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Review of Developments in Intellectual Property Law

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Deciphering the Patent-Eligibility Message in Prometheus, Myriad and Classen

It has been a little more than eighteen months after the Supreme Court issued its opinion on the patent-eligibility of (business) method claims in *Bilski v. Kappos*.[1] In that time, the Federal Circuit has issued opinions in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*,[2] *Classen Immunotherapies, Inc. v. Biogen Idec*,[3] and *Association for Molecular Pathology v. U.S. Patent and Trademark Office*[4] ("*Myriad*") relating to diagnostic method claims. These decisions came in the wake of the Supreme Court's *Bilski* decision, and two of them (*Prometheus* and *Classen*) were decided on remand from the Court for reconsideration in view of *Bilski*. The Federal Circuit decided the *Prometheus* case on remand, finding (again) that the claims recited patent-eligible subject matter. The Supreme Court has again granted *certiorari* for *Prometheus*; oral arguments were heard late last year and a decision is due by the end of the Court's current term in June. Of the other two diagnostic method claims cases, the Federal Circuit decided that some but not others of the *Classen* claims were patent-eligible, and that none of the method claims at issue in *Myriad* satisfied the Supreme Court test for patent eligibility. Petitions for *certiorari* have been filed in both the *Classen* and *Myriad* cases.

These decisions reflect the struggle in the Supreme Court and the Federal Circuit with the scope of patent eligibility for method claims that produce information rather than a tangible product (something reflected a generation ago in the *Benson v. Gottschalk*,[5] *Parker v. Flook*,[6] *Diamond v. Diehr*[7] cases). Given that the question of patent eligibility is completely dependent on the scope and meaning of properly construed claims, it is curious that in none of the pending cases were the claims construed by the lower courts. Here we provide a comparison of the claims in *Prometheus*, *Myriad*, and *Classen* that might shed some light on the reasoning used by the Federal Circuit in arriving at the answers to the patent-eligibility question posed in each

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Accelerated Examination v. Prioritized Examination

The Leahy-Smith America Invents Act (AIA) provides for the establishment of a program to allow the expedited examination of patent applications.[1] The U.S. Patent and Trademark Office (USPTO) refers to this program interchangeably as Prioritized Examination and Track I.[2] However, expedited examination is not a new concept. In addition to Prioritized Examination, the USPTO provides another expedited examination process known as Accelerated Examination.[3] Prioritized Examination does not replace Accelerated Examination, but rather offers applicants an additional option for expedited examination.

So which is the best option for having applications examined quickly? This article considers the differences between these two programs in

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of these cases and a guide (subject to Supreme Court review) for drafting patent-eligible diagnostic method claims.

Perhaps the most clear-cut decision by the Federal Circuit involves the method claims in the patents in the *Myriad* case. These claims all require the steps of "analyzing" or "comparing" a mutated BRCA gene sequence with the wildtype, "normal" sequence without any express claim language requiring that either sequence be determined as part of the claim; claim 1 of U.S. Patent No. 5,709,999 and U.S. Patent No. 5,710,001 (fully recited in the footnote) are illustrative.[8]

Significantly, other diagnostic method claims, including ones using antibodies to detect altered BRCA proteins, were not at issue in the case. Also not recited in these claims were "additional, transformative steps," including "the steps of (1) extracting DNA from a human sample, and (2) sequencing the *BRCA* DNA molecule, ... steps [that] necessarily precede the step of comparing nucleotide sequences."[9]

The Federal Circuit panel unanimously agreed that these claims do not satisfy the "machine or transformation" (MOT) test under *Bilski*. These claims "recite[] nothing more than the abstract mental steps necessary to compare two different nucleotide sequences," according to Judge Lourie's majority opinion.[10] Also significant for the Court is that the specification required the term "sequence" to refer "more broadly to the linear sequence of nucleotide bases of a DNA molecule" *per se*.[11] The panel found that Myriad's method claims can be satisfied (*i.e.*, infringed) by "mere inspection" alone, and thus encompass merely an abstract idea.[12]

