entities already have difficulty absorbing litigation costs, so such a provision would certainly increase the incentive to settle.

Customer Stay

"Patent Trolls" have increasingly been thought to target end-user customers rather than the manufacturers of infringing devices. The conventional wisdom is that the end user is at a disadvantage because it does not have the requisite knowledge of the mechanics of infringement. Moreover, the end-user customers might not be as patent savvy, and therefore more willing to settle. As a result, Congress has proposed various "customer-stay" provisions to address this perceived behavior.

The ultimate problem with these pending provisions, however, is that it is not clear whether they will be useful. For example, they require that both the manufacturer and the customer be sued, that they both agree in writing to a stay, that the end user agrees to be bound by the manufacturer litigation, and that the request be filed early in litigation. Of course, as a patent holder, if you have a legitimate reason to target an end-user customer base, it would be prudent to delay suing the manufacturer, unless a customer stay would not be detrimental to your efforts.

Attorney Fee-Shifting

Finally, "patent trolls" are thought to have little disincentive to bring patent infringement lawsuits because the current fee-shifting statute makes it difficult for a falsely accused alleged infringer to shift its fees to the losing party. As a result, the economically rational course for an alleged infringer is to settle the case for a "nuisance-value" payment. Unfortunately, this is thought to encourage "trolls" to target multiple companies or individuals, even if the scope of the claims is stretched beyond their reasonable scope. The Supreme Court is presently considering the issue, and may make it much easier to seek attorney fees under the current statute. Notwithstanding that fact, fee-shifting has been at the forefront of most legislative agendas.

At this time, there are several fee-shifting proposals. For example, the provision in the Innovation Act changes the default to a loser-pays system, unless the actions of that party were reasonably justified. In any event, it is likely that any new provision will lower the barrier to obtain fees. As a result, this could have a "chilling effect" on the legitimate assertion of patents, especially for smaller entities that might rely more heavily on their intellectual property rights. In addition, the ability to obtain fees will likely not be limited to prevailing accused infringers. Therefore, this provision could backfire, as risk-adverse accused infringers faced with the (perhaps, unlikely) possibility of paying a "trolls"

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Evolving Data Protection Regimes in the Asia-Pacific Arena and Their Impact on Litigation:

Part II—Country-Specific Policies

By S. Richard Carden

Part I of this article addressed basic concepts of data privacy as set out in the policies of numerous regional and multilateral organizations, including the Organisation for Economic Co-operation and Development ("OECD"), Asia-Pacific Economic Cooperation ("APEC"), and the Association of Southeast Asian Nations ("ASEAN").[1] In Part II, we discuss the specific policies of several Asia-Pacific nations and provide a general framework for addressing data privacy issues throughout the litigation process.

Australia

Australia has had a very robust set of data privacy laws for nearly 30 years. In the Privacy Act 1988, Australia, recognizing the privacy rights in the International Covenant on Civil and Political Rights (to which it was a party), and further recognizing the efforts of the OECD relating to data privacy, specifically adopted measures to protect personally identifiable information. Just as with the OECD Guidelines, the Australian privacy laws seek to balance the need for legitimate transfers of information between organizations and across borders with the privacy interests of individuals. While the Privacy Act has seen frequent amendments, a substantial revision has taken place in the past three years. On March 12, 2014, Australia's existing National Privacy Principles ("NPPs;" applicable to private sector entities) and Information Privacy Principles ("IPPs;" applicable to government entities) were replaced with a new set of 13 Privacy Principles ("APPs").[2] The APPs mirror in large measure the eight original OECD Guideline principles,[3] although they provide a greater degree of granularity. Specifically the 13 APPs are:

- Open and transparent management of personal information
- Anonymity and pseudonymity
- Collection of solicited personal information
- Dealing with unsolicited personal information
- Notification of the collection of personal information
- Use or disclosure of personal information
- Direct marketing
- Cross-border disclosure of personal information
- Adoption, use or disclosure of government related identifiers
- Quality of personal information
- Security of personal information
- Access to personal information
- Correction of personal information[4]

