Patent Prosecution Update

November 2016

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A Privileged Place for Patent Agents

by Jeffrey M. Jacobstein

Should client communications with U.S. patent agents have the same protection against discovery afforded to communications with attorneys? That was the question recently addressed by the Federal Circuit on a writ of mandamus from the Eastern District of Texas. *In re Queen's Univ. at Kingston*, No. 2015-145 (Fed. Cir. Mar. 7, 2016). Pointing to the inconsistent treatment of patent agent communications in prior district court cases, and the legal nature of a patent agent's work, the Federal Circuit held that communications with patent agents were indeed privileged, but only in the limited context of "obtaining legal advice on patentability and legal services in preparing a patent application." *Id*. at 18.

Background

Queen's University at Kingston (Queen's) and its innovation arm PARTEQ own three patents directed to "Attentive User Interfaces" for monitoring when to turn off display screens based on eye movement. *Id*. at 2. Queen's filed suit in the Eastern District of Texas in 2014, alleging that Samsung infringed the patents in several of their mobile devices. *Id*.

During discovery, Samsung sought to obtain correspondence between Queen's and their patent agents discussing prosecution strategy for the patents-in-suit, contending that U.S. law did not afford a privilege for patent agents. *Id*. at 3. Queen's acknowledged that a patent attorney was not involved in the communications sought by Samsung, but argued that a similar privilege should extend to patent agents. *Id*. The district court disagreed and issued a motion to compel disclosure. *Id*. Queen's subsequently sought and obtained a stay of the district court proceeding pending a petition to the Federal Circuit for a writ of mandamus to address the issue. *Id*.

Federal Circuit Decision

In a split panel decision, the majority granted the writ of mandamus and then extended a limited prosecution privilege to patent agents. The majority emphasized that Rule 501 of the Federal Rules of Evidence authorized federal courts to define privilege under the common law unless barred by the Constitution, a federal statute, or rules prescribed by the Supreme Court. *Id*. at 11. At the same time, the court acknowledged a general presumption against recognizing new privileges because "the public … has a right to every man's evidence." *Id*. at 11-12 (internal citations omitted). For instance, the court noted the refusal to extend privilege to "non-attorney client advocates, such as accountants." *Id*. at 12, *citing Couch v. United States*, 409 U.S. 322, 335 (1973); *see also United States v. Arthur Young & Co*., 465 U.S. 805, 817 (1984).

Despite these reservations, however, the court concluded that a patent agent privilege should exist, relying heavily on the Supreme Court's decision in *Sperry v. State of Florida ex rel. Florida Bar*, 373 U.S. 379 (1963). In *Sperry*, the Supreme Court held that Florida could not regulate the practice of patent agents because (1) those agents practiced patent law, (2) Congress authorized patent agents to practice that law, and (3) Congress delegated the authority to regulate patent agents to the U.S. Patent and Trademark Office. *Id*. at 13-15. Based on *Sperry*'s guidance, the Federal Circuit majority concluded that "[t]o the extent Congress has authorized non-attorney patent agents to engage in the practice of law before the Patent Office, reason and experience compel us to recognize a patent-agent privilege that is coextensive with the rights granted to patent agents by Congress." *Id*. at 18.

In support of their newfound privilege, the majority emphasized that a client has "a reasonable expectation that all communications relating to obtaining legal advice on patentability and legal services in preparing a patent application will be kept privileged." *Id*. at 18-19 (internal citations omitted). And since patent agents practice law, according to *Sperry*, the expectation reasonably extends to them as well. *Id*. The court also highlighted public policy considerations, analogizing the patent agent privilege to attorney-client and spousal privileges, which are similarly "rooted in the imperative need for confidence and trust," in this case, the trust that patent legal advice will be privileged. *Id*. at 22. In contrast, denying a patent agent privilege would "undermin[e] the real choice Congress and the Commissioner have concluded clients should have between hiring patent attorneys and hiring non-attorney patent agents." *Id*. Indeed, in a footnote, the Federal Circuit highlighted how clients had been copying patent attorneys on all correspondence with patent agents because of the uncertainty regarding agent privilege, which "is unsuitable for a system designed to give a real choice between selecting a non-attorney patent agent and a patent attorney," and indeed, "prejudices most of those independent inventors who may not have the resources to hire a patent attorney to maintain the privilege." *Id*. at 22, n.7.

Turning to the dissent's points that (1) a privilege is not needed and (2) the Federal Circuit is not the proper venue to create a new privilege, the majority rebutted both arguments. First, the majority pointed to *Sperry*'s explanation that patent agents practice law as evidence of the need for a corresponding privilege. *Id*. at 25. Second, the majority noted that Congress granted federal courts authority to "prescribe rules to govern the practice and procedure in civil actions at law," and under Rule 501 of the Federal Rules of Evidence, the court was merely exercising its authority to recognize a patent agent privilege. *Id*. at 26.

While the majority concluded that a patent agent privilege did exist, it took steps to clarify the narrow boundaries of the privilege. Only those communications "which are reasonably necessary and incident to the preparation and prosecution of patent applications or other proceeding before the Office involving a patent application or patent in which the practitioner is authorized to participate receive the benefit of the patent-agent privilege." *Id*. at 25 (internal citations omitted). Indeed, the court cautioned that "communications with a patent agent who is offering an opinion on the validity of another party's patent in contemplation of litigation or for the sale or purchase of a patent, or on infringement, are not reasonably necessary" (*id*.) and "likely would constitute the unauthorized practice of law." *Id*. at 25, n.8.

Thus, while the decision in *Queen's University* addressed some of the ambiguity surrounding the existence of a U.S. patent agent privilege, caution should still be taken to ensure that agent communications remain within the boundaries defined by the court.

