

FULL DISCLOSURE

Patent Prosecution Update

June 2013

U.S. Supreme Court News:

On June 13, 2013, the U.S. Supreme Court delivered its much-anticipated decision in the case of the *Association of Molecular Pathology v. Myriad Genetics*, concerning the patent eligibility of claims to “isolated” genomic DNA sequences and cDNA sequences. The Court found Myriad’s claims to isolated genomic DNA sequences to be ineligible for patenting but claims to cDNA sequences to be patent-eligible. A copy of the opinion may be downloaded [here](#).

Biomarker and Personalized Medicine Patent Claims One Year After *Mayo v. Prometheus*

It is now just over a year since the U.S. Supreme Court delivered its opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), and nearly a year since the U.S. Patent and Trademark Office (USPTO) issued its guidelines based on that decision: the 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature, of July 3, 2012. [More](#)

USPTO Publishes Proposed Rules to Implement the Patent Law Treaty of 2000

In April 2013, the U.S. Patent and Trademark Office (USPTO) proposed changes to the rules of practice for consistency with the changes in the Patent Law Treaty (PLT) and title II of the Patent Law Treaties Implementation Act of 2012. The goal of the PLT is to harmonize and streamline formal procedures pertaining to the filing and processing of patent applications.

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Biomarker and Personalized Medicine Patent Claims One Year After *Mayo v. Prometheus*

by Elizabeth A. Doherty, Ph.D.

It is now just over a year since the U.S. Supreme Court delivered its opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), and nearly a year since the U.S. Patent and Trademark Office (USPTO) issued its guidelines based on that decision: the 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature, of July 3, 2012. Despite the passage of time, there have been very few subsequent court decisions considering the patent eligibility of diagnostic method claims. There has been one Federal Circuit decision on diagnostic methods, which found the claims ineligible for patenting, and only a small handful of unpublished decisions from the lower courts that addressed the issue.¹ In addition, a recent Federal Circuit case concerning business methods shows that U.S. judges currently disagree about how to draw the line between patent-eligible and nonpatent-eligible method claims, signaling more uncertainty ahead.^{2, 3}

So, how should a patent applicant who wishes to protect a biomarker or personalized medicine invention proceed? First, it is helpful to recognize the type of claim that might come under increased scrutiny in view of *Mayo*, in order to be prepared to handle a rejection from the USPTO. The claim addressed by the Supreme Court in *Mayo* was a method claim and recited as follows:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6–thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6–thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6–thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6–thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

See *id.* at 1295 (emphases and citation omitted). The Court analyzed whether this claim was patent eligible in two steps. The Court considered (1) whether the claimed method recited some natural law or natural phenomenon, and if so, (2) whether the surrounding active method steps were sufficient to transform that unpatentable natural law into a patentable *application* of the natural law.

Specifically, the Court concluded that the relationship between the concentration of the 6-thioguanine

metabolite and the likelihood that the drug will be effective is a “law of nature.” See *id.* at 1293, 1296. The Court then turned to the method steps to see whether or not they recited a patentable application of this natural law—that the 6-thioguanine level predicts a response to a thiopurine drug—and concluded that the steps of the method were not sufficient to limit the claim to a patentable application. See *id.* at 1294, 1297. In the Court’s view, the “administering” and “determining” steps recited in the claims “consist of well-understood, routine, conventional activity already engaged in by the scientific community,” while the “wherein” clauses “simply tell a doctor about the relevant natural laws.” *Id.* at 1297-98. An overriding concern of the Supreme Court seemed to be a fear of allowing a patent to hinder basic scientific research. In the Court’s view, “[a]nyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.” *Id.* at 1298.

The USPTO guidelines for examining method claims based on *Mayo* follow this same two-step analysis. One of the USPTO’s example claims is as follows:

A method of determining the increased likelihood of having or developing rheumatoid arthritis in a patient, comprising the steps of:

obtaining a serum sample from a patient;

contacting the serum sample with an anti-IgM antibody; and

determining that the patient has rheumatoid arthritis or an increased likelihood of developing rheumatoid arthritis based upon the increased binding of the anti-IgM antibody to IgM rheumatoid factor in the serum sample.