The Privacy Act as amended by the Privacy Amendment (Enhancing Privacy Protection) Act 2012 defines "personal information" for purposes of the APPs as:

> [I]nformation or an opinion about an identified individual, or an individual who is reasonably identifiable:
> (a) whether the information or opinion is true or not; and
> (b) whether the information or opinion is recorded in a material form or not.[5]

Among the changes embodied in the APPs are changes to the provisions for cross border transfers of personal information. APP 8.1 provides:

> Before an APP entity discloses personal information about an individual to a person (the *overseas recipient*):
> a. who is not in Australia or an external Territory; and
> b. who is not the entity or the individual;
> the entity must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach the Australian Privacy Principles (other than Australian Privacy Principle 1) in relation to the information.[6]

APP 8 eliminates a number of exceptions previously present in the NPPs related to enforcement of contracts, as well as an exception originally allowing for a transfer where the data subject would likely have consented, but it would not have been practical to obtain consent. A number of exceptions still apply, including consent of the data subject, however, the exception of most potential applicability in litigation is where the disclosing entity:

> Reasonably believes that:
> i. the recipient of the information is subject to a law, or binding scheme, that has the effect of protecting the information in a way that, overall, is at least substantially similar to the way in which the Australian Privacy Principles protect the information; and
> ii. there are mechanisms that the individual can access to take action to enforce that protection of the law or binding scheme.[7]

Note that this exception is similar to the European Union ("EU") safe harbor program, and will likely be subject to the same concerns recently expressed by the EU when, ironically enough on March 12, 2014, it suspended the safe harbor program in view of the National Security Agency scandal.

The open question, and one that bears watching as time passes, is whether a court enforceable protective order in US litigation will be deemed to provide similar protections as those available in Australia, particularly once information obtained through discovery is then used in open court proceedings.

China

China does not presently have an omnibus data protection regime, however, there are a number of existing laws and proposals that address data privacy. For some years, China has been pursuing implementation of a more formal policy, but has yet to fully implement it.

In 2013, however, a non-binding standard for the protection of personal information was implemented. The Information Security Technology Guidelines for Personal Information Protection on Public and Commercial Services Information System ("the Guidelines") define "personal information" as "[c]omputer data that is handled in computer

systems, that are related to a specific natural person, and that can be used independently or in combination with other information to distinguish that specific natural person."[8] The Guidelines define eight governing principles, which are similar in concept and scope to the OECD principles.[9] The Guidelines also distinguish between "common" personal information and "sensitive" personal information, the disclosure of which "may bring about harmful influence to the subject of the indicated personal information."[10]

Transfers of personal information under the Guidelines are primarily subject to the consent of the data subject. Perhaps of most significance to US litigation is the guideline related to transfers to foreign entities, which states:

> Without explicit consent by the subject of personal information, or clear provisions in laws or regulations, or without the agreement of the controlling departments, personal information administrators may not transmit personal information to foreign personal information receivers, including individuals abroad or foreign-registered organizations and institutions.[11]

Notice and consent are also requirements for the collection and processing of personal information under the guidelines.[12]

Given the breadth of the Guidelines, there are potentially substantial hurdles involved when parties are seeking discovery from a Chinese entity.

Japan

Japan has an established data protection framework, implemented in 2003 through the Act on the Protection of Personal Information (Act No. 57 of 2003) ("APPI"). As with other data protection laws, the APPI seeks to balance the need for legitimate transfers of information against individual rights.[13]

The APPI defines "personal information" as "information about a living individual which can identify the specific individual by name, date of birth or other description contained in such information (including such information as will allow easy reference to other information and will thereby enable the identification of the specific individual)."[14] As with the Chinese Guidelines, the APPI limits transfer without consent of data subject or legal authority.[15]

Implications for Litigation Involving Entities Outside the United States

Given the breadth of the definitions of personal information, and the strong interest among the Asia-Pacific nations in ensuring that the balance between disclosure and protection is properly enforced, much of the data sought in modern patent litigation is potentially subject to data protection laws and restrictions on cross-border transfer. Particularly in view of the fact that litigation now often involves terabytes of data (much of which is of marginal or little actual relevance or use), the potential for disclosure of personal data is high. And given the ever increasing penalties implemented or under consideration for breaches of privacy laws, parties to a US litigation would be well-advised to address these issues head on, rather than waiting for them to be brought up in a discovery motion or a sanctions motion.