Foreign Patent Attorneys and Agents

A related question that *Queen's University* did not address is the scope of privilege afforded by U.S. courts to correspondence involving foreign patent attorneys and foreign patents. While there has not been a recent Federal Circuit decision on that point, a review of the available district court decisions suggests that U.S. courts will generally afford privilege to foreign patent attorneys and patent agents under U.S. rules where they are assisting in U.S. patent matters, but only to the extent a foreign country's law provides for privilege where the correspondence at issue involves foreign patent matters.

For instance, the District Court for the Southern District of New York held in *Astra Aktiebolag v. Andrx Pharmaceuticals, Inc.*, 208 F.R.D. 92 (S.D.N.Y. 2002) that communications touching on U.S. patent issues were controlled by U.S. privilege law, while communications *solely or predominantly* involving a foreign patent were governed by that country's rules. Where foreign law governs, courts generally assess whether the foreign nation extends privilege to a particular person (for example, a patent agent or a barrister) and whether that person was acting in their privileged capacity with respect to the document or communication being sought in discovery. *2M Asset Mgmt., LLC v. Netmass, Inc.*, 2007 WL 666987 (E.D. Tex. Feb. 28, 2007).

Of note, while most countries in Europe afford at least some type of privilege, until recently the European Patent Office (EPO) did not expressly offer privilege for registered European Patent Attorneys. Recent changes to the European Patent Convention have added a privilege against disclosure for European Patent Attorneys acting in their representative capacity "in proceedings before the European Patent Office." European Patent Convention, Rule 153. While this rule would likely prevent a U.S. court from ordering disclosure of European patent-related correspondence with a European Patent Attorney, it is possible that the court might not extend the privilege to correspondence addressing questions of infringement or litigation in European national courts, where the EPO lacks regulatory authority.

Thus, when preparing communications with U.S. or foreign agents involving U.S. prosecution or litigation, it is still probably best practice to include U.S. attorneys on the correspondence. Likewise, if the communication relates to foreign prosecution or litigation matters, it may be beneficial to check which types of attorneys or agents are afforded privilege in that foreign country and to include them on the correspondence.

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FairWarning or Fair Weather for Patentees?

by Elliot C. Cook

Following Alice Corp. v. CLS Bank International, 134 S. Ct. 2347 (2014), accused infringers have favored the tactic of filing an early motion to dismiss. The perceived effectiveness of these motions, coupled with their potential to nip a litigation in the bud, propelled their use. This trend met resistance in BASCOM Global Internet Services, Inc. v. AT&T Mobility LLC, 827 F.3d 1341 (Fed. Cir. 2016) and McRO, Inc. v. Bandai Namco Games America, Inc., No. 2015-1080 (Fed. Cir. Sept. 13, 2016), where claims survived early dispositive motions. But in the recent case FairWarning IP, LLC v. Iatric Systems, Inc., No. 2015-1985 (Fed. Cir. Oct. 11, 2016), the Federal Circuit affirmed the early invalidation of claims under Alice. This further refinement of patent-eligibility jurisprudence is important for all patent attorneys, both prosecutors and litigators.

FairWarning IP, LLC's (FairWarning) patent relates to ways of detecting fraud and misuse by identifying suspicious patterns in the accessing of sensitive data, such as protected health information (PHI). Claim 1 of the patent recites a method for generating rule data, recording PHI data, analyzing PHI data in view of a rule, and providing a notification if the analysis identifies potential misuse. The patent's specification acknowledges that prior art systems recorded audit log data regarding access to PHI.

FairWarning sued Iatric Systems, Inc. (Iatric) in U.S. District Court for the Middle District of Florida, alleging infringement of FairWarning's patent. Iatric responded with a motion to dismiss under Fed. R. Civ. P. 12(b)(6), arguing that the patent is invalid under 35 U.S.C. § 101. The district court granted the motion based on *Alice*'s two-step test for patent-eligibility. According to the district court, the claims were directed to the abstract idea of "analyzing records of human activity to detect suspicious behavior" and did not recite additional subject matter that could transform the abstract idea into a patent-eligible concept. The district court thus dismissed the case.

On appeal, the Federal Circuit likewise applied the *Alice* two-step test. Under the first step, the Federal Circuit agreed with the district court's articulation of the abstract idea embodied by the claims. The Federal Circuit's analysis was guided by the patent's specification, which included a similar description of the field of invention. The Federal Circuit explained that its prior cases found "collecting information" and "analyzing information by steps people go through in their minds, or by mathematical algorithms," to represent abstract ideas. *FairWarning,* slip op. at 6. Consistent with those prior cases, the Federal Circuit found that the recited process for generating rule data, recording PHI data, analyzing PHI data in view of a rule, and providing a notification if the analysis identifies potential misuse was an abstract idea. Further, unlike in *McRO*, where claims for using automated rules that allowed computers to generate accurate and realistic lip synchronization and facial expressions were found not to be abstract, here FairWarning's

claims "merely implement an old practice in a new environment." *Id*. at 7. Further, "[a]lthough FairWarning's claims require the use of a computer, it is this incorporation of a computer, *not* the claimed rule, that purportedly 'improve[s] [the] existing technological process' by allowing the automation of further tasks." *Id*. at 8 (emphasis in original).

