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Patent Prosecution Update

November 2015

Drafters Beware: Does Your Specification Enable the Prior Art?

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Means-Plus-Function Claims and the Search for Adequate Structural Support

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Drafters Beware: Does Your Specification Enable the Prior Art?

by Elliot C. Cook

Shortly before Halloween, the Federal Circuit gave patent drafters a (modest) scare. At issue in *In re Morsa*, No. 2015-1107 (Fed. Cir. Oct. 19, 2015), was whether a prior art reference was enabled. The Federal Circuit agreed with the U.S. Patent and Trademark Office (USPTO) that it was enabled, but its reasoning was supported primarily by statements in the applicant's own specification. With Halloween now behind us, practitioners should bear the case in mind when drafting applications, but the case is not a horror story.

Morsa involved a patent application directed to managing "benefits," which were described in the specification as "things of value" given away to target entities. The claims at issue generally involved receiving a benefit information request from a user, searching a benefit information database for benefits matching the request, and returning benefit information to the user. The claims involved various computer components, such as a "physical memory device" and a "computer compatible network."

In an earlier appeal to the Federal Circuit, the applicant challenged the rejection of certain claims based on a prior art reference titled "Peter Martin Associates Press Release" or "PMA." Specifically, the applicant argued that its invention antedated PMA and that PMA was not enabled. The applicant also challenged PMA's teachings on the merits. Regarding enablement, the Federal Circuit found that, while prior art applied by the Patent Trial and Appeal Board (Board) is generally presumed to be enabled, an applicant may overcome that presumption such that the Board must present evidence of enablement. *In re Morsa*, 713 F.3d 104, 110 (Fed. Cir. 2013). Because in this case the applicant rebutted the presumption and the Board did not substantively respond, the Federal Circuit vacated and remanded with respect to the affected claims. *Id.* at 110-11.

On remand, the Board found that PMA was enabled. According to the Board, only "ordinary" computer programming skills were needed to make and use the claimed invention. The Board's conclusion was based principally on the applicant's specification, which described what knowledge of computer programming a person of ordinary skill would possess. According to the Board, the disclosure of PMA combined with that knowledge rendered PMA enabling with respect to the claims at issue.

The applicant once again appealed the Board's rejections. On appeal, the Federal Circuit affirmed, finding that PMA was properly deemed to be enabled by the Board. As the Federal Circuit noted, enablement generally requires that a "reference teach a skilled artisan—at the time of filing—to make or carry out what it discloses in relation to the claimed invention without undue experimentation." *Morsa*, No. 2015-1107, slip op. at 4. The court further commented that, "[f]or a prior-art reference to be enabling, it need not enable the claim in its entirety, but instead the reference need only enable a single embodiment of the claim." *Id.* In this case, the Federal Circuit agreed that the application at issue contained several admissions regarding what a person of ordinary skill in the art would have known, including that central processing units and memories were "well known" and could be used for processing requests for benefit information. Further, the specification admitted that its disclosure could be "implemented by any programmer of ordinary skill in the art using commercially available development tools." *Id.* (citation omitted). Primarily due to these admissions, the Federal Circuit agreed with the Board that PMA was enabling vis-à-vis the challenged claims, since only "ordinary" computer programming

skills were needed to bridge the gaps between the reference and the claims.

The applicant also argued on appeal that the USPTO improperly made new grounds of rejection. According to the applicant, the USPTO commented that “database-searching is old and well known and thus the focus on the present application is not on searching databases generally, but on the specific type of data used and the specific searches performed,” and these comments formed the basis for new grounds of rejection. *Id.* at 5. The Federal Circuit again disagreed, finding that the Board’s statements were “merely descriptive” and not part of the USPTO’s enablement analysis. *Id.* at 5-6.

The Federal Circuit also made short shrift of the applicant’s argument that PMA would have required “undue experimentation” to implement. As the Federal Circuit explained, the statements in the application itself demonstrated what knowledge a person of ordinary skill in the art would have possessed, and in view of that knowledge, “only ordinary experimentation would be needed to make the claimed program.” *Id.* at 6. The court further clarified that it was not using the specification’s statements as prior art, but was instead assessing the knowledge that a person of ordinary skill would possess based on those statements. According to the court, “[t]here is a crucial difference between using the patent’s specification for filling in gaps in the prior art, and using it to determine the knowledge of a person of ordinary skill in the art.” *Id.*

Judge Newman issued a dissent, criticizing the majority opinion for confusing issues of anticipation and obviousness, as well as the application of the enablement requirement. According to Judge Newman, there were undisputed “gaps” between the claim limitations and PMA, which could not be filled by the “knowledge” possessed by a person of ordinary skill or any official notice taken by the USPTO. She explained that enablement of a prior art reference must come from the reference itself, not from the applicant’s specification.

Morsa’s application of the enablement requirement for prior art warrants attention by practitioners. When drafting an application, practitioners inevitably make decisions about the level of detail to include. Judge Rich’s adage that “a patent need not teach, and preferably omits, what is well known in the art,” provides some guidance. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

Consistent with this principle, practitioners often omit features from patent applications that are deemed too commonplace or too granular when compared to the claimed invention. Thus, for a patent claim directed to mobile device software, the application need not describe the semiconductor composition of the microprocessor in the mobile device. *Morsa*, however, highlights one limitation to the practice of omitting well-known features in a patent application. In *Morsa*, an applicant’s own statements in its specification about computer programming being “well known” served as admissions that rendered a prior art reference enabling. Nevertheless, *Morsa* does not require practitioners to follow an extreme approach of either (1) including all imaginable detail in an application or (2) omitting all acknowledgements of basic prior art teachings. Adept practitioners should instead recognize that there is a tradeoff: applications need not be encyclopedias of the relevant field of invention, but any inventive concepts not described cannot be claimed. Practitioners should thus ensure that they fully understand and robustly describe an invention in an application. Only when this is done can practitioners also decide what material to omit from an application.