Given the breadth of the definitions of personal information, and the strong interest among the Asia-Pacific nations in ensuring that the balance between disclosure and protection is properly enforced, much of the data sought in modern patent litigation is potentially subject to data protection laws and restrictions on cross-border transfer.

In order to properly assess the impact of data privacy issues on US litigation, one must consider how they arise in various stages of litigation, as presumptions of privacy differ markedly throughout the process. During the discovery phase, there is no presumption that the public can or should have access to materials exchanged between the parties, or in materials obtained from non-parties. However, once information is introduced into the courtroom, whether in motion practice, hearings, or at trial, the presumption shifts. At this point, there is an overriding interest in providing the public access to the courts. It is therefore important for the parties to consider what data will be needed at each stage in order to appropriately afford the greatest degree of protection to personally identifiable information.

The parties should address data privacy issues well before discovery actually begins. There are a number of potential options for limiting the unnecessary disclosure of personal information, and many can actually provide benefits to the parties through a reduction in the overall amount of information collected and reviewed and through a reduction of costs associated with collection, production, and review. While most parties will look primarily to the protective order as a mechanism for protecting the confidentiality of data,[16] a protective order in and of itself many not be fully sufficient, particularly once the data is needed for use in an open proceeding. Moreover, given the volume of information associated with modern patent litigation, redaction of personal information is often completely impractical. The parties should instead seek to address these issues as part of the Federal Rules of Civil Procedure Rule 26(f) discovery plan.

As an initial matter, each party should attempt to identify the information it will likely need to produce that may contain personally-identifiable information. Each party should also consider what information it intends to seek that may be subject to privacy laws in foreign jurisdictions, and whether the benefits of the discovery outweigh any potential individual privacy concerns (consistent with the proposed amendments to Fed. R. Civ. P. Rule 26(b)(1)).[17] The parties can then reasonably discuss methods for limiting the amount of information exchanged that may raise privacy concerns. For example, the parties may consider staged discovery such that the earlier stages involve a much more limited set of information, and then expand that discovery if and when it becomes necessary.

Companies involved in patent litigation may also consider some proactive measures to

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Trademark Functionality and Fashion — Tips for Clients

By Sydney R. Kokjohn and Nicole E. Reifman

Trademark protection is very important in the fashion industry. The ability to protect certain logos and design features may determine the success of a fashion designer's business. Thus, it is crucial to understand how to protect your fashion trademarks and trade dress.

Trademark Functionality and Fashion

In the fashion industry, trademarks or trade dress may include logos, fashion designs, and even color. Trademark law protects marks or design features that are "distinctive."[1] A mark is determined to be "inherently" distinctive if "[its] intrinsic nature serves to identify a particular source."[2] Marks that are not inherently distinctive may, however, "acquire" distinctiveness by developing "secondary meaning" in the public mind.[3] "A mark has acquired secondary meaning when, in the minds of the public, the primary significance of a product feature is to identify the source of the product rather than the product itself."[4]

A valid and protectable trademark is only infringed if there is a likelihood of consumer confusion with another's use of a similar mark.[5] Even if a likelihood of confusion is established, a defendant may assert a defense of "functionality" of the mark. Two types of functionality exist: utilitarian functionality and aesthetic functionality. Under the doctrine of utilitarian functionality, a mark is functional if (1) it is "essential to the use or purpose of the article" or (2) if it "affects the cost or quality of the article."[6] For example, a mark is functional if its features are dictated by the functions to be performed or permit the article to be manufactured at a lower cost.[7]