The Federal Circuit next addressed step two of *Alice*, concluding that the claims contained nothing sufficient to transform the claimed subject matter into a patent-eligible invention. Although the Federal Circuit's abstract idea analysis was focused on independent claim 1 of the patent, it addressed FairWarning's arguments regarding other claims under step-two of *Alice*. Nevertheless, the Federal Circuit found that none of these additional claims—including several "system" claims—satisfied step-two of *Alice*. In particular, the claims recited limitations "analogous" to those found in independent claim 1, and added only "basic computer hardware," such as "non-transitory computer-readable" media. *Id*. Because "FairWarning's system claims merely graft generic computer components onto otherwise-ineligible method claims," they do not transform the claimed abstract idea into something patent-eligible. *Id*. at 11. Further, the Federal Circuit rejected FairWarning's argument that the claims solved "technical problems unique to the computer environment." *Id*. According to the Federal Circuit, even if the claims involved a combination of "data sources," that would be insufficient to demonstrate a solution to a problem "specifically arising in the realm of computer" technology, as was the case in *DDR Holdings., LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014). *Id*. at 12.

Lastly, FairWarning challenged the early nature of the district court's dismissal, arguing that the court improperly engaged in fact-finding beyond the pleadings, and did so adversely to FairWarning. The Federal Circuit disagreed, concluding that the district court properly characterized the abstract idea, even after viewing the facts in FairWarning's favor. Further, the Federal Circuit rejected FairWarning's argument that the district court improperly found the claims to "preempt the field of HIPAA regulation compliance." *Id*. at 14. The Federal Circuit explained that, even if the claims did not cause such preemption, the lack of preemption does not save the claims.

FairWarning contains several important teachings for patent prosecutors. In addition to providing yet another example of claim language that prosecutors can compare to language they are drafting themselves, *FairWarning* highlights risks that a patent's specification may pose in a patent-eligibility analysis. In *FairWarning*, the patent specification's description of the field of invention was used to help formulate the abstract idea embodied by the claims. Further, the specification's acknowledgement that preexisting technologies accomplished a similar task helped establish that the claims did not represent anything substantially more than the abstract idea. Accordingly, practitioners should be mindful when drafting specifications and attempt to avoid providing a roadmap for a future patent-eligibility challenge.

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IP5 Offices

Kind Codes

by Arpita Bhattacharyya, Ph.D.

In this edition, we have compiled the Kind Codes that categorize patent documents in the IP5 offices. Because patent documents in many intellectual property offices retain the same identifying number throughout the patenting process, the documents are given a letter, known as a Kind Code, immediately after the identifying number to indicate where the document is in the patenting process. The Kind Code helps to distinguish the kind of patent document (e.g., issued patent, patent application publication, plant patent, design patent, utility model), the level of publication (e.g., first publication, republication, corrected publication), and whether a patent has undergone post-issuance review (e.g., reexamination, opposition). A common thread among the Kind Codes of most of the IP5 offices is that the letter “A” generally represents a published patent application and the letter “B” generally represents a granted patent, with small variations among the different offices.

United States

Summary of USPTO Kind Codes Used on Documents Published Beginning January 2, 2001	
Kind Code	**Kind of Document**
A1	Patent application publication
A2	Patent application republication
A9	Corrected patent application publication
B1	Patent (no pre-grant publication)
B2	Patent (having pre-grant publication)
C1, C2, C3	Reexamination certificate
E	Reissue patent
H	Statutory Invention Registration (SIR)
P1	Plant patent application publication
P2	Plant patent (no pre-grant publication)
P3	Plant patent (having pre-grant publication)
P4	Plant patent application republication
P9	Corrected plant patent application publication
S	Design patent

Because of the new post-grant proceedings introduced in the USPTO following the America Invents Act

(AIA) of 2011, new Kind Codes were added to designate patents that have undergone a post-grant proceeding.

Summary of USPTO Kind Codes Added After AIA	
Kind Code	**Kind of Document**
F1, F2, F3	Supplemental Examination Certificate
J1, J2, J3	Post Grant Review Certificate
K1, K2, K3	Inter Partes Review Certificate
O1, O2, O3	Derivation Certificate

Europe

The EPO follows the standard of document Kind Codes set by the World Intellectual Property Organization (WIPO):

Summary of EPO Kind Codes Used on Documents Published 18 Months After Filing With The EPO or 18 Months After The Priority Date	
Kind Code	**Kind of Document**
A1	European patent application published with European search report
A2	European patent application published without European search report (search report not available at publication date)
A3	Separate publication of European search report
A4	Supplementary search report
A8	Corrected title page of A document, i.e., A1 or A2 document
A9	Complete reprint of A document, i.e., A1, A2, or A3 document.

Summary of EPO Kind Codes Used on European Patent Specifications	
Kind Code	**Kind of Document**
B1	European patent specification (granted patent)
B2	New European patent specification (amended specification after opposition procedure)
B3	European patent specification (after limitation procedure)
B8	Corrected title page of B document (i.e., B1 or B2 document)
B9	Complete reprint of B document (i.e., B1 or B2 document)

Japan

The JPO used to have a more complicated Kind Code system, but it has been simplified to a large extent to follow the WIPO standards, as shown in the table below.

Summary of Kind Codes of Industrial Property Documents Stored at JPO	
Kind Code	**Kind of Document**
A	Unexamined patent publication (including those based on international applications)
B1	Examined patent publication (A-coded document has not been

	published)
B2	Examined patent publication (A-coded document has been published)
U	Unexamined utility model publication (including those based on international applications)
Y1	Examined utility model publication (U-coded document has not been published)
Y2	Examined utility model publication (U-coded document has been published)
A1	Domestic re-publication of PCT international application
H	Corrected patent specification
I	Corrected registered utility model specification
S	Registered design publication

China

SIPO simplified its Kind Codes in April 2010 to generally follow the WIPO standard. The current SIPO Kind Codes are listed below:

Summary of Kind Codes of Kind Codes Currently Used by SIPO	
Kind Code	**Kind of Document**
A	Publication of patent application
B	Granted patent publication
U	Registered utility model publication
S	Registered design publication

Korea

The KIPO Kind Codes are an amalgam of the JPO and SIPO Kind Codes, as shown in the table below.