In contrast, on remand, the Federal Circuit found the claims in *Prometheus* (fully recited in the footnote) to satisfy the MOT test and thus recite patent-eligible subject matter, whether the claim recites an affirmative drug administration step or not.[13] The distinction between the claims in *Myriad* and claim 1 of the *Prometheus* patent can be appreciated in light of the difference in what is being detected in each claim: a naturally occurring nucleic acid in *Myriad* and an administered drug or its metabolite in *Prometheus*. Insofar as patent eligibility for method claims must either satisfy the *Bilski* machine or transformation test or otherwise not be so abstract as to entirely preempt an abstract idea, law of nature, or natural phenomenon, the fact that a drug must be administered would appear to provide the Federal Circuit with its rationale regarding the patent eligibility of the claim 1 of the *Prometheus* patent. Claim 46, on the other hand, does not have an affirmatively recited administration step. However, the "detecting" step recites that 6-thiopurine or one of its metabolites is detected from "a subject administered [one of the recited] drug[s]," again encompassing only those patients who have been transformed by drug administration.

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It remains the case that including active, technology-dependent steps in method claims is prudent, and claims should be drafted that minimize the likelihood that the invention will be characterized as merely an "abstract idea."

It would seem that the Court refused to exalt form over substance by making a distinction between claims that recite administration of the drug to a subject and claims that are restricted to detecting a drug or its metabolites only in that subset of subjects to whom the drug has been administered; in either case, the Federal Circuit discerned a transformation. Neither of these considerations are likely to be before the Supreme Court, however, since defendant's *certiorari* petition and argument focused on the purported interference these claims create with the practice of medicine as well as the allegation that the portions of the claim that recited the transformation step are not "inventive." In this regard it should be remembered that the case that raised this aspect of medical diagnostic method claims, *Laboratory Corp. v. Metabolite Labs., Inc.*[14] (*LabCorp*), was, like *Myriad*, directed at detecting a naturally occurring metabolite, homocysteine, and not an administered drug as in *Prometheus*.

The most surprising Federal Circuit decision relating to diagnostic method claims is the most recent, the *Classen* case. There, a divided panel found a distinction between the claims of U.S. Patent No. 5,723,283 (fully recited in the footnote), which the majority found *not* to be patent-eligible,[15] and the claims of U.S. Patent Nos. 6,420,139 and 6,638,739 (claim 1 of the '739 patent being representative, and fully

recited in the footnote) that *were* patent-eligible according to the majority.[16]

The difference for the panel majority appears to be in whether the determination of an appropriate immunization schedule directs an affirmative (and transformative) step or steps. In the '283 claim, the majority construed the scope of the claim to encompass mere comparison of the results of immunization schedules that produce a conclusion (*i.e.*, information) without any further steps in the claimed method. The claims in the '739 patent, in contrast, require that an appropriate immunization schedule be determined, and *then* that a mammal or mammals be immunized according to that schedule to achieve the beneficial result of immunization with the least "incidence, prevalence, frequency or severity" of deleterious side effects.

Another salient difference between the *Myriad* claims and the '283 claim in *Classen* on the one hand, and the *Prometheus* claims and the '739 patent claims in *Classen*, on the other, is that the former claims involve producing intangible information, while the latter use the information to direct the claim practitioner to perform a tangible, transformative step. Claims that only produce information may not be patent-ineligible *per se*; however, as in *Bilski* (and *Benson* and *Flook*) they are more likely to raise patent eligibility concerns. Indeed these considerations arose in the concurring Justices' opinion in *Bilski*.[17]

It remains the case that including active, technology-dependent steps in method claims is prudent, and claims should be drafted that minimize the likelihood that the invention will be characterized as merely an "abstract idea." While this advice is admittedly of a general nature, it does provide a mechanism for assessing claims for patent eligibility: if the claim contains no active, transformative step, or recites mere comparison of information or data, it is likely to be open to a subject matter eligibility attack, either in the Office or in litigation. Insofar as the invention involves a novel (and non-obvious) appreciation of relationships between phenomena (particularly natural phenomena), it is wise to include an "active" step wherein detection of the relationship leads to some activity that is itself transformative. For claims currently in force, it may also be advisable to determine whether reissue in favor of claims reciting an active transformation step is possible to reduce the likelihood of such a challenge. But the simple fact is that any advice is subject to revision the next time the Supreme Court or Federal Circuit opines on patent eligibility of method claims.