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Means-Plus-Function Claims and the Search for Adequate Structural Support

by Amanda L. Lutz

In *Media Rights Technologies, Inc. v. Capital One Financial Corp.*, No. 2014-1218 (Fed. Cir. Sept. 4, 2015), the Federal Circuit affirmed the district court's determination of invalidity for indefiniteness. It found the claims at issue to be means-plus-function claims, and lacking adequate support in the specification for the two disputed claim terms' recited functions. This case follows in the wake of *Williamson v. Citrix Online, LLC*, 792 F. 3d 1339 (Fed. Cir. 2015) (en banc), where the en banc Federal Circuit expressly overruled the "strong" presumption that limitations lacking the word "means" are not subject to 35 U.S.C. § 112, ¶ 6 (pre-AIA).

Media Rights filed suit against Capital One, alleging infringement of U.S. Patent No. 7,316,033 ("the '033 patent"), entitled "Method of Controlling Recording of Media." The '033 patent prevents unauthorized recording via a "compliance mechanism," which diverts incoming media content protected by law or agreement from being outputted by a system, in order to stop the illegal copying or sharing of that content.

All of the claims include the limitation "compliance mechanism," as shown by illustrative claim 1:

1. A method of preventing unauthorized recording of electronic media comprising:

activating a **compliance mechanism** in response to receiving media content by a client system, said **compliance mechanism** coupled to said client system, said client system having a media content presentation application operable thereon and coupled to said **compliance mechanism**;

controlling a data output path of said client system with said **compliance mechanism** by diverting a commonly used data pathway of said media player application to a controlled data pathway monitored by said **compliance mechanism**; and

directing said media content to a custom media device coupled to said **compliance mechanism** via said data output path, for selectively restricting output of said media content.

'033 patent col. 36 11. 19-34 (emphases added).

On the same day that Capital One filed its opening claim construction brief in district court, it also filed a motion for judgment on the pleadings for invalidity under 35 U.S.C. §§ 101 and 112(b). As the motion largely turned on claim construction of the '033 patent, the district court held a *Markman* hearing and heard argument on a Rule 12(c) motion that same day. It concluded that all of the claims of the '033 patent are invalid because they all contain the terms "compliance mechanism" and "custom media device," which were deemed indefinite.

On appeal, the Federal Circuit affirmed the invalidity of all the claims in the '033 patent for reciting

“compliance mechanism”—a means-plus-function term lacking an adequately disclosed structure to perform all of its function.

The parties as a threshold matter disputed whether “compliance mechanism” is a mean-plus-function term. Under 35 U.S.C. § 112, ¶ 6 (pre-AIA), means-plus-function claim limitations are permitted “as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof.” These types of claims are construed to only cover “the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof.” *Williamson*, 792 F. 3d at 1347.

While a claim that uses the word “means” “invokes a rebuttable presumption that § 112, ¶ 6 applies,” *Apex Inc. v. Raritan Comput., Inc.*, 325 F.3d 1364, 1371 (Fed. Cir. 2003) (citation omitted), the opposite is also true: there is a presumption that a claim lacking the term “means” is not a means-plus-function claim. A party can overcome the presumption against applying § 112, ¶ 6, by “demonstrat[ing] that the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’” *Williamson*, 792 F. 3d at 1349 (quoting *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000)). The Federal Circuit asks “if the claim language, read in light of the specification, recites sufficiently definite structure to avoid § 112, ¶ 6.” *Robert Bosch, LLC v. Snap-On Inc.*, 769 F.3d 1094, 1099 (Fed. Cir. 2014).

The '033 patent's term “compliance mechanism” does not contain the word “means,” and the parties agreed that the claims recited functions for the “compliance mechanism term.” The parties did not agree, however, whether the specification provided sufficient structure for performing the recited functions. Media Rights analogized the “compliance mechanism” term to “modernizing device” described in *Inventio AG v. Thyssenkrupp Elevator Americas Corp.*, 649 F.3d 1350 (Fed. Cir. 2011), *overruled by Williamson*, 792 F. 3d 1339. Unlike *Inventio*'s “modernizing device” term, the Federal Circuit found the '033 patent's “compliance mechanism” was not used as a substitute for anything that might connote a definite structure. In *Inventio*, the specification supported the use of a “modernizing device” as a substitute for an electrical circuit. The '033 patent's specification, however, does not disclose adequate structural support for the “compliance mechanism” term.

Further, the court noted that it has never found the term “mechanism,” without more, to connote an identifiable structure, and adding the modifier “compliance” to “mechanism” does not make an identifiable structure. See *Mass. Inst. of Tech. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006). *Inventio* also applied the prior law teaching that the absence of the term “means” gives rise to a strong presumption against finding a claim to be a means-plus-function format. That has now been overruled en banc.