Summary of Kind Codes Currently Used by KIPO	
Kind Code	**Kind of Document**
A	Unexamined patent publication
B1	Examined patent publication (A-coded document has not been published)
B2	Examined patent publication (A-coded document has been published)
U	Unexamined utility model publication
Y1	Examined utility model publication (U-coded document has not been published)
Y2	Examined utility model publication (U-coded document has been published)
S	Examined design publication

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Design Patents

Sneakers and Fancy Dresses Provide Guidance on Written Description Requirements for Design Patents

by Elizabeth D. Ferrill

In last month's column, we looked at recent design IPR decisions that focused on anticipation and obviousness arguments. In this column, we will consider recent cases that touch on the application of 35 U.S.C. § 112 to design patents.

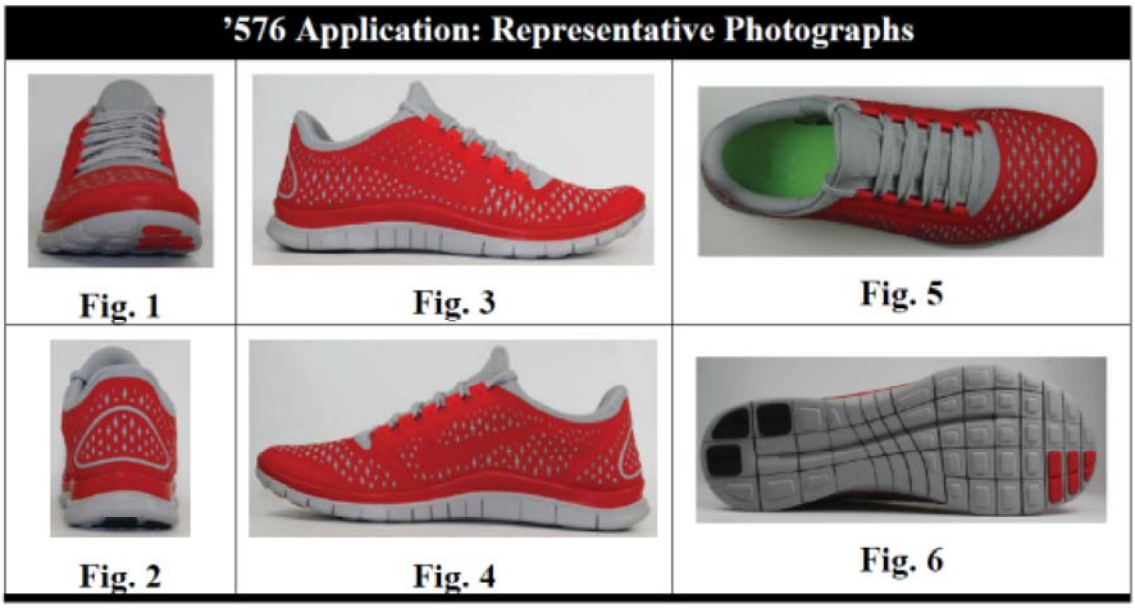
In February 2014, and again in April 2016, the United States Patent and Trademark Office (USPTO) issued proposed guidelines for the application of § 112 to design patents. In the later set of guidelines, the USPTO asked for examples to illustrate proposed approaches to application of the proposed guidelines. Each time, the design patent bar provided comments to the USPTO. In some comments, the bar noted that the law regarding written description had not changed and thus there was no need for new guidelines. Moreover, in the bar's view, any examples should come from litigation or appeals to the Patent Trial and Appeal Board (PTAB), rather than hypothetical ones.

While we are not aware of recent ex parte appeals to the PTAB or the Federal Circuit that might include such examples, some recent post-grant cases at the PTAB that could provide some insight on this issue.

Section 112 is typically considered in a number of contexts for design patents. Two are relevant here. First, when an applicant files an application that claims priority to a prior application, the examiner may reject the claim of priority on the grounds that differences or changes in the later application are not supported by the former application. Second, during prosecution, when an applicant attempts to amend the application, the examiner may reject the change as being directed to "new matter"—meaning not being supported by the original disclosure. The two post-grant matters discussed below illustrate these situations.

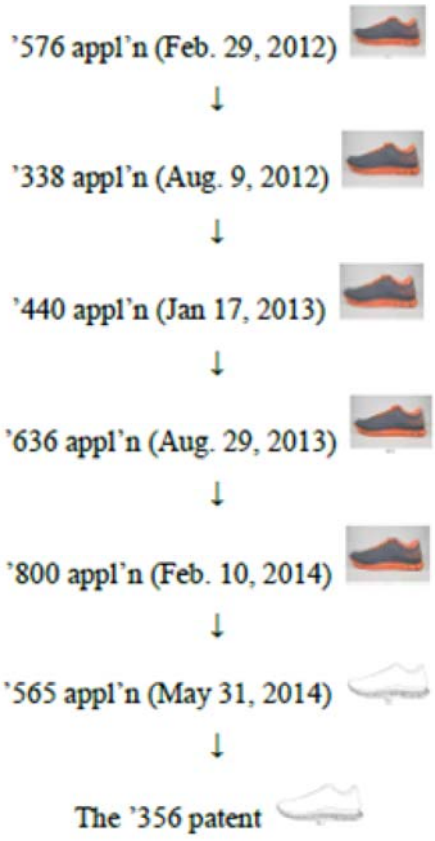
Skechers USA, Inc. v. Nike, Inc., IPR2016-00870