USPTO Guidelines at 11. According to the USPTO, the relationship between IgM rheumatoid factor levels and rheumatoid arthritis is a natural law, while the steps in the above claim merely recite the natural law with no more than a general instruction to use it, and for that reason, are not sufficient to make the claim patent eligible. *Id.* at 11-12.

These examples suggest that any process or method claim in which measuring a parameter, e.g., the expression level of a biomarker, is used to predict whether or not a natural event will occur, e.g., a response to a drug or an increased risk for a disease, may be scrutinized for patent eligibility in the USPTO. The examiner may find the fact that the parameter predicts the event to be a “natural law,” and may then look to the individual steps of the method to determine if they are, in the words of the Supreme Court, “well-understood, routine, conventional activity already engaged in by the scientific community.” *Mayo*, 132 S. Ct. at 1298. If so, the examiner will likely consider the claim not eligible for patenting. Moreover, the USPTO has indicated that even if the relationship between parameter and the event it predicts is newly discovered or is very narrowly claimed, the claims may still be found ineligible for patenting, as these are not factors in the USPTO’s analysis. USPTO Guidelines at 3.

Accordingly, patent applicants who wish to claim diagnostic methods may need to convince the USPTO that the steps of their methods are *not* “well-understood, routine, [and] conventional.” At present, with very little case law to draw upon, this may be a difficult task. In the absence of such case law, the USPTO seems to have taken a conservative approach, considering method steps to be nonconventional when the steps are themselves novel and nonobvious in view of the prior art or when they incorporate reagents that are novel and nonobvious. For example, the USPTO considers the above example claim, which recites measuring the biomarker level with an antibody, to be unpatentable, but considers narrower claims, in which either the antibody used or the specific method steps are novel and nonobvious, to be patentable. *Id.* at 11-12. From an applicant’s point of view, those narrower claims may be very easy for a competitor to design around and thus of little commercial value.

So, how should an applicant proceed? First, applicants who wish to continue to use method claims to protect biomarker applications should be prepared to argue that their methods are somehow not conventional in the art and thus will not impinge on basic researchers who want to study the relationship of the biomarker and the event it predicts. With this in mind, practitioners preparing new applications should consider incorporating appropriate fall-back disclosures or dependent claims that recite unique or nonconventional method steps or reagents.

Practitioners handling pending applications as well as preparing new applications should also consider other types of claims. For example, an applicant who is the first to measure a particular biomarker might be able to draft a claim to a method of generating a complex between that biomarker and a detection reagent. Such a claim, in effect, recites a method of generating a non-natural composition and, accordingly, should be patent eligible. Alternatively, given that *Mayo* concerns only method claims, an applicant may consider composition claims, such as claims reciting a kit of reagents and instructions for carrying out a diagnostic method. In addition, a Federal Circuit case decided prior to *Mayo* held that a claim reciting a method of treating a patient that incorporates information from a diagnostic assay method is patent eligible. *Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057, 1067-98 (Fed. Cir. 2011). For example, such a claim might look like the USPTO example claim above incorporating a subsequent step of treating the patient for rheumatoid arthritis with an appropriate drug if the diagnostic assay reveals that the patient suffers from the disease. However, it might be difficult to ultimately prove infringement of such a claim given that a single actor may not perform both the patient treatment and the diagnostic assay steps. Thus, patent applicants should consider whether they can draft a pure method-of-treatment claim that incorporates information from the diagnostic assay, but where all of the steps are likely to be performed by a doctor. Such a claim might have a better chance of withstanding a noninfringement argument.

Note that these alternative strategies such as nonconventional diagnostic assay methods, kits, and method-of-treatment claims generally may result in narrower claims than the traditional diagnostic method claims found patent ineligible by the Supreme Court. Applicants who desire protection for current diagnostic products may wish to consider pursuing these alternatives in spite of their disadvantages, however. In addition, practitioners preparing new applications should consider all of the above claiming strategies when drafting a new application in order to ensure that there will be sufficient support in the application disclosure for such claims. Finally, it may also be helpful to keep applications pending at the USPTO until further case law on diagnostic method claims develops and provides more clarity. In particular, applicants whose products are not expected to go onto the U.S. market soon may wish to delay prosecution of their applications in order to wait for further clarifying case law to emerge.