After determining that the claims are means-plus-function claims, the court construed the claims. All the parties agreed that the term “compliance mechanism” performs four functions: (1) controlling data output by diverting a data pathway; (2) monitoring the controlled data pathway; (3) managing an output path by diverting a data pathway; and (4) stopping the play of media content. “Where there are multiple claimed functions, as there are in this case, the patentee must disclose adequate corresponding structure to perform *all* of the claimed functions.” *Media Rights*, No. 2014-1218, slip op. at 12. Failure to do so renders the claim term indefinite, according to the court. In addition, because the recited functions are computer-implemented functions, the disclosed structure must be an algorithm for performing the claimed function. A general purpose computer or microprocessor does not provide adequate structural support to the term.

The '033 patent specification failed to disclose an operative algorithm for two of the four claimed elements, i.e., for “controlling data output” and “managing output path” functions. Expert testimony showed the C++ source code that Media Rights claimed was the operative algorithm returned only error messages. Further, the specification did not disclose sufficient structure for the “monitoring” function. The set of rules in the specification that Media Rights relied upon provides no detail about the rules themselves or how the “copyright compliance mechanism” determines whether the rules are being enforced. Without further disclosure, the “monitoring” function lacks adequate structural support, and the

term “compliance mechanism” was held indefinite.

Media Rights joins *Williamson* as a cautionary tale of invalidity by indefiniteness. Claims with terms lacking specific structural support linked to the recited functions may be considered means-plus-function by the court. To avoid this result, patentees should specifically claim the structure and include sufficient support in the specification. *Media Rights* also reinforces the importance of drafting patent specifications as legal documents that provide adequate technical disclosure.

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IP5 Offices

Language and Translations

by Eric P. Raciti

In this edition, we consider the language and translation requirements of the IP5 offices¹. While it is not surprising that all of the IP5 offices require filings to be translated into certain languages, many filings outside a filer's home jurisdiction are accomplished using the Patent Cooperation Treaty (PCT) in the filer's home language. PCT Article 22 specifies that applicants "shall furnish" a copy of the application "and a translation thereof (as prescribed)," leaving the formalities of translation filing to the national or regional designated office.

This article will look at each of the IP5 countries' requirements for language and translations, and how these requirements might differ based on whether filing is via the national stage of the PCT or a direct national filing.

China

Rule 3 of the Implementing Regulations of the Patent Law of the People's Republic of China states that "any document submitted in accordance with the provisions of the Patent Law and these Implementing Regulations shall be in Chinese."

In addition, Rule 3 requires that "the standard scientific and technical terms shall be used if there is a prescribed one set forth by the State." Where there exists no generally accepted translation in Chinese for a foreign name or scientific or technical term, the term "shall also be indicated" in its original language. Therefore, applicants employing nonstandard terminology should be especially attentive to translations into Chinese to ensure accuracy.

The Revised Guidelines for Patent Examination, which entered into force on February 1, 2010, also provide that where any required "certificate or certifying document" is in a foreign language, the State Intellectual Property Office of the People's Republic of China (SIPO) may request a Chinese translation of the document into Chinese within a specified time period.

South Korea

Article 4 of the Patent Regulations as amended by Ordinance No. 215 of the Ministry of Commerce, Industry and Energy of December 31, 2003, states that, except for priority documents, all documents to be submitted to the Korean Intellectual Property Office (KIPO) shall be prepared in the Korean language.

United States

A detailed section of the Code of Federal Regulations, 37 CFR § 1.52, includes language, paper, writing, margins, and compact disc specifications. Subsection (b)(1)(ii) of that provision requires that the "application or proceeding and any amendments or corrections to the application" be "in the English language or be accompanied by a translation of the application and a translation of any corrections or amendments into the English language together with a statement that the translation is accurate." Most filers from outside of the United States are accustomed to the pervasive requirements for certificates or declarations attesting to the truthfulness of filings made in the U.S. Patent and Trademark Office (USPTO), and translations are no exception.

European Patent Office

The European Patent Convention (EPC) Article 14 specifies that the official languages of the European Patent Office (EPO) are English, French, and German. Subsection (2) states that a European patent application “shall be filed in one of the official languages or, if filed in any other language, translated into one of the official languages in accordance with the Implementing Regulations.” Under Rule 40(3) of the Implementing Regulations (June 2012), a two-month time period for filing a translation is provided.

Japan

The regulations under the Japanese Patent Act, including the amendments entered into force on April 1, 2012, specify at Chapter I, § 2, that all documents (except for the power of attorney) must be written in the Japanese language, unless otherwise stipulated by law. Subsection (2) stipulates that a power of attorney, a nationality certificate, or other documents written in a foreign language “shall be accompanied by the translation” when filed at the Japan Patent Office (JPO).

Time Periods for Filing Translations

As can be seen above, the EPO is the only authority among the IP5 that permits direct filing in any language. All other offices require filing in the official language. When entering the national stage from the PCT where the international application is not in the official language of the IP5 jurisdiction, time periods for filing the translation are as follows:

- Japan and China, which are 30-month PCT states, each provide a two-month extension for the filing of a translation. A surcharge is charged by SIPO, but there is no surcharge by the JPO.
- South Korea, which is a 31-month PCT state, requires a translation at the time of entering the national stage.
- The United States, which is a 30-month PCT state, provides for a seven-month extension of time in which to file a translation and complete a national stage entry under 35 § 371. An applicant is given two months from the date of the notification by the USPTO or 32 months from the priority date, whichever is later, to provide the translation, which may be extended for up to five additional months pursuant to the provisions of 37 C.F.R. § 1.136(a), for a surcharge.
- The EPO, which is a 31-month PCT office, provides a two-month extension for the filing of the translation, without surcharge.

Conclusion

While many aspects of patent law around the world enjoy increased harmonization, language and translation requirements at major patent offices still require practitioners to become versed in local regulations.