Skechers filed a series of petitions against Nike involving design patents directed to athletic shoes. In IPR2016-00870, like the other petitions, Nike had filed a series of design patent applications claiming priority to single application, in this case, Application No. 29/414,576:

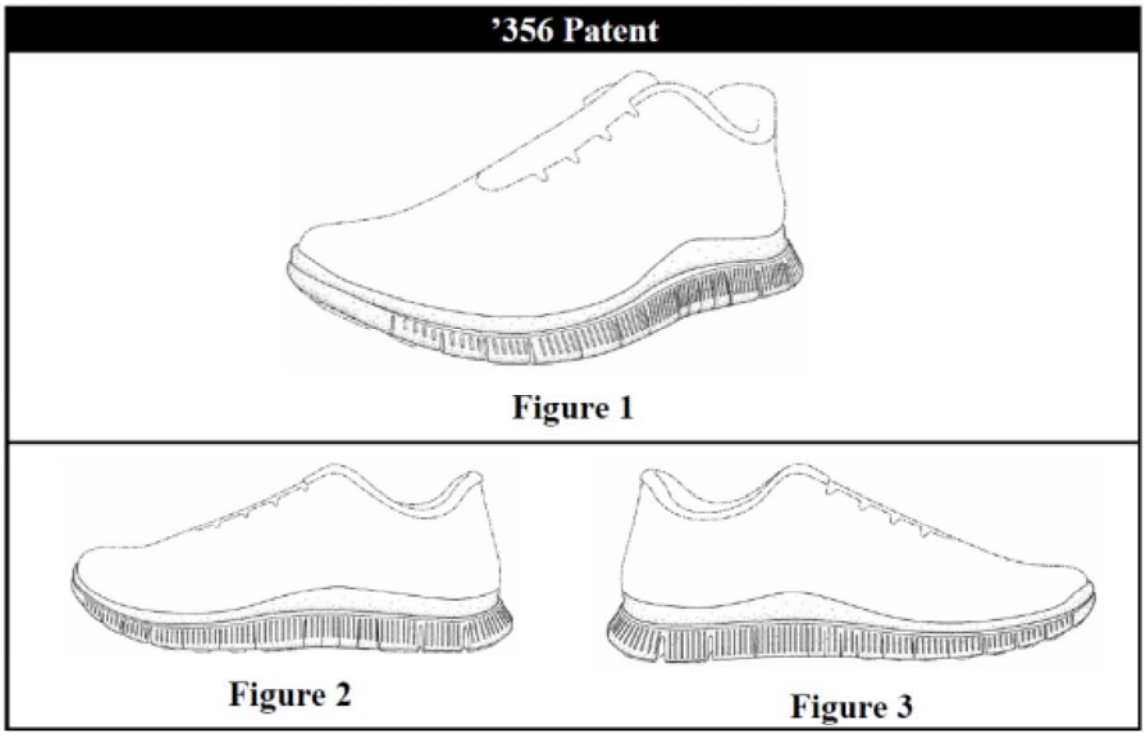


Figs 1-6 (of 69 total color images in '576 application)

Over the next couple of years, Nike filed a series of continuation applications claiming priority to the '576 application, culminating with the D725,356 patent, the subject of this IPR.



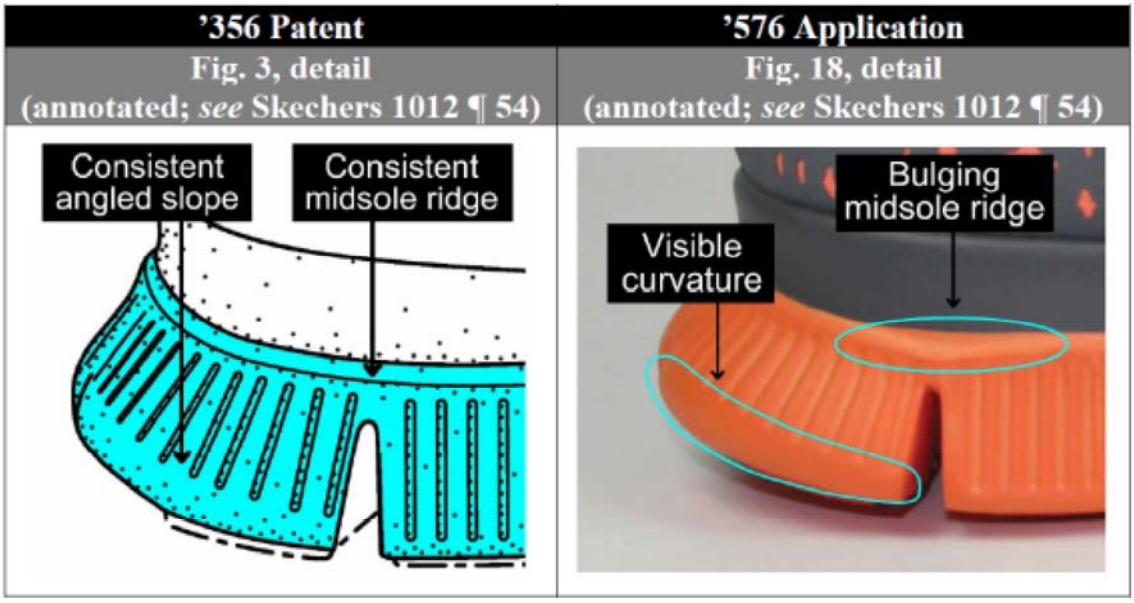
Unlike the original '576 application, the '356 patent did not claim priority to the entire shoe design, but rather only to the bottom sides and sole of the shoe.