¹ See, e.g., *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65 (Fed. Cir. 2012); *Shire LLC v. Impax Labs., Inc.*, 2012 WL 1980803 (N.D. Cal. 2012); *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 2012 WL 2599340 (N.D. Cal. 2012); *Tessenderlo Kerley, Inc. v. Or-Cal, Inc.*, 2012 WL 2054994 (N.D. Cal. 2012); *SmartGene, Inc. v. Advanced Biological Labs., SA*, 2012 WL 1059611 (D.D.C. 2012); *SmartGene, Inc. v. Advanced Biological Labs.*, 2013 WL 40321 (D.D.C. 2013).

² *CLS Bank Int'l v. Alice Corp. Pty., Ltd.*, No. 2011-1301 (Fed. Cir. May 10, 2013).

³ The Supreme Court case *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398, decided June 13, 2013, involving claims to "isolated" DNA molecules further shows that patent eligibility is currently an area of very active litigation in the United States. This Supreme Court decision concerned claims drawn to isolated DNA molecules comprising stretches of genomic or cDNA encoding for two proteins frequently mutated in women with a high risk of developing breast cancer. The Supreme Court did not address the patent eligibility of diagnostic method claims in its June 13 opinion.

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USPTO Publishes Proposed Rules to Implement the Patent Law Treaty of 2000

*by Jennifer Johnson, Ph.D. and Lauren J. Dowty**

In April 2013, the U.S. Patent and Trademark Office (USPTO) proposed changes to the rules of practice for consistency with the changes in the Patent Law Treaty (PLT) and title II of the Patent Law Treaties Implementation Act of 2012. The goal of the PLT is to harmonize and streamline formal procedures pertaining to the filing and processing of patent applications. The most noteworthy changes of these proposed rules are (1) the filing date requirements for applications; (2) the restoration of patent rights for abandoned applications and acceptance of delayed fee payments solely on an “unintentional” basis; and (3) the restoration of the right of priority to a foreign application or the benefit of a provisional application by allowing a two-month grace period after the statutory period has expired.

Filing Date Requirements for Nonprovisional Applications

Under the proposed rules, nonprovisional utility and plant applications will no longer require a claim to secure a filing date. The filing date of an application will be the date the USPTO receives a specification.

Note that the PLT does not apply to design applications. Design applications are still required to have a claim and any required drawings in order to receive a filing date. Any applications that take advantage of this provision and have been filed without any claims must be amended to include at least one claim within three months from the filing date, unless the applicant has provided a correspondence address, in which case the USPTO will notify the applicant of the time period the applicant has to file at least one claim. Even where a correspondence address is provided, however, to avoid any problems, it may be best to provide the claims within three months of the filing date.

Also, under the proposed rules, a nonprovisional application can be filed “by reference” to a previously filed application instead of by resubmitting the specification and drawings of the prior application. In this case, the reference to the previously filed application will constitute the specification and any drawings of the subsequent application for the purposes of receiving a filing date. A copy of any referenced specification and drawings must be filed within three months, or if a correspondence address was filed, within the time period the USPTO gave the applicant.

Although the proposed rules will allow applicants to file applications without a single claim or by reference to a previously filed application, there are important considerations when using such methods of filing. Notably, the proposed rules call for “the reduction of any patent term adjustment if an application is not in condition for examination within eight months of its filing date.” In particular, for each day beyond eight months that the application is not in a condition for examination, any patent-term adjustment will be reduced an equal number of days. Moreover, compliance with the filing-date requirements ensures only entitlement to a filing date, and in the USPTO’s words, is not necessarily a “best practice.” Given the requirements of 35 U.S.C. §§ 112 and 113, filing an application without any claims or drawings runs the risk of receiving written-description and enablement rejections if there is insufficient information in the specification as filed to support the later-filed claims. Perhaps for this reason, the USPTO recommends viewing the ability to file an application without a claim or drawing merely as a “safeguard against the loss of a filing date due to a technicality.” Where there is likely sufficient information in the specification to

support later claims, however, filing an application that just meets the minimum requirements to receive a filing date could allow applicants to get an earlier filing date in competitive circumstances where being the first to file is paramount.