Those in the fashion industry more often deal with the doctrine of aesthetic functionality. The Supreme Court has held "when the aesthetic design of a product is itself the mark for which protection is sought, we may also deem the mark functional if giving the markholder the right to use it exclusively would put competitors at a significant non-reputation-related disadvantage . . . even if there is no indication that the mark has any bearing on the use or purpose of the product or its cost or quality."[8] Thus, even if the design feature of a mark is not functional under the doctrine of utilitarian functionality, a court may still consider the mark functional if its design features are "essential to effective competition" in the relevant market.[9]

In a recent case discussing aesthetic functionality in the fashion industry, *Christian Louboutin S.A. v. Yves Saint Laurent America Holding, Inc.*, the Court of Appeals for the Second Circuit held that the bright, red lacquered outsoles of Christian Louboutin shoes could be protected as a trademark.[10] The Court of Appeals reversed the District Court's order denying trademark protection of the red lacquered outsoles, finding that there is no "*per se* rule of functionality for color marks in the fashion industry."[11] But the Court limited the protection to use of a red lacquered outsole that contrasts with the remainder of the shoe.[12]

Tips for Clients in the Fashion Industry

Focus on protecting the specific design feature you want to use

The narrower the design feature you are trying to protect, the less likely the court will consider it to put competitors at a disadvantage. For example, in another recent case, *Audemars Piguet Holding S.A. v. Swiss Watch Int'l, Inc.*, the District Court for the Southern District of New York found that the octagonal shape of Plaintiffs' watches was not functional.[13] The Court noted that Plaintiffs were trying to protect the octagonal shape with other design features, not the octagonal shape alone.[14] The Court also focused on the fact that Plaintiffs did not allege infringement by Defendants' watch which utilized the octagonal shape, but not the other design features.[15]

Use your mark as a source identifier

One of the most important things you can do to ensure trademark protection of your fashion design features is to use your mark as a source identifier. As noted above, a mark is distinctive, and thus protectable, if it serves to identify a particular source. If consumers decide to purchase a product because its design features identify a certain source, it is less likely that a court will find the features to be functional. In *Knitwaves, Inc. v. Lollytogs Ltd.*, the Court of Appeals for the Second Circuit found that Knitwaves' fall motif sweater design was not functional because Lollytogs would not be precluded from using all fall designs, just those that would cause confusion.[16] However, the Court found that Knitwaves' designs were not protectable because they were not primarily intended for source identification.[17] To the contrary, in *LeSportsac, Inc. v. K Mart Corp.*, the same Court affirmed the District Court's finding that the combination and arrangement of design features on LeSportsac's bags were non-functional and served the purpose of source identification.[18]

Be careful in how you advertise

In advertising any design feature you wish to protect, you should be careful to avoid making any statements that may be used as evidence of functionality. For example, in discussing why he chose red for the outsoles of his shoes, Christian Louboutin stated that he chose red "to give his line of shoes 'energy,'" and that "he regarded [red] as 'engaging, flirtatious, memorable and the color of passion,' as well as 'sexy.'"[19] While the Court of Appeals ultimately reversed the District Court's finding of functionality of the red lacquered soles, the District Court noted that "Christian Louboutin himself has acknowledged significant, nontrademark functions for choosing red for his outsoles" in determining that the red outsoles should not be granted trademark rights.[20]

Establish your trademark rights

If possible, you should register your fashion trademark with the United States Trademark Office. A certificate of registration is *prima facie* evidence that a mark is a valid trademark.[21] Thus, it would be up to a

defendant to prove that the mark should not be registered. In addition, once a registered mark has been used in commerce for five consecutive years, it is deemed incontestable, meaning that it is protected from many cancellation arguments.[22]

Enforce your rights

Failure to enforce your trademark rights over time may lead to the inability to enforce your rights in the future. Infringers may assert defenses of laches, acquiescence, or waiver if they have been using your mark for an extended period without any effort on your part to enforce your rights. Moreover, if others are using the same mark, it may lose its distinctiveness.