¹ The “IP5” are the patent offices of the five predominant intellectual property jurisdictions in the world, namely, the United States of America, the European Union, Japan, South Korea, and China.

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Design Patents

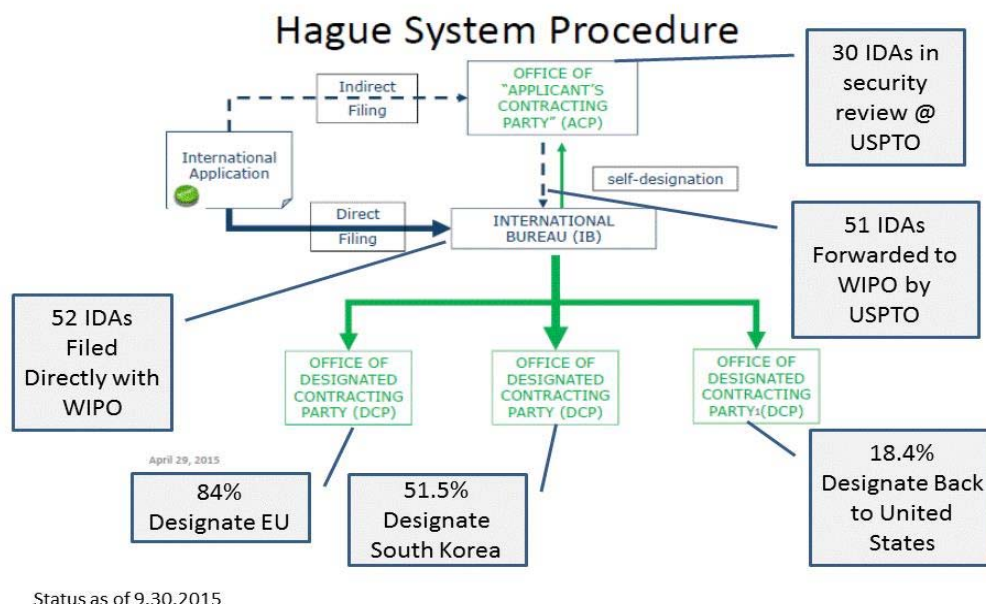
Understanding the Hague System—Six Months Later: How's It Going So Far?

by Elizabeth D. Ferrill

Back in [June](#), we wrote about the United States joining the Hague Agreement Concerning the International Registration of Industrial Designs. Since May 13, 2015, it has been possible for U.S. applicants to file an International Design Application (IDA), either directly with the World Intellectual Property Organization (WIPO) or through the U.S. Patent and Trademark Office (USPTO), as an office of indirect filing. It has also been possible for applicants from other Hague member countries and jurisdictions to file IDAs and designate the United States as a country to receive the IDA. We will now consider the early results of both of these types of transactions.

Hague Applications Filed by U.S. Applicants

From May 2015 through September 2015, WIPO reports that 103 IDA applications from the United States have been filed with WIPO. After a slow start in May, June through September averaged 25 applications per month.



- **Which Office Did U.S. Applicants Use to File?** WIPO reports that about half of the applications were filed directly with WIPO and the rest were filed with the USPTO as an office of indirect filing. The USPTO has been taking about 50 days to forward IDAs to WIPO, but WIPO expects this turnaround time to be shorter as the USPTO reviews more IDAs.¹ Also, another 30 applications had been filed at the USPTO, but not yet forwarded to WIPO, because those applications are still undergoing the mandatory security review.

- **How Do the U.S. Numbers Compare?** By comparison during this period, European Union applicants filed more than 540 IDAs, the most of any Hague jurisdiction.
- **How Many IDAs from U.S. Applicants Claim Priority to Another Application?** WIPO reports that 82.5% of the 103 applications from the U.S. claim priority to a U.S. design application. Thus, it seems that most U.S. applicants file first in the United States and then file a Hague IDA application as one part of their foreign filing strategy.
- **What Other Countries Do U.S. Applicants Designate?** Of these same 103 applications, the applications on average designated ten other contracting parties, including the European Union (84%), South Korea (51.5%), Japan (48.5%), Switzerland (29%), and the United States (18.4%). Presumably, the applications that designate back to the United States do not claim priority to an earlier filed U.S. application.
- **What Does WIPO Say About These Applications?** The WIPO representative at the 2015 Annual American Intellectual Property Law Association (AIPLA) Meeting offered some general advice to filers.

First, WIPO reminds filers not to number the figures, because the Hague system does this automatically. And filers are also reminded to include only one figure per page.

Second, WIPO says to rely on the data fields provided in the application, not additional documents. For instance, rather than submitting a separate specification, filers should use the description field in the application to describe their figures. Adding additional pages will likely create delay because the WIPO examiner might be confused about any differences between the description field and the additional specification.