Restoration of Patent Rights

Under the proposed rules, petitions for revival of abandoned applications and for acceptance of delayed payment of fees, including maintenance fees, will be accepted solely on the basis of “unintentional delay.” The alternative “unavoidable” delay standard will be eliminated. The “unavoidable” delay standard is considered more burdensome on the USPTO because the “unavoidable” delay standard requires applicants to submit evidence that the delay was “unavoidable,” whereas the “unintentional” delay standard requires only a statement that the application was abandoned because of an “unintentional” error. Of note, the filing fee for a petition to revive an unavoidably abandoned application is lower than the filing fee for a petition to revive an unintentionally abandoned application. Thus, under the proposed rules, applicants filing a petition to revive an abandoned application will be required to pay the higher fee under the “unintentional” delay standard.

Restoration of the Right of Priority

The right of priority to an earlier-filed application will receive an additional two-month grace period if the delay in subsequent filing was “unintentional.” With respect to the right of priority to a foreign application, if the subsequent application is filed within two months of the expiration of the twelve-month statutory period (or six-month statutory period for design applications), “the right of priority in the subsequent application may be restored under PCT Rule 26bis.3 for an international application or upon petition” and payment of the applicable fee if the delay was unintentional. Similarly, with respect to the benefit of a provisional application, if the subsequent application is filed within two months of the expiration of the twelve-month statutory period, “the benefit of the provisional application may be restored upon petition and payment of the applicable fee if the delay in filing the subsequent application within the twelve-month period was unintentional.”

Even if this proposal is adopted, however, whenever possible, subsequent applications should be filed within the appropriate statutory period to ensure the right of priority to a foreign application or benefit of a provisional application is received. This will help avoid not only extra filing fees, but also the risk of the delay being found deliberate, leading to denial of a claim for priority. The USPTO considered comments until June 10, 2013.

The Federal Register Notice can be found here:

<http://www.gpo.gov/fdsys/pkg/FR-2013-04-11/pdf/2013-07955.pdf>.

**Lauren J. Dowty is a Law Clerk at Finnegan.*

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Rule Review

Preissuance Submissions Under the America Invents Act

by Rebecca Harker Duttry

As revised by the America Invents Act (AIA), 35 U.S.C. § 122(e) provides the general standards for preissuance submissions of patents, published patent applications, or other printed publications in patent applications. Preissuance submissions may be filed by any member of the public, including private persons and corporate entities. The only limitation is that the third party may not be the applicant or any individual who has a duty to disclose information with respect to the application under 37 C.F.R. § 1.56. This change under the AIA improves opportunities for third-party input into the examination process and expands the scope of access to prior art for examiners in an effort to increase transparency and improve patent quality. At the same time, this new procedure presents additional hurdles and challenges for patent practitioners.

The new preissuance submission procedure went into effect on September 16, 2012, and applies to all pending patent applications filed either before or after that effective date. A preissuance submission may be made in any nonprovisional utility, design, or plant application as well as in any continuation, divisional, or continuation-in-part application. A preissuance submission must contain:

1. a list identifying the printed publications being submitted;
2. a concise description of the relevance of each publication listed;
3. a legible copy of each document listed, unless it is a U.S. patent publication or issued U.S. patent;
4. an English language translation of any non-English language item listed;
5. a statement by the party making the submission that the submission complies with the statute and the associated U.S. Patent and Trademark Office (USPTO) rules; and
6. the required fee (currently \$180 per ten documents submitted, which may be waived if three or fewer documents are submitted).

The new preissuance submission procedure improves upon a prior and very rarely used U.S. third-party observation procedure by allowing the third party to provide not only a set of publications, but also a concise description of their relevance to the pending application. Nonetheless, this concise description of relevance may not be used to propose rejections of the claims, submit arguments against patentability, or set forth conclusions regarding whether one or more claims are patentable. Instead, the concise description should be used to set forth facts explaining how an item listed is of potential relevance to the examination of the application in which the third-party submission has been filed by pointing out relevant pages or lines of the respective document or providing a focused description to draw the examiner's attention to the relevant issues. There is no requirement for how the concise description must be presented; it may be presented as a narrative or as a claim chart mapping various portions of a submitted printed publication or different claim elements. To help ensure that the submission is properly considered by the examiner, the USPTO recommends providing the concise description of relevance for each document submitted as a separate page of the submission, and to prominently identify the printed publication to which each concise description pertains on that page.