Endnotes

1 *Christian Louboutin S.A. v. Yves Saint Laurent Am. Holding Inc.*, 696 F.3d 206, 216 (2d Cir. 2012).
2 *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 768 (1992).
3 *Christian Louboutin*, 696 F.3d at 216 (quoting *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844 (1982)).
4 *Id.* (quotations omitted).
5 *Id.* at 217.
6 *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 850 n.10 (1982).
7 *LeSportsac, Inc. v. K Mart Corp.*, 754 F.2d 71, 76 (2d Cir. 1985) (citing *Warner Bros., Inc. v. Gay Toys, Inc.*, 724 F.2d 327, 330 (2d Cir. 1983)).
8 *Christian Louboutin*, 696 F.3d at 219 (citations omitted).
9 *Landscape Forms, Inc. v. Colum. Cascade Co.*, 70 F.3d 251, 253 (2d Cir. 1995).
10 696 F.3d at 225.
11 *Id.* at 223-24.
12 *Id.* at 225.
13 No. 12 Civ. 5423, 2014 WL 47465, at *13-14 (S.D.N.Y. Jan. 6, 2014).
14 *Id.* at *14.
15 *Id.*
16 71 F.3d 996, 1006 (2d Cir. 1995).
17 *Id.* at 1009.
18 754 F.2d 71, 78 (2d Cir. 1985).
19 *Christian Louboutin v. Yves Saint Laurent Am.*, 778 F. Supp. 2d 445, 447 (S.D.N.Y. 2011).
20 *Id.* at 453-54.
21 35 U.S.C. 1057(b).
22 35 U.S.C. 1065.

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deal with privacy concerns. For instance, to the extent that there is any reasonable expectation of privacy on behalf of an employee that has not already been contractually addressed, a company may consider providing a specific notice of potential disclosure when implementing legal holds. Of course, given the variety of potentially applicable laws, any notice methods should be drafted in view of the controlling laws in the collection jurisdiction so as to avoid arguments of ineffective notice.

The parties should also specifically address potential disclosure issues for discovery that will likely be used in open court. Can personal information be appropriately redacted or anonymized? Or must the parties provide notice to the data subject and allow an opportunity for them to oppose disclosure?

At the end of the day, there are many considerations the parties to a US litigation must address with respect to the increasing number of data privacy laws worldwide. However, proper advance planning will substantially limit the number of issues that will actually arise, and also potentially provide the parties with a more streamlined and cost-effective discovery process.

Endnotes

1 There have also been significant recent developments in other regions that are beyond the scope of this article. Perhaps the most significant of these occurred in March 2014, when the European Union suspended its safe harbor program, and reenergized its efforts to implement a new data protection regulation that would harmonize privacy laws throughout the EU. The draft regulation (as recently amended) includes penalties of up to $100 million euros or 5% of worldwide turnover for breaches of the regulation, whichever is greater. For more information, *see, e.g.*, Memorandum from European Comm'n, Progress on EU Data Protection Reform Now Irreversible Following European Parliament Vote, MEMO/14/186 (March 12, 2014), *available at* http://europa.eu/rapid/press-release_MEMO-14-186_en.htm.
2 In addition, a new Privacy Regulation went into effect on March 12, 2014. The Office of the Australian Information Commissioner provides a thorough and detailed analysis of the changes in effect as of March 2014 on its website. *See Privacy Law Reform*, Office of the Australian Information Commissioner, http://www.oaic.gov.au/privacy/privacy-act/privacy-law-reform (last visited April 14, 2014).
3 *See OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data 1980,* pt. 2, paras. 7–14 (Austl.).
4 *Privacy Act 1988 (as amended 2013)* (Cth) sch 1, (Austl.).
5 *Id.* pt II, div. 1, s 6 (Austl.).
6 *Id.* sch 1, pt 3, cl. 8(1) (emphasis in original).
7 *Id.* sch 1, pt 3, cl. 8(2).
8 Information Security Technology Guidelines for Personal Information Protection on Public and Commercial Service Information Systems (promulgated by the Ministry of Indus. and Info. Tech., effective Feb. 1, 2013) Art. 3.2 (China).
9 *Id.* art. 4.2.
10 *See id.* arts. 3.7, 3.8.
11 *Id.* art. 5.4.5.
12 *Id.* arts. 5.2.3, 5.3.4.
13 Act on the Protection of Personal Information, Act. No. 57 of 2003, art. 1, http://www.cas.go.jp/jp/seisaku/hourei/data/APPI.pdf (Japan).
14 *Id.* art. 2(1).
15 *Id.* art. 23.
16 *See, e.g.,* the protective order entered in *In re Actos (Pioglitazone-Products Liab. Litig.)*, which specifically has a provision entitled "Discovery Material and Foreign Law." No. 6-11-MD-2299, 2012 WL 3899669, at *2 (W.D. La. July 30, 2012).
17 *See* Comm. on Rules of Practice and Procedure of the Judicial Conference of the United States, *Preliminary Draft of Proposed Amendments to the Federal Rules of Bankruptcy and Civil Procedure*, at 289–90 (2013), *available at* http://www.uscourts.gov/uscourts/rules/preliminary-draft-proposed-amendments.pdf.