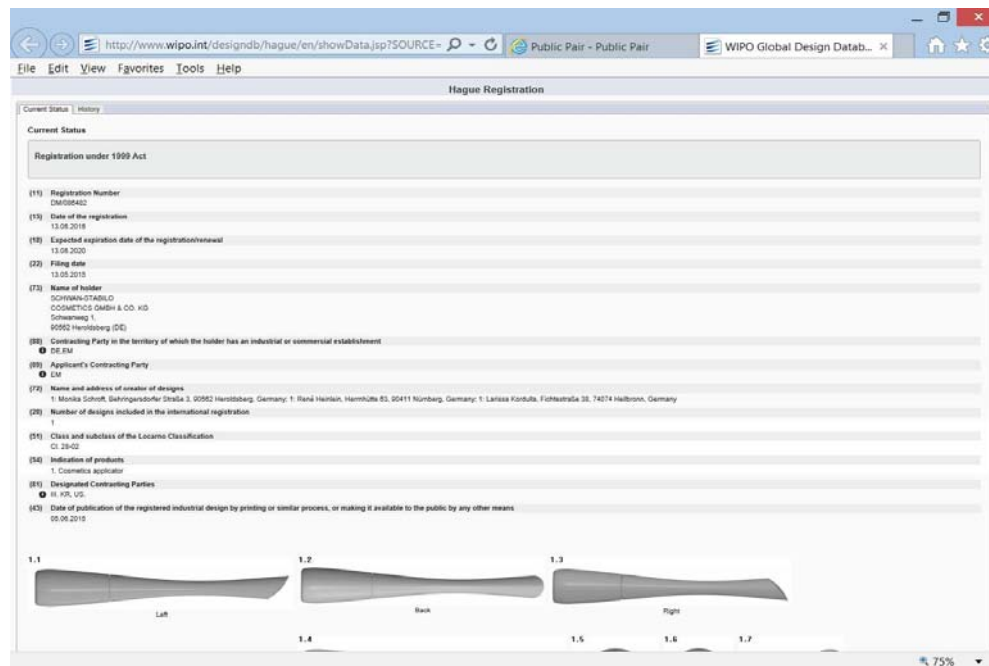
Finally, WIPO reminds filers that filing directly with WIPO will give filers access to the WIPO interface, which includes many error-checking functions. Filing directly with WIPO (provided that U.S. filers already have a U.S. foreign filing license) also eliminates certain fees and allows filers to use the WIPO Portfolio Manager function to manage all Hague applications from a single interface.

Hague Applications Designating the United States

From May 2015 through September 2015, according to WIPO, 536 IDAs have designated the United States, meaning that the applicant wished to have the IDA examined by the USPTO in hopes of getting a U.S. design patent. But as of early November, only 236 applications have made it to the USPTO and been posted on Public PAIR.

- **What Is the Status of These Applications?** One application, Application No. 35/500,001, has been allowed (more on that below). The remaining 235 applications are visible on Public PAIR, because the applications have been published by WIPO and loaded into the PAIR system.
- Filing receipts were sent by the USPTO in another ten applications in early July and another four in early October. As part of the filing receipt process, it appears that the USPTO has undergone verification of small and micro entity status for these applications. Some substantive examination appears to have taken place for one of these applications. But the majority of applications appear to still be in “preexamination.”
- **What Does the USPTO Say About This Progress?** The USPTO representative at the 2015 Annual AIPLA Meeting stated that the applications are usually available on Public PAIR within a week of publication by WIPO. The USPTO has processed two test cases (perhaps Application Nos. 35/500,001 and 35/500,014) and will process additional applications soon. This appears to be consistent with the information available on Public PAIR, as noted above. The USPTO’s current plan is to distribute the IDAs to a group of ten examiners.

- **What is Available on Public PAIR?** The tabs for a Hague application are similar to a standard design application. The Image File Wrapper includes the application broken down as a typical application would be, with drawings, claims, specification, oath or declaration, etc. Notably, “Published Documents” has a link to the Hague Application “publication,” which is electronic. The “publication” itself is a webpage titled “Hague Registration” and includes the originally filed figures. Below is an example for Application No. 35/500,001, also known as Dm/086482:



Another interesting feature is that the “Address & Attorney/Agent” has the correspondence address for the applicant, but no Attorney/Agent data are listed. This is important because, if the USPTO issues any sort of substantive office action (such as requiring a restriction, or objecting or rejecting the pending claim), then the applicant will need to retain a representative with a USPTO Registration Number in order to respond to the pending action. In the case of a restriction requirement, with only a two-month period for response, applicants should probably consider in advance whom they plan to retain, if necessary.

- **What About the Application that Was Allowed?** On October 23, 2015, the USPTO issued a Notice of Allowance in Application No. 35/500,001. This appears to be the first Hague IDA to receive a notice of allowance. The application is titled “Cosmetics applicator” and includes a single embodiment with seven figures (currently numbered 1.1 to 1.7). The figures are computer-generated images of the claimed design. The applicant has only provided single-word descriptions for each figure (e.g., “1.1 : Left,” “1.2 : Back,” “1.7 : Perspective”). The application also includes the traditional claim, “The ornamental design for a cosmetics applicator as shown and described.” It will be interesting to see if, in formatting this application for printing as a patent, the USPTO changes the figure numbers to single digits (e.g., “1.1” to “1”) and if the USPTO adds any further language to the description, to conform with current practice for U.S. design patent applications.

The application was allowed as a first action. Thus, it appears that, in this case, if the applicant pays the issue fee in a timely manner, the applicant will receive a U.S. design patent without retaining U.S. local counsel. This is an important cost savings goal of implementing the Hague system.

- **Any Predictions on the Other Hague Applications?** A small sampling of applications in the pipeline reveal that the road to a Notice of Allowance might be more challenging for some applications than for others. For instance:
 - Application No. 35/500,004, directed to a design for a “Flowerpot,” contains five figures: the first is

a photograph and the remaining four are line drawings. Under M.P.E.P. § 1503.02, photographs and line drawings are not permitted to be combined as formal drawings in a single application.