Unlike third-party observations in other jurisdictions such as the European Patent Office, U.S. preissuance submissions may only be made within strict time periods prior to examination. First, no submission can be made after the USPTO mails a Notice of Allowance to the applicant. Second, a preissuance submission can only be filed *before the later* of (1) six months after the date on which the application is first published, or (2) the mailing date of the first rejection on the merits of any claim by the examiner, i.e., an Office Action that includes at least one claim rejection and not merely a restriction or election of species requirement.¹ Essentially, as long as there is no Notice of Allowance, those wishing to file a preissuance submission will have at least six months after publication within which to file the submission, and possibly considerably longer, given that the average time before newly filed applications receive an Office Action on the merits is currently about nineteen-twenty months based on the USPTO's own statistics. Based on these timing parameters, patent practitioners wishing to file a preissuance submission should remain alert and monitor relevant patent publications closely to ensure compliance with these timing guidelines. Further, practitioners should be aware that there may be potential to combine third-party observations filed in other jurisdictions with U.S. preissuance submissions to broaden the impact of the submission. If a third-party observation has already been filed in another jurisdiction, there will be a greater opportunity to refile the document in a preissuance submission in the United States.

As a result of this new procedure in the USPTO, patent practitioners may find themselves up against a broader scope of prior art during examination. Patent practitioners should take care to become fully versed in the scope of the potential prior art in an effort to avoid surprises and achieve maximum patent protection. Further, counsel interested in filing preissuance submissions on behalf of clients should consider the potential impact such a submission may have in subsequent litigation or on a post-grant proceeding, such as a post-grant review or *inter partes* review, that challenges a resulting patent. Many third parties may ultimately prefer to wait until they are threatened with an issued patent to reveal their best prior art.

Statistics published by the USPTO indicate that over 600 third-party preissuance submissions have been filed since the institution of the new procedure. *Available at* http://www.uspto.gov/aia_implementation/statistics.jsp. According to a recent news report, of these 600 submissions, only about 25% have led to a rejection. <http://www.law360.com/articles/440264/aia-prior-art-submission-system-picks-up-steam>. This low rate of rejections indicates that these submissions should only be used when the submitted documents are very strong. Further, this procedure should only be utilized after considering the potential disadvantages of submitting documents through the preissuance submission procedure as opposed to through a post-grant challenge in which the submitter is a real party to the proceeding and can exercise more control over it.

There are several disadvantages of using this procedure to weigh carefully. Beyond submitting the potentially relevant documents to the USPTO, third parties filing preissuance submissions have no other opportunity to further argue the applicability of their filing. Thus, there is a chance that the USPTO may misapply the prior art. Further, requiring the applicant to draft around the prior art may make the resulting patent stronger and more likely to withstand later invalidity challenges. If, however, a third party is already practicing the prior art, setting forth the prior art in a preissuance submission might force broad claims to be narrowed around the prior art. Despite these possible drawbacks, at a filing fee of only \$180 per ten documents, preissuance submissions are much less expensive than the other options in the USPTO, which often have filing fees in the mid-five figures. Therefore, the potential risks and benefits should be carefully considered before filing a preissuance submission.

¹ Preissuance submissions filed on the same date the first rejection is mailed when the application has already been published for more than six months are untimely and will not be entered.

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EPO Practice

European “Reissue” - Limitation and Revocation Procedures at the EPO

by Martin D. Hyden and Jeremy P. Bond

A reissue procedure at the U.S. Patent and Trademark Office (USPTO) allows a patent holder to correct a defect or error in an unexpired U.S. patent. Once accepted, the entire reissue application is examined under the same rules and requirements as a nonprovisional application. Any original and new claims are reviewed, if possible, by the same examiner who granted the original patent. A successful reissue procedure results in surrender of the original patent when the granted reissue application comes into effect.