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attorney's fees might feel compelled to settle early. In any event, even if small companies have the promise of recouping fees at the conclusion of litigation, it is possible that many of them will not be able to survive until the conclusion of litigation.

What course of action should a patent holder or accused infringer take in view of these proposals? Most fee-shifting provisions being discussed have a "justification" component. As such, it might become prudent to seek "justification" opinions of counsel. Therefore, before embarking on a demand-letter campaign, or after receipt of such a demand letter, seeking an independent opinion on the merits of the case might become a best business practice.

Conclusion

It is very possible that we will see abusive-patent-litigation legislation sometime this year. And, regardless of what version passes, there will likely be unintended consequences for the legitimate assertion of patents. Nevertheless, by paying attention to the details, you can prevent these proposed patent reforms from seriously disrupting your patent practice.

Endnotes

1 A companion piece was presented in an earlier edition of this newsletter (Andrew W. Williams, *"Patent Trolls" Beware – Congress Tackles Vexatious Patent Litigation*, 12 Snippets, Winter 2014, at pp. 4-5).
2 *See, e.g.*, Laura Sydell, *Taking the Battle Against Patent Trolls to the Public*, All Tech Considered (August 30, 2013), http://www.npr.org/blogs/alltechconsidered/2013/08/30/217272814/taking-the-battle-against-patent-trolls-to-the-public.
3 *See, e.g.*, *Exec. Bus. Meeting of S. Comm. on the Judiciary*, 113th Cong. (March 27, 2014), accessible at http://www.judiciary.senate.gov/meetings/executive-business-meeting-2014-03-27.
4 Transparency in Assertion of Patents Act, S. 2049, 113th Cong. (2014).
5 *Id.*
6 *See, e.g.*, S. 3405, 98th Gen. Assem., Reg. Sess. (Ill. 2014).
7 *See* Press Release, The White House, FACT SHEET: White House Task Force on High-Tech Patent Issues (June 4, 2013), accessible at http://www.whitehouse.gov/the-press-office/2013/06/04/fact-sheet-white-house-task-force-high-tech-patent-issues.
8 Changes to Require Identification of Attributable Owner 79 Fed. Reg. 4,105 at 4,112-13, 4,120.

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Functional Claim Language—"Adapted To" and "Configured To"—Having Narrow Interpretations

By Alexander D. Georges and Joseph A. Herndon

Patent claim drafting is a challenging exercise that requires balancing potential infringement of the claim against the prior art. A patent practitioner may easily draft a claim of very narrow scope, but if such claim has a low likelihood of being infringed, the value of the claim is extremely diminished.

Analyzing potential infringement of a claim requires consideration of who may be an infringer. An infringer is generally defined as "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor."[1] It is often desirable to draft a claim to potentially cover the possible infringing activities of making, using, or selling the patented invention. However, selection of claim terms, or even simple selection of verb tense in a claim, may limit infringement to only one category of infringing activity.

> Analyzing potential infringement of a claim requires consideration of who may be an infringer.