- Application No. 35/500,100, directed to a “Base for a safety child seat,” contains no figure descriptions for its seven figures. Instead, the entire description is “Base for a child seat to be mounted on the rear seat of a car.” While M.P.E.P. § 1503.01(II) does not require that descriptions be written in any particular format, if the descriptions “do not describe the views of the drawing clearly and accurately, the examiner should object to the unclear and/or inaccurate descriptions and suggestion language which is more clearly descriptive of the views.” Thus, it seems that some sort of description is necessary under current USPTO rules.
- Application No. 35/500,235, directed to a “Graphical user interface [computer screen layout]”, likewise contains no description beyond the title. First, the title does not appear to comply with USPTO procedures for describing this type of article of manufacture. See M.P.E.P. § 1504.01(a) (requiring titles such as “computer screen with icon”). Moreover, the single figure does not appear to depict “a computer-generated icon shown on a computer screen” as required by M.P.E.P. § 1504.01(a) and *Ex parte Strijland*, 26 U.S.P.Q.2d 1259 (B.P.A.I. 1992).

Growing Pains for Applicants on Both Sides

While it is definitely still early, it seems that many IDAs in the pipeline will test the integration of Hague applications into the USPTO examination system. Undoubtedly, there will be office actions, and applicants will need to learn how to respond to those office actions on the road to allowance of their claimed design. Likewise, U.S. applicants will need to learn the ways of the Hague system as they navigate the road to design rights in other Hague-member countries. It will be exciting to see everyone get more comfortable with the Hague system as it becomes a more viable option for all members seeking rights outside their homeland.

¹ As reported by a WIPO representative at the Annual AIPLA Meeting in Washington, DC, at the end of October 2015.

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Rule Review

USPTO Changes Its Practice Regarding Corrections to Foreign Priority Claims

by Mary E. Chlebowski

On October 6, 2015, the U.S. Patent and Trademark Office (USPTO) issued a Notice in the Federal Register informing the public that it is amending its practice regarding an applicant's request to correct a foreign priority claim. See 80 Fed. Reg. 60,367 (Oct. 6, 2015). In short, as of November 5, 2015, the USPTO will require an applicant to comply with all the requirements of 35 U.S.C. § 1.55, including the requirement to submit a formal petition to accept an unintentionally delayed benefit claim in order to amend an incorrect application number in a foreign benefit claim, as is currently required to correct a domestic benefit claim.

Background

Prior to the Leahy-Smith America Invents Act (AIA), a U.S. patent application publication was only prior art as of its U.S. filing date, not its prior foreign filing date. See 35 U.S.C. § 102(e)(1) (pre-AIA) ("A person shall be entitled to a patent unless . . . (e) the invention was described in – (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent . . ."). For any correction to a domestic benefit claim after the time period for filing a priority or benefit claim, the USPTO required a petition to accept an unintentionally delayed benefit claim. See 37 C.F.R. § 1.78(e). The USPTO would then republish the application with the corrected domestic priority information.

To correct an error in the application number in a foreign benefit claim outside the time period set forth for filing a claim, an applicant was technically required to file the same type of petition. See 37 C.F.R. § 1.55(e). In practice, however, the USPTO would accept a correction to the foreign application number even if an applicant only filed a corrected Application Data Sheet (ADS) or declaration. Because no formal petition was filed, the application would not be republished with the corrected application number. The fact that the application would not be republished was not important, in the USPTO's view, because the filing date of a prior foreign application did not affect the effective prior art date of the U.S. patent application publication.

After the AIA, the filing date of an earlier foreign patent application may be the effective prior art date for the subject matter disclosed in a U.S. patent application publication. See 35 U.S.C. § 102(a)(2) (post-AIA) ("A person shall be entitled to a patent unless . . . the claimed invention was described . . . in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention."). Thus, the rationale for not requiring a petition to correct an error in the foreign priority claim is no longer appropriate.

Accordingly, the USPTO is changing its practice and will now require applicants to make any correction to their foreign priority claims using the formal petition procedure laid out in 37 C.F.R. § 1.55(e). Once a petition is granted, the application will be republished with the correct foreign benefit claim. Republishing applications to reflect the accurate foreign priority information will minimize the burden on examiners, applicants, and members of the public in assessing the effective prior art date of a U.S. patent application publication under the AIA.

Correcting a Foreign Benefit Claim

A benefit claim must be made within four (4) months of the filing of the application or 16 months from the filing date of the prior application, whichever is later. 37 C.F.R. § 1.78 (domestic benefit claim); 37 C.F.R. § 1.55 (foreign benefit claim). As noted above, should a benefit claim need to be corrected outside this time period, the USPTO will now require a petition to accept an unintentionally delayed benefit claim for corrections to domestic *and* foreign priority claims in accordance with 37 C.F.R. § 1.78(e) and § 1.55(e), respectively.

The exact requirements for such a petition to accept an unintentionally delayed foreign benefit claim are set out in 37 C.F.R. § 1.55(e), which provides that the petition must be accompanied by (1) the priority claim, specifically identifying the foreign application to which priority is claimed by the application number, country (or intellectual property authority), day, month, and year of its filing, unless previously submitted; (2) a certified copy of the foreign application, unless previously submitted or an exception applies¹; (3) a petition fee; and (4) a statement that the entire delay between the date the priority claim was due and the date the priority claim was filed was unintentional. Section 1.55(e) also provides that the Director may require additional information where there is a question whether the delay was unintentional.

The change in practice will not affect applicants who were already strictly adhering to the rules. For others, the change will make the process of correcting one's foreign priority claim more formal and will require the applicant to pay a fee and make a statement that the delay was unintentional.