Figs 1-3, '356 patent

Petitioner Skechers charged that this claim of priority did not meet § 112, because it disclosed seven features not present in the priority application. As such, according to Skechers, the '356 patent should only be entitled to its actual filing date, not the filing date of the '576 application. As a result, in Skechers' view, the '356 patent was not valid because it was anticipated by Nike's own European filing directed to this same design registered two years prior to the filing of the '356 patent.

To support its point, Skechers engaged in a detailed comparison of the disclosure in the '356 patent and the '576 application, often relying on enlarged views of the two disclosures with extensive annotations:



In its preliminary response, patent owner Nike first challenged Skechers' backdoor attempt to challenge § 112 and priority in an IPR. Nike noted that during prosecution it asked for, and received, a determination from the examiner confirming its claim of priority back to the '576 application, and urged the PTO not to revisit this issue. Nike also noted that the examiner was aware of the contemporaneous Nike European registration. On the merits, Nike asserted that Skechers had not considered the two disclosures "as a whole" but rather that Skechers had "selectively reli[ed] on inaccurate and misleading illustrations" and engaged in improper "microanalysis."[1] On the contrary, Nike urged the Board to recognize that the design of the '356 patent was disclosed in the '576 application and that the portions of the '356 patent were not arbitrary, but rather had basis in the parent application. In arguing it case, Nike relied on Federal Circuit case law, including *Racing Strollers, Inc. v. TRI Industries, Inc.,* 878 F.2d 1418 (Fed. Cir. 1989) and *In re Daniels,* 144 F.3d. 1452 (Fed. Cir. 1998), Board decisions, and the PTO's written description guidelines released in April 2016, discussed above.

The Board denied institution.[2] In its decision, the Board initially noted that the examiner considered Nike's priority claim and "had an evidentiary and factual basis" for his determination regarding the priority claim. Moreover, the Board was not "persuaded by Skechers' comparative micro-analysis of the drawings in the '356 patent and the photographs of the '576 application, e.g., comparisons detailing minor drawing inconsistencies, slight shading variations, and use of broken lines to indicate unclaimed subject matter, that 'Nike has claimed an entirely new design in the '356 Patent[.]'"[3] By using enlarged images of parts of the design, the Board found Skechers' comparisons to be "excessively critical micro-analysis that any observer, when comparing the photograph to the respective line drawing, would be hard-pressed to discern."[4] Moreover, citing to *In re Daniels*, the Board found the drawings in a continuation need not be "*exactly* the same as the photographs of the parent."[5] and where, as here, the drawings are sufficiently consistent with the photographs, the Board determined that the inventor had possession of the claimed design in the '356 patent at the time of the filing of the parent application.[6]

Finally, the Board also distinguished the present case from the Board's Decision in *Munchkin, Inc. v. Luv N' Care Ltd.*,[7] in which the Board found that the parent utility patent did not support the priority claim to the later-filed design patent. First, the Board noted that, in *Munchkin*, a side-by-side comparison was made "without any embellishment or magnification of the drawings" and that based on that comparison, the Board found that two key features of the spout design in the originally-filed drawings were substantially different in relative size, shape, and structure from the claimed design.

David's Bridal, Inc. v. Jenny Yoo Collections, Inc., PGR2016-00041

Filed on September 8, 2016, the petitioner, David's Bridal, argues that the '723 patent is invalid as indefinite under § 112, as well as anticipated under § 102 and obvious under § 103.[8] The '723 patent was filed as a divisional application to a prior application, which included disclosure directed to both a long and short version of a dress.[9]

In the prior application, the examiner issued a restriction requirement between two embodiments, noting that the long version of the dress appeared to be missing sufficient views and was thus "nonenabling."[10] The applicant elected to proceed with the short version of the dress and later filed a divisional application (which issues as the '723 patent) directed to the long version. When the applicant filed the divisional application, the applicant added three figures:

Figures Added to D744723

David's Bridal contends that these three figures were new matter, and thus the '723 patent should not be afforded the earlier priority date of the parent application. As a result, David's Bridal argues that the '723 patent is eligible for PGR review and further, is invalid in view of the patent owner's own intervening public disclosure of the long dress design.

A Preliminary Patent Owner Response is due by early December and the Board should issue its Institution Decision in March 2017. It will be interesting to see how the Board treats the issue of eligibility for PGR review and the introduction of additional figures.

Lessons Learned

As with previous post-grant cases, these cases have or will provide helpful insights for prosecution of design patents in the future. As with the *Munchkin* IPR, these cases will serve as examples of the application of § 112 to design patents. In addition, the Board seems to have credited the examiner's determination during prosecution that Nike's child application should be afforded the priority date of the parent, suggesting that this may be a helpful strategy. Likewise, the David's Bridal case will offer important insight into the effect on a priority claim by adding figures to the later-filed application. Those engaged in design patent prosecution will likely find following the PTAB post-grant design cases helpful.

[1] Nike Preliminary Patent Owner Response, IPR2016-00870, Paper 7 at 3.

[2] Institution Decision, IPR2016-00870, Paper 6 at 3.

[3] *Id.* at 9.

[4] *Id.* at 14.

[5] *Id.* at 20 (emphasis in original).

[6] *Id.* at 21.

[7] IPR2013-00072 (PTAB April 21, 2014).

[8] David's Bridal, Inc. v. Jenny Yoo Collections, Inc., PGR2016-00041, filed Sept. 8, 2016.

[9] The '723 patent claims priority to an application that was filed before the AIA was enacted. Thus, this application would not appear to qualify for PGR review. However, the petitioner argues that this priority claim is not valid, and thus the '723 patent should be treated as being filed on August 10, 2013, and thus qualified for PGR review.