For inventions characterized by functional elements, a claim may recite a device or component of the device that is "configured to" or "adapted to" perform a function, in contrast to a claim that recites a device or component that "performs" the function. A claim that explicitly recites that a device "performs" a particular function raises a question of whether making or selling the device would infringe the claim, since neither the act of making or selling the device would generally require the device to actually perform the function (of course, an end user of the device could use the device to perform the claimed function, but patent holders generally avoid suing such parties).

Claims that recite a device that is "configured to" or "adapted to" perform a particular function have a greater likelihood that making or selling the device could infringe the claim. However, claims that recite such "configured to" or "adapted to" language have recently been construed by courts in a more limited manner similar to means-plus-function claim terms. This may have unintended consequences for claim drafters.

In re Raymond Giannelli—"adapted to"

As one example, in *In re Raymond Giannelli*, the Court of Appeals for the Federal Circuit found that the claim term "adapted to" had been incorrectly construed to have the same meaning as "capable of."[2] Due to this overly broad interpretation of the claim term "adapted to," the Federal Circuit reversed the final rejection of the patent claims.[3]

The applicant had filed a patent application disclosing "an exercise machine on which a user can perform a rowing motion against a selected resistance, thereby strengthening the back muscles."[4] On appeal, representative claim 1 recited:

> 1. A row exercise machine comprising an input assembly including **a first handle portion adapted to be moved from a first position to a second position by a pulling force exerted by a user on the first handle portion in a rowing motion**, the input assembly defining a substantially linear path for the first handle portion from the first position to the second position.

The Board of Patent Appeals at the US Patent Office (the "Board") characterized the dispositive issue as being whether the chest press machine was "capable of being used by exerting a pulling force on the handles in a rowing motion."[5] Affirming an obviousness rejection, the Board deemed it reasonable that a user could face the handles of the chest press machine of a prior art patent and exert a pulling force on its handles in a rowing motion.[6]

On appeal, the Federal Circuit found that the Board erred in sustaining the examiner's rejections that the claims were obvious over the prior art patent chest press machine.[7] In particular, the Federal Circuit emphasized that the phrase "adapted to" within the claims of the application should have been given a narrower meaning, i.e., "that the claimed machine is designed or constructed to be used as a rowing machine whereby a pulling force is exerted on the handles."[8] This reasoning was in line with the applicant's argument that the Board's decision was "based on an incorrect assertion that the chest press machine disclosed in the '447 patent could be used as a rowing machine rather than considering how it would be used."[9]

Although the Federal Circuit recognized that the claim phrase "adapted to" can also mean "capable of" or "suitable for," in this situation, the Court stressed that the specification made it clear that "adapted to" has a narrower meaning in the claimed machine.[10] In particular, the Court reasoned that the specification discussed how the particular position of the handles relative to the primary and secondary lever arms and the resistance mechanism renders them "adapted" to be moved by the user's pulling force.[11] The Court found that the location of those handles relative to other components is one of their structural attributes that enables performance of the rowing motion against the selected resistance and, thus, interpreted "adapted to" to mean "configured to."[12] In making its decision, the Court referenced other decisions that also involved limiting the claim term "adapted to" to a narrower definition, such as "configured to."[13]

Thus, using a narrow interpretation for the phrase "adapted to," the Court found that the cited prior art failed to disclose handles that are adapted to be pulled in a rowing motion, but rather described a structure that "simulates as natural a human musculoskeletal outward pushing motion as possible while maintaining proper biomechanical alignment of the joints" and "the proper alignment of the wrists."[14] Although the result was positive for the applicant by requiring an interpretation

of the claims that was more specific to the structure/function described in the patent application (using somewhat of a means-plus-function analysis) so as to distinguish over prior art, this holding may cause concern for how courts are now interpreting functional claim language.