As always, applicants are encouraged to make a proper and accurate benefit claim as early as possible and especially within the time set forth in the rules. In addition, applicants should confirm that the priority claim listed on the filing receipt is correct and should request any correction as soon as possible. If the correction needs to be in a petition to accept an unintentionally delayed benefit claim, even though § 1.55 (e) does not explicitly state an ADS is required, it is recommended that an applicant use an ADS to avoid a possible rejection of the claim by the USPTO.

¹ Exceptions are noted in 37 C.F.R. § 1.55(h), (i), and (j).

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EPO Practice

Infringement of Second Medical Use Claims in the United Kingdom

by Hazel Ford

At the time of writing this article, Warner-Lambert and Pfizer have already been before the U.K. courts at least seven times in 2015 in disputes over the drug pregabalin. The patent protection for pregabalin itself expired in 2013. Warner-Lambert also has a later-filed second medical use patent including claims in the “Swiss form,” directed to the use of pregabalin in the manufacture of a medicament for treating pain.

Warner-Lambert licensed the patent to Pfizer, which holds the marketing authorization for the pregabalin product Lyrica. Its regulatory data protection for this product expired in July 2014, and immediately after that expiry, Actavis applied for marketing authorization to sell generic pregabalin under a “skinny label” that referred only to the treatment of anxiety and epilepsy.

It is common in the U.K. healthcare system for doctors to prescribe drugs based on their International Non-Proprietary Name (e.g., pregabalin), rather than using the brand name of the drug product (e.g., Lyrica). Pfizer therefore sought to prevent Actavis (and others) from selling pregabalin in the United Kingdom on the basis that, irrespective of what was stated on the label, it would in practice be prescribed and used for the treatment of pain.

Patent Infringement

Among the many issues considered across these decisions, one of the most interesting related to infringement, and whether Actavis’s manufacture and sale of pregabalin under a skinny label that did not mention the treatment of pain would be an infringement of such a second medical use claim. Despite having been used in Europe since the 1980s, there has been very little litigation that has considered the scope of the Swiss-form claim, and what is actually required to show infringement. One of the key issues considered in these Warner-Lambert decisions was the effect of the limitation “for treating” in such a claim.

Early in 2015, the High Court judge, Justice Arnold, concluded that “for treating” requires subjective intent on the part of the manufacturer that its product be used for the patented indication.¹ The Court of Appeal disagreed, and concluded that proof of intent by the manufacturer was not required, only that it was reasonably foreseeable to the manufacturer that the drug would intentionally be used to treat the patented condition.²

The case then returned to Justice Arnold in the High Court, where he followed the Court of Appeal’s foreseeability test, but found there was no infringement by Actavis.³ He reasoned that the Court of Appeal’s test still required proof of intention, but that it shifted the intention from the manufacturer to the downstream suppliers/users of the product. He concluded that a doctor who prescribes a drug using its International Non-Proprietary Name does not specifically intend for the Actavis product to be used. Similarly, he found that the pharmacist who supplied the drug will generally not know which condition the drug will be used to treat, so has no specific intention to provide the Actavis product for the patented indication. Finally, Justice Arnold concluded that the patient being treated has no specific intention to use Actavis’s product to treat pain because the patient will simply do what the doctor instructs, without having any input on the choice of drug.

Justice Arnold therefore concluded that the instances of actual infringement (e.g., where the pharmacist prescribes Actavis's drug despite knowing that it will be used to treat pain) were de minimis and that there was therefore no case for infringement of the patent by Actavis.

The End of the Matter?

Justice Arnold has granted Warner-Lambert leave to appeal against his decision on infringement, so we may yet see further developments from the Court of Appeal in this case. It will be interesting to see whether they agree with the way in which Justice Arnold applied their "foreseeability" test.

Second Medical Use Claim Formats

The claims in this case are in the Swiss form, which is considered to be a process claim directed to a manufacturing step in which a medicament is produced. However, since December 2007, the European Patent Office (EPO) has also allowed claims in the purpose-limited product format: "product X for use in a method of treating disease Y." Indeed, this is the only second medical use claim format allowed by the EPO on more recent patent applications. This new claim is considered to be a product claim rather than a process claim, and the EPO and others have suggested that it may have broader scope than the equivalent Swiss-form claim.

It is unclear whether the same conclusions would have been reached by the U.K. courts if the claims had been in this purpose-limited product format. The product claim still includes a feature of "for use in" and so it is possible that the same question of specific intent by the ultimate supplier or user of the drug may still apply.

An Alternative Approach?

Justice Arnold suggested that second medical use claims should be enforced by improving the system for drug prescriptions in the United Kingdom to ensure that only the branded product produced under license from the patent proprietor was used to treat the patented indication.

In one of the decisions in this series, Pfizer successfully obtained an injunction 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 was for use in treating pain.⁴ The pharmacist would then be required to dispense only the Pfizer product against that prescription.

This appears to have been somewhat successful for Pfizer: NHS England guidance has been updated to reflect this requirement, and the proportion of pregabalin prescribed by reference to the brand name Lyrica had risen to 34% by October 2015 (from as little as 1% in January 2015). However, this compares with an estimate that 70% of pregabalin prescriptions in the United Kingdom are for the treatment of pain. It therefore appears likely that this approach has not yet succeeded in preventing "skinny label" pregabalin being supplied for the patented indication in the United Kingdom. Justice Arnold has suggested that a more effective system of guidance, and enforcement of that guidance, is still required.