The reissue procedure is not without limitations. For example, any defect or error must be significant enough to render the granted patent wholly or partly inoperable or invalid. This can include, for example, a defective specification, a defective priority claim, or the claims being too broad or too narrow in scope to cover the subject matter the inventor(s) had a right to claim. Broadening the scope of any claim to any extent is possible only if the reissue application is filed within two years of the original patent’s grant, but adding narrower dependent claims is possible at any time during the life of the patent. Reissue cannot recapture claimed subject matter surrendered during prosecution of the original application.

The European equivalents of reissue—limitation and revocation procedures—were enacted by the European Patent Convention 2000 and came into effect in 2007. Requests for limitation and revocation allow a European patent holder to amend or revoke (i.e., surrender) a European patent using a centralized *ex parte* procedure at the European Patent Office (EPO). This avoids the need to file separate requests in each contracting state where the granted patent is in force.

While only the patent holder can file a request for limitation or revocation, these can be filed at any time during the term of a European patent. The request cannot be filed if the patent is subject to a pending opposition proceeding (Article 105a EPC). Moreover, limitation and revocation proceedings do not take priority over national proceedings. In situations where both occur, the national proceeding is stayed or continued based on national law or practice.

Limitation and revocation procedures, unlike reissue, do not require a defect or error that renders the granted patent “wholly or partly inoperable or invalid.” The requester may provide information about the purpose of the request or why the request is allowable, but this information is not required. Rule 90 EPC explicitly states that the purpose underlying the request is of no relevance to the question of the request’s allowability.

As set forth in Rule 92 EPC, a request for limitation or revocation must be in writing in one of the official languages of the EPO (English, French, or German). The request should identify the patent number, the states in which the patent has been validated, the requestor, and any other proprietors having an interest in the patent and the requestor’s right to act on their behalf. Also required are any amended claims, description, and drawings. The current EPO fees are €1105 for limitation and €500 for revocation. Any deficiencies with the request are normally allotted two months’ time for correction, although this period is

extendable under exceptional circumstances.

If a request for limitation is accepted, the matter is sent to the Examining Division for processing. If the matter had previously undergone an opposition or limitation procedure, the patent as amended in the most recent procedure is examined. A requester may withdraw a request at any time, provided that it is still pending, but fees are not refundable. It is also possible to request a limitation or revocation following one or more earlier requests for limitation, whether accepted or not.

If a request for revocation is accepted, the Examining Division will revoke the patent and notify the requestor. The decision takes effect on the date of its publication in the European Patent Bulletin and applies to all contracting states where the patent was granted. It is not possible to selectively revoke a granted European patent in only some contracting states.

A limitation procedure is appropriate if new prior art comes to light that affects the validity of any of the claims or the claims have been found to have problems with clarity (such as missing essential features) or added subject matter that can be addressed by limiting their scope. With regard to claim amendments, the limitation procedure is restricted to assessing issues of clarity (Article 84 EPC) and allowable amendments (Article 123(2) & (3) EPC). A claim amendment must be fully supported and cannot add subject matter beyond the scope of the original application or result in the amended patent claiming subject matter extending beyond the scope of the originally granted claims. The Examining Division, however, will not determine if the subject matter of the claim amendment is patentable. As such, no new inquiry is made into novelty or inventive step.

Rule 95(2) EPC interprets "limitation" as meaning a reduction in the extent of protection conferred by the claims. Claim amendments that merely clarify or encompass different subject matter are not considered a "limitation." Likewise, amendments to the description that only improve the patent or constitute cosmetic changes not necessitated by the limited claims are not allowed. Amending only dependent claims to introduce a new limitation is permitted. But introducing nonlimiting amendments to the claims or description is not permitted if the amendments are not required by the new limitation.

Rule 95(2) EPC allows one opportunity to make amendments during a limitation procedure. However, a response that addresses previous objections but gives rise to new objections will normally make a further communication necessary. The EPO should grant a request for oral proceedings if the request for limitation is not allowable, but no further amendments are possible during oral proceedings if the request has previously been amended.

Three months after the amended claims have been approved, the patent holder must pay a fee and have the amended claims translated into two official languages of the EPO. The decision to limit the patent takes effect on the date the decision is published in the European Patent Bulletin. Shortly afterwards, the EPO will publish the amended patent. Any decision rejecting a request or terminating a procedure by the Examining Division is appealable to the Boards of Appeal at the EPO.