[10] PGR2016-00041, Paper 1 at 7.

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Rule Review

Don't Delay: PTO Wins Patent Term Adjustment Dispute

by Christopher B. McKinley

Patent examination at the United States Patent and Trademark Office (USPTO) can be a lengthy affair. Aware of the backlog, the USPTO currently offers several options for jumping the queue and getting applications examined out of turn. These include Accelerated Examination (AE), Track One Prioritized Examination (Track One), Petition to Make Special, and the First Action Interview Pilot Program (which allows an applicant to request an early interview prior to a first office action, increasing the likelihood that the examiner will subsequently pick the case up for examination sooner than scheduled). Not all the programs are equally well-used by applicants. Currently, the most popular option is Track One, where an applicant can request examination out of turn under certain conditions by paying a fee. The program does not require the applicant to provide a search report or other examination document. AE, in contrast, adds a requirement to conduct a pre-examination search and submit an accelerated examination support document. Understandably, these added steps limit the program's popularity.

On August 16, 2016, the USPTO published several changes to the AE program in an effort to harmonize it with recent treaties and other law changes enacted since the program began in 2006. *Changes in Accelerated Examination Practice*, 81 Fed. Reg. 54,564 (Aug. 16, 2016). Hidden in the technical changes to the rules was a brief remark suggesting that the USPTO is considering ultimately terminating the program:

> Subsequent to the implementation of the AE program in 2006, the Office implemented the prioritized examination program (referred to as ''Track I'') provided for in the AIA in a final rule published on September 23, 2011. . . Since implementation of Track I in 2011, the USPTO has received fewer than 200 AE requests annually. In view of the relatively low usage of the AE program, the USPTO plans to publish a request for comments in the Federal Register to seek public input on whether there is value in retaining the AE program in view of the more popular Track I program.

Id. at 54,565. Thus, while the USPTO has attempted to modernize AE, its days may also be numbered.

Technical Changes to the AE Program

As the USPTO acknowledged in the Federal Register notice, after implementing the AE program in 2006, "the patent landscape has witnessed numerous legal changes such as the America Invents Act (AIA), the

Patent Law Treaties Implementation Act (PLTIA) implementing the provisions of the Patent Law Treaty (PLT), and the USPTO's adoption of the Cooperative Patent Classification system (CPC) along with changes to USPTO systems." *Id*. at 54,564. Those changes, inter alia, redefined the scope of available prior art, required the USPTO to afford applicants at least two months to respond to USPTO communications, and changed the USPTO's patent classification scheme to harmonize it with the system used in Europe. To bring the AE program into conformity with these new laws, the USPTO made the following changes:

- Require applicants to conduct a pre-examination classification search based on the common classification system (CPC) rather than the United States Patent Classification system (USPC);
- Instruct applicants to identify in their accelerated examination support document whether an application is a pre-AIA or post-AIA application, and then provide appropriate indications of whether pre-AIA 35 U.S.C. § 103(c) (disqualifying prior art under the CREATE ACT) or post-AIA 35 U.S.C. § 103(b)(2)(C) (expanding the scope of disqualified art) applied to any references identified in the pre-examination search;
- Provide applicants with at least two months to respond to office actions, rather than the one month or thirty days previously afforded by the AE program;
- Amend the rule barring petitions, particularly petitions to designate a person with sufficient proprietary interest as the applicant or to accept a delayed priority claim;
- Amend the rule on priority claims to refer to an application data sheet rather than the first sentence of the specification;
- Require the filing of AE requests only through the USPTO's EFS-Web electronic filing system; and
- Explain that while an oath/declaration is no longer required on filing an application after the AIA, it is a requirement under 37 C.F.R. § 1.51 and thus must be present upon filing for entry in the AE program.

Id. at 54,565-66.

Comparison of AE to Track One

Unlike the AE program, Track One does not require a pre-examination search or an accelerated examination support document. Rather, an applicant need only pay a fee and have (or amend) its application to present a maximum of four independent claims, thirty total claims, and no multiple dependent claims. 37 C.F.R. § 1.102(e). As with AE, Track One permits an applicant to take extensions of time, but doing so will result in expulsion from the program. Both programs have an average first action pendency of about four to five months, as compared to eighteen months for a standard application.

As Track One does not force an applicant to conduct a pre-examination search and put on record its analysis of the identified art, it has generally been more popular (despite having a substantially higher fee for entrance into the program). The USPTO stated in the recent AE Federal Register notice that it receives an average of fewer than 200 AE requests *annually*. 81 Fed. Reg. at 54,565. In contrast, the USPTO's most recent statistics show it received between 700-1200 Track One requests *per month* for the twelve months to July 2016. USPTO Data Visualization Center, Patents Dashboard, http://www.uspto.gov/corda/dashboards/patents/main.dashxml?CTNAVID=1007 (last visited on Aug. 19, 2016). Given this significant disparity in usage, it is not surprising that the USPTO is considering whether to terminate the AE program.

Regardless, at present, both programs are available, and an applicant desiring to have a case considered out of turn should consider the benefits and drawbacks of each option. If cost is a concern, then AE may be a better option. But if an applicant is willing to pay for faster examination while seeking to minimize prosecution history, then Track One may be the preferred choice.

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EPO Practice

Infringement of Second Medical Use Claims in Europe

by Hazel Ford Ph.D.