¹ [Warner-Lambert Co. v. Actavis Grp. Ptc EHF \[2015\] EWHC 72 \(Pat\)](#).

² [Warner-Lambert Co. v. Actavis Grp. Ptc EHF \[2015\] EWCA Civ 556](#).

³ [Warner-Lambert Co. v. Actavis Grp. Ptc EHF \[2015\] EWHC 2548 \(Pat\)](#).

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

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At the Federal Circuit

A U.S. Patent's § 102(e) Reference Date

by Wen Li

In *Dynamic Drinkware, LLC v. National Graphics, Inc.*, No. 2015-1214 (Fed. Cir. Sept. 4, 2015), the Federal Circuit affirmed the final written decision of the Patent Trial and Appeal Board (Board) that U.S. Patent No. 7,153,555 (“the ‘555 patent”) does not anticipate under 35 U.S.C. § 102(e) (post-AIA) claims 1 and 12 of U.S. Patent No. 6,635,196 (“the ‘196 patent”) owned by National Graphics, Inc. Specifically, agreeing with the Board, the Federal Circuit concluded that Dynamic failed to prove that the ‘555 patent qualified as a § 102(e) reference as of the filing date of the provisional application to which the ‘555 patent claims priority. The Federal Circuit, however, seemingly based its conclusion on reasons different from those relied upon by the Board.

The ‘196 patent is directed to making molded plastic articles bearing a “lenticular” image. The ‘196 patent was granted from an application filed on November 22, 2000, claiming priority to a U.S. provisional application filed on June 12, 2000.

Dynamic petitioned the Board for inter partes review of the ‘196 patent, arguing that claims 1, 8, 12, and 14 of the ‘196 patent were anticipated by the ‘555 patent. The ‘555 patent issued from an application filed on May 5, 2000, which claims the priority date of a U.S. provisional application (the “Raymond provisional application”) filed on February 15, 2000. The Board instituted trial on claims 1 and 12 only.

The Board concluded that Dynamic failed to prove by a preponderance of the evidence that the ‘555 patent anticipated claims 1 and 12 of the ‘196 patent under § 102(e). The Board found that National Graphics reduced to practice its inventions by March 28, 2000, which is before the May 5, 2000, filing date of the ‘555 patent, but after the February 15, 2000, filing date of the Raymond provisional application. The Board further found that Dynamic failed to prove that the ‘555 patent was entitled to the filing date of February 15, 2000, when the Raymond provisional application was filed. The Board explained:

To be entitled to rely on the February 15, 2000 provisional filing date, Petitioner had to establish that it relies on subject matter from [the ‘555 patent] that is present in and supported by its provisional. *In re Giacomini*, 612 F.3d 1380, 1383 (Fed. Cir. 2010) (“Therefore, an applicant is not entitled to a patent [under § 102(e) (2)] if another’s patent discloses the same invention, which was carried forward from an earlier U.S. provisional application”); *Ex Parte Yamaguchi*, 88 USPQ2d 1606 (BPAI 2008) (precedential).

...

Petitioner has not provided the analysis of common subject matter required by *Yamaguchi* and *Giacomini*. Instead, Petitioner’s chart compares only one ‘196 patent claim to the Raymond provisional. It does not compare the portions of [the ‘555] patent]’s patent relied on by Petitioner to the Raymond provisional, to demonstrate that those portions were carried over from the provisional. We therefore conclude that Petitioner has failed to carry its burden of proof that [the ‘555 patent]’s effective date is earlier than May 5, 2000.

On appeal, the Federal Circuit referred to the Board's common subject matter analysis, upon which the Board based its conclusion that the '555 patent is not a § 102(e) reference as of the filing date of the Raymond provisional application. The court, however, did not make clear in its opinion whether the Board's requirement that common subject matter be present in both the patent and the parent provisional is sufficient, necessary, or not actually required at all for a U.S. patent to qualify as a § 102(e) reference as of the filing date of the parent provisional.

Instead, the Federal Circuit required the analysis of a reference's date to be conducted under the framework of § 112, ¶ 1 (pre-AIA). According to the court:

A provisional application's effectiveness as prior art depends on its written description support for the claims of the issued patent of which it was a provisional.

Dynamic, No. 2015-1214, slip op. at 11.

In other words, under the Federal Circuit's view, in determining whether the '555 patent is a § 102(e)(2) reference as of the filing date of the Raymond provisional application, *Dynamic*, the petitioner, has the burden to prove that the Raymond provisional application provides both written description and enablement support for the claims of the '555 patent. The Federal Circuit found that "[n]owhere, however, does *Dynamic* demonstrate support in the Raymond provisional application for *the claims of the [555] patent.*" *Id.* The Federal Circuit affirmed the Board's decision.

While the decision is not explicit, practitioners need to be aware that, under a reading of *Dynamic*, for a U.S. patent to qualify as a § 102(e) reference as of the filing date of a parent provisional application, both the common subject matter requirement and § 112, ¶ 1, should be satisfied. Under this reading, a U.S. patent which previously would have been believed to qualify as a § 102(e) reference as of the filing date of the parent provisional may no longer be qualified. For example, practitioners previously would have considered that a U.S. patent is effective as a § 102(e) reference as of the filing date of the parent provisional if the patentability or validity defeating subject matter is present in both the parent provisional and the U.S. patent. Under *Dynamic*, however, that U.S. patent may no longer qualify as a § 102(e) reference as of the filing date of the parent provisional if the claims of the U.S. patent cannot find support in the parent provisional. Further case law will likely be needed to clarify this point.

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