Central limitation at the EPO provides a relatively quick and easy way to amend a patent to address issues that might affect its ability to be enforced in any of the member states. Unlike reissue in the United States, a request for central limitation cannot result in the European patent being found invalid and does not require the patent holder to make comments on prior art that may need to be put before the USPTO or courts in corresponding proceedings.

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FULL DISCLOSURE

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At the Federal Circuit

Patent Eligibility of Business Methods After CLS Bank

by Eric P. Raciti

The highly anticipated en banc decision in *CLS Bank International v. Alice Corp. Pty. Ltd.*, No. 2011-1301, 2013 WL 1920941 (Fed. Cir. May 10, 2013) (en banc), did little to clarify the boundaries of patent eligibility for U.S. applicants, but the per curiam decision provided interesting clues to how individual Federal Circuit judges view the question. These clues can assist patent prosecutors in drafting claims that will withstand patent-eligibility challenges.

Alice sued CLS Bank for infringing U.S. Patent Nos. 5,970,479 (“the ‘479 patent”), 6,912,510 (“the ‘510 patent”), 7,149,720 (“the ‘720 patent”), and 7,725,375 (“the ‘375 patent”) directed to managing “settlement risk” in financial transactions by relying on a trusted third party. The ‘479 and ‘510 patents claim methods, and the ‘720 patent claims data-processing systems. The ‘375 patent claims both data-processing systems and computer-readable media.

All claims of the patents were found invalid by the U.S. District Court for the District of Columbia as directed to patent-ineligible subject matter under 35 U.S.C. § 101. In particular, the district court found that Alice’s method claims were directed to an unpatentable abstract idea. Further, the system and media claims were also found invalid, as allowing the claims would preempt the use of the abstract concept on any computer, which, as a practical matter, is how the concept would be implemented.

On appeal, a Federal Circuit panel reversed. *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 685 F.3d 1341 (Fed. Cir. 2012). CLS Bank then filed a petition for rehearing en banc. In its order granting rehearing en banc, the court invited the parties to address two questions: (1) What test should be adopted to determine whether a computer-implemented invention is a patent-ineligible “abstract idea” and when, if ever, does the presence of a computer in a claim lend patent eligibility to an otherwise patent-ineligible idea? (2) In assessing eligibility under § 101 of a computer-implemented invention, should it matter whether the invention is claimed as a method, system, or storage medium? In its en banc decision, although a majority of the court (seven out of ten judges sitting) affirmed the district court’s holding that Alice’s asserted method and media claims were patent ineligible, the judges could not agree on the reason. Additionally, an equally divided court affirmed the district court’s finding of ineligibility for the asserted system claims. As a result, other than the holding, nothing in the 135-page opinion can be cited as precedent.

A total of six concurring and dissenting opinions were filed. In addition to the finding of patent ineligibility of the method and computer-readable-media claims, a majority of the court (eight out of ten judges sitting) agreed that the method and system claims should “rise or fall” together (i.e., have their patent-eligibility determined together). However, because none of the opinions were joined by a majority, none have precedential weight.

Judge Lourie, joined by Judges Dyk, Prost, Reyna, and Wallach, concurred in the affirmance of the district court’s holding all claims patent ineligible under 35 U.S.C. § 101. Judge Lourie further proposed

an “integrated approach” to § 101 questions based on an analysis of five Supreme Court cases concerning patent eligibility. Judge Lourie extracted three common themes. First, patents should not preempt fundamental tools of discovery by claiming a natural law, natural phenomenon, or abstract idea. Second, the substance of a claim is more important than its form in determining patent eligibility. Third, courts should avoid rigid rules regarding subject-matter eligibility.

With these themes in mind, Judge Lourie adopted a four-step “integrated” approach for analyzing the patentability of claims:

1. verify the claim fits into one of the four statutory classes of invention (process, machine, manufacture, or composition of matter);
2. determine whether the claim raises § 101 abstraction concerns at all;
3. if abstraction concerns arise, unambiguously identify the fundamental concept or abstract idea;
4. after identification of the abstract idea, evaluate the remainder of the claim to determine whether it contains an “inventive concept” in the form of a “genuine human contribution” above and beyond the involved abstract idea.