It is possible to obtain a patent from the European Patent Office (EPO) based on a new medical use of a known drug. The claim can be directed to using the drug to treat a different disease, or using the drug in a new method of treatment, such as a new route of administration or a new dosage. The EPO has well-established requirements for the patentability of these so-called "second medical use" claims, but it does not consider issues of patent infringement. Infringement in Europe is currently assessed on a country-by-country basis by individual national courts.

Although these second medical use claims have been available in Europe since the 1980s, until recently it has been unclear how the manufacture and sale of a drug for a patented use can be distinguished in practice from the manufacture and sale of the same drug for a non-patented use. The English Court of Appeal has now clarified how infringement of such second medical use claims should be assessed in the United Kingdom[1].

The Pregabalin Case in the United Kingdom

As discussed in our earlier article,[2] Warner-Lambert has been involved in litigation across Europe relating to a second medical use patent granted by the EPO, directed to the use of pregabalin in the manufacture of a medicament for treating pain.

Pregabalin is approved for use in the United Kingdom in the treatment of general anxiety disorder (GAD), epilepsy, and neuropathic pain. Actavis was sued for infringement by Warner-Lambert after it applied for approval to sell pregabalin in the UK under a "skinny label" that referred only to the treatment of GAD and epilepsy, not covered by Warner-Lambert's patent. Warner-Lambert argued that the Actavis product would inevitably be used by physicians and prescribed by pharmacists for the treatment of pain, even though that treatment was not specifically mentioned on the product packaging.

The Court of Appeal concluded that Warner-Lambert's patent was invalid, and so there was no requirement to consider infringement. However, it took the opportunity to clarify the test that should be applied when considering infringement in this situation. The Court acknowledged that it is not straightforward to find a suitable balance between the needs of the parties: "The law is struggling on the one hand to give the patentee a proper reward for his contribution to the art by elucidating the new use for the drug, whilst at the same time not excluding the competing manufacturer from making and marketing the drug for its known purpose."

A key issue was whether a second medical use claim will only be infringed when it can be shown that the manufacturer specifically intends for its product to be used to treat the patented indication. The Court reviewed decisions from a number of other European courts that considered this issue, but found a variety of different approaches. In some cases, only the uses stated on the product packaging were taken into account, others looked at whether there was some element of encouragement by the manufacturer, and others considered whether steps had been taken by the manufacturer to prevent use for the patented indication.

The Court of Appeal concluded that one needs to consider what the manufacturer knows or can reasonably foresee as the consequences of its actions in order to determine whether the manufacturer intended its product for the patented use. It may be possible to find such an intention when the product is formulated specifically for the infringing use, or is indicated for that use in the packaging or labelling. However, the Court concluded that the absence of the patented use from the drug label cannot be enough to conclude that there was no intention to use the drug for the patented use. A negative intention can only be concluded where the manufacturer has taken all reasonable steps within its power to prevent the patented use from occurring.

The Court concluded that the question to be considered was whether Actavis knew, or could foresee, that at least some of the prescriptions written generically for pregabalin to treat pain would be fulfilled with its drug. The Court recognised an obligation on a manufacturer to take active steps if it is to enter a market where it stands to benefit from the patentee's patented invention. In order to avoid infringement, the manufacturer must show that it has taken all reasonable steps in its power to prevent its drug from being used in accordance with the patent.

What Must Be Done To Avoid Infringing Uses?

The approach proposed by the UK Court is consistent with the findings in related French proceedings,[3] which assessed what another manufacturer, Sandoz, had done to prevent use of its pregabalin product for the patented indication in France. Sandoz had sent an information email to doctors and pharmacists prior to launch, stating that its product was not indicated for neuropathic pain. Sandoz had also agreed to send more explicit messages to physicians and pharmacists to describe how to prescribe or dispense its drug, in order to avoid infringement. Although Sandoz had a larger share of the market than was represented by non-pain use, the French court concluded that Sandoz had done enough to avoid direct infringement of Warner-Lambert's patent.

It is not clear from the UK decision what steps a manufacturer might need to take in the UK to establish that it did not intend for its product to be used for a patented indication. There is clearly a burden on the manufacturer to try to limit the use of its product to the non-patented uses. However, the Court's test does suggest that factors that are outside the control of the manufacturer, such as those based on the structure and processes of the healthcare system, will not be held against it.

In view of the flexibility that is afforded to individual doctors and pharmacists in the UK, it is unlikely that the efforts required by this test will be able to completely prevent the off-label use of generic products for patented uses. In some cases, patentees may need to consider taking further action themselves to enforce the prescription of only their approved drug for the patented use. For example, Pfizer has successfully obtained an injunction in the UK against NHS England (which oversees the operations of the English National Health Service), requiring them to instruct doctors to prescribe pregabalin only by the Pfizer brand name Lyrica when it is for use in treating pain[4].

Despite the inability to completely prevent physicians and pharmacists from prescribing a generic drug for a patented indication, it is clear from this decision that a second medical use patent can be valuable. It can impose a burden on other manufacturers to try to prevent their products being used in accordance with the patent. A patent filing strategy involving follow-up patent applications directed to specific uses of a drug can therefore limit, or at least disrupt, the market for third party products, even after the basic patent protection for the product itself has expired

[1] *Warner-Lambert Company LLC v Generics (UK) Ltd.* (t/a Mylan) & Ors [2016] EWCA Civ 1006 (13 October 2016)

[2] Infringement of Second Medical Use Claims in the United Kingdom - Full Disclosure Patent Newsletter, November 2015

[3] *Warner-Lambert Company & Pfizer v. Sandoz*, order of the presiding judge of the Tribunal de Grande Instance de Paris of 26 October 2015, Docket № 15/58725

[4] *Warner-Lambert Co. v. Actavis* Grp. Ptc EHF [2015] EWHC 485 (Pat).

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