Superior Industries, Inc. v. Masaba, Inc. — "configured to"

Some interesting claim construction principles were also discussed in *Superior Industries, Inc. v. Masaba, Inc.*, which was a non-precedential opinion from the Federal Circuit in which the Court remanded the case for further clarification.[15]

Superior alleged that Masaba infringed multiple claims of five patents directed towards a dump truck.[16] In general, the patents asserted by Superior fell into two categories, referred to by the parties as the "undercarriage patents" and the "unloader patents."[17] The district court had previously construed multiple terms in the "unloader patents" to be consistent with the constructions proposed by Masaba, including constructions for the claim features of "configured to support an earthen ramp at a level even with the drive over surface," and "frame member configured to support an end of an earthen ramp constructed against the frame member."[18] As a direct result of the claim constructions of the district court, Superior conceded that it could not prevail on its infringement claims against Masaba, and successfully moved for summary judgment of non-infringement and dismissal of Masaba's invalidity counterclaims.[19] Thereafter, Superior appealed the district court's claim construction.

> As the courts continue to sort out how to interpret so-called functional claim terms, applicants may consider avoiding "adapted to," "configured to," or other possible functional terms when unnecessary.

On appeal, the Federal Circuit reversed the district court's decision and remanded the case for clarification due to the district court's failure to explain how its claim term constructions would affect the patentee's infringement claims and for sufficient factual context.[20] Although Superior acknowledged that it originally could not establish infringement under the district court's claim construction, the district court's opinion did not provide any context with respect to how disputed claim construction rulings related to accused products.[21] Thus, the Federal Circuit felt that the missing context made it difficult to understand the issues and provide meaningful review.[22]

However, in a concurring opinion, Chief Judge Rader articulated a few claim construction principles for the district court to consider when deciding subsequent constructions of the claims on remand. Judge Rader decisively indicated that "a system claim generally covers what the system is, not what the system does…[t]hus, it is usually improper to construe non-functional claim terms in system claims in a way that makes infringement or validity turn on their function."[23]

As a result, Judge Rader seemed to imply that a system claim covers the structure, not the function for the system disclosed in the specification. This interpretation seems to contradict the decision issued a few days earlier by the Federal Circuit in *In re Giannelli*, as discussed above. Perhaps the statements by Judge Rader may be considered in-line with the previous decision; however, it is unclear how Judge Rader would define a "non-functional claim term" versus a "functional claim term."

Conclusion

As the courts continue to sort out how to interpret so-called functional claim terms, applicants may consider avoiding "adapted to," "configured to," or other possibly functional terms when unnecessary. But, in contrast to means-plus-function claim terms, "adapted to" or "configured to" is not currently an automatic trigger for the narrow interpretations limited to the structure/function described in the specification, and may depend on further details in the claims.

Optionally, a patent applicant may draft multiple claim sets including claims that have functional terms and claims without functional terms. With increasing excess claim fees, however, this is not always a practical option, and some choices must be made to balance cost with the potential risks of unwanted claim interpretations.

Endnotes

1 35 U.S.C. § 271(a).
2 *In re Giannelli*, 739 F.3d 1375, 1380 (Fed. Cir. Jan. 13, 2014).
3 *Id.* at 1381.
4 *Id.* at 1376.
5 *Id.*
6 *Id.*
7 *Id.* at 1379.
8 *See Id.*
9 *Id.*
10 *Id* at 1380.
11 *Id.*
12 *Id.*
13 *See Sta-Rite Indus., LLC v. ITT Corp.*, 682 F. Supp. 2d 738, 753 (E.D. Tex. 2010) (construing "adapted to," in context, to mean "designed or configured to," not "having the capacity to"); *Boston Scientific Corp. v. Cordis Corp.*, 2006 WL 3782840 (N.D. Cal. Dec. 20, 2006) (construing "adapted to," in light of patent as a whole, to mean "configured to," not "capable of").
14 *Id* at 1380.
15 *Superior Indus., Inc. v. Masaba, Inc.*, 2013-1302, 2014 WL 163046 (Fed. Cir. Jan. 16, 2014).
16 *Id.*
17 *Id.*
18 *Id* at 2.
19 *Id.*
20 *Id.* at 4.
21 *Id.*
22 *Id.*
23 *Id.* at 5; *see also Paragon Solutions, LLC v. Timex Corp.*, 566 F.3d 1075, 1091 (Fed. Cir. 2009); *Hewlett–Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990).

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