Judge Lourie then applied this approach and found all the method claims patent ineligible under § 101. Specifically, Judge Lourie identified the claim as a process and the abstract idea as “a form of escrow.” Judge Lourie evaluated the remainder of the claim and found that the requirement to implement the method through a computer failed to supply an “inventive concept” because it did no more than add generic computer functionality to make the processing faster. Judge Lourie then found the media claims invalid as merely “method claims in the guise of a device.” Judge Lourie similarly found the system claims invalid, as they only served to limit the method to a particular technological environment, which was not enough to satisfy § 101.

Judge Lourie’s opinion found, at least in this case, that the method and system claims should “rise or fall” together, so that the substance of a claim controls its eligibility under § 101, rather than how skillfully it was drafted.

Chief Judge Rader, joined by Judges Linn, Moore, and O’Malley, dissented, and would have found the system claims patent eligible. However, Chief Judge Rader, joined only by Judge Moore, concurred with the court’s judgment that the method and media claims were not patent eligible. Additionally, Judge Moore wrote separately, in an opinion joined by Judges Linn, Rader, and O’Malley, to emphasize the eligibility of the system claims under § 101. Judges Linn and O’Malley, who did not join Judge Rader and Moore, wrote separately to express their view that the method and media claims were also patent eligible.

Somewhat similar to the “inventive concept” approach favored by Judge Lourie, Chief Judge Rader focused on whether a claim includes “meaningful limitations,” restricting it to an application rather than claiming an abstract idea itself. However, unlike Judge Lourie, Chief Judge Rader limited the scope of this requirement. In order to avoid mixing patent-eligibility requirements with the separate requirements for novelty, nonobviousness, and enablement, only those limitations that are “inherently” required to implement the abstract ideas were excluded by Chief Judge Rader as nonmeaningful (“inherency test”). Using this approach, Chief Judge Rader found that limiting a method to a particular machine could be sufficient for patent eligibility because a computer is not inherently required for an escrow arrangement. That does not mean, however, that such a claim would be novel and nonobviousness.

Chief Judge Rader, joined only by Judge Moore, also concurred with the court’s judgment that the media and method claims were ineligible using the “inherency test.”

Judge Linn, joined by Judge O’Malley, wrote separately to express his view that the method and media claims were also patent eligible under § 101. Judge Linn, however, agreed with Judge Lourie that the

method, system, and media claims must “rise or fall” together. Applying the reasoning employed by Chief Judge Rader for the system claims, Judge Linn found the method and media claims patent eligible, because of the district court’s finding that those method claims inherently required a computer limitation.

Judge Newman, though agreeing that the method, system, and media claims should “rise or fall” together, dissented with the court’s judgment, finding all the claims patent eligible.

Judge Newman proposed eliminating the abstract idea, law of nature, and natural phenomenon exceptions to § 101 and simply establishing eligibility if the claimed subject matter falls within one of the statutory classes of machine, manufacture, process, or composition of matter. As a result, since the claims in Alice’s patents are directed to methods and systems, eligibility is established.

Judge Newman proposed to expand the “experimental use” exception to patent infringement to cover commercially motivated experimental uses. By expanding the experimental-use exception, Judge Newman concluded, many of the concerns driving the desire to limit the patenting of abstract ideas that preempt the use of those ideas in all fields would disappear.

Although none of the opinions carry precedential weight, the insights provided in this lengthy opinion provide important guidance to patent prosecutors for claim drafting. Specifically, moving forward, patent prosecutors should draft patent specifications and claims that include both method and system claims where appropriate. For those judges that see a distinction between method and system claims, as in the case of Judges Rader and Moore, the inclusion of physical limitations in a system claim can help ensure patenteligibility.

Further, including multiple claim types in a patent application could also increase the chances of clearing the § 101 hurdle, even where system and method claims must rise and fall together. As Judge Linn’s dissent illustrates, including system claims gives rise to the possibility of construing accompanying method claims to include all of the limitations of the accompanying system claims, thus preserving § 101 validity.

Ultimately, however, this case shows that claims that do more than implement a method through a computer have the highest chance of success. These are claims where a computer-implemented method comprises only a portion of the claim rather than the entire claim, and the results of that method are used to accomplish some other real-world task.

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