Endnotes

1 130 S. Ct. 3218 (2010).
2 628 F.3d 1347 (Fed. Cir. 2010).
3 659 F.3d 1057 (Fed. Cir. 2011).
4 653 F.3d 1329 (Fed. Cir. 2011).
5 409 U.S. 63 (1972).
6 437 U.S. 584 (1978).
7 450 U.S. 175 (1981).
8 1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1. (the '999 patent)

2. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises gene comparing a first sequence selected form the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample. (the '001 patent)

9 *Myriad,* 653 F.3d at 1356.
10 *Id.*
11 *Id.*
12 *Id.* at 1357.
13 1. 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 8x108 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 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

46. A method of optimizing therapeutic efficacy and reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising:
(a) determining the level of m6-thioguanine or 6-methylmer-captopurine in a subject administered a drug selected from the group consisting of 6-mercaptopurine, azathiop[urine, 6-thioguanine, and 6-methylmercaptoriboside, said subject having said immune mediated gastrointestinal disorder,

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wherein the level of 6-thioguanine less than about 230 pmol per 8x108 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 8x108 red blood cells or a level of 6-methylmercaptopurine greater than about 7000 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject. (U.S. Patent No. 6,355,623)

14 370 F.3d 1354 (Fed. Cir. 2004).

15 A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

16 1. A method of immunizing a mammalian subject which comprises:

(i) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

(ii) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

17 *Bilski*, 130 S. Ct. at 3256 "For even when patents encourage innovation and disclosure, "too much patent protection can impede rather than 'promote the Progress of . . . useful Arts.'" *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U. S. 124, 126–127 (2006) (BREYER, J., dissenting from dismissal of certiorari). . . . Patents "can discourage research by impeding the free exchange of information," for example, by forcing people to "avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented" methods. *Id.*, at 127.").

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order to address this question. A point-by-point comparison is provided in Table 1.

Application Requirements
Perhaps the most significant difference between Accelerated Examination and Prioritized Examination are the additional filing requirements for an Accelerated Examination application. Notably, these requirements can be a source of prosecution history estoppel.

When filing an application under Accelerated Examination, an applicant must include, among other documents, a Statement of Pre-Examination Search, and an Accelerated Examination Support Document.[4] To this end, the applicant must conduct (or engage a search firm to conduct) a search on the patentability of each of the filed claims. The Statement of Pre-Examination Search must identify the databases searched and the searching methods used, and must disclose any relevant references discovered.[5] In addition, the applicant must prepare the Accelerated Examination Support Document, which identifies the references most closely related to the claims, discloses which references teach which claimed features, and sets forth the applicant's arguments for the patentability of each claim.

The Statement of Pre-Examination Search and the Accelerated Examination Support Document both have the potential to create prosecution history estoppel. Particularly, the applicant is admitting to the relevance of the references cited therein, and the relation of these references to the claims. Thus, an applicant should evaluate the risk of such estoppel before proceeding with an Accelerated Examination filing. For many applicants, this risk of estoppel may override any other considerations that favor Accelerated Examination.

In contrast to Accelerated Examination, filing an application under Prioritized Examination requires only a Certification and Request for Prioritized Examination, that the Oath is filed with the application, and upfront payment of the publication fee.[6] Indeed, Prioritized Examination creates no more estoppel than regular examination.

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When deciding between Accelerated Examination and Prioritized Examination, applicants should weigh the preparation costs involved in Accelerated Examination against the USPTO fees for Prioritized Examination.

Cost
Another difference between Accelerated Examination and Prioritized Examination is the total cost of preparing and filing applications. In many cases, the cost of preparing an Accelerated Examination application may exceed that of preparing a Prioritized Examination application. On the other hand, the cost of filing an Accelerated Examination application is significantly lower than that of filing a Prioritized Examination application.

More specifically, between the Statement of Pre-Examination Search and Accelerated Examination Support Document, filing an application under Accelerated Examination is similar to preparing both an Office Action (usually the responsibility of an Examiner at the USPTO) and a Response to the Office Action, all before the application is filed. Thus, the preparation of these documents will entail an additional cost that should be considered by applicants. By comparison, preparing an application for Prioritized Examination is in most respects identical to preparing an application for standard examination. As noted above, there are few additional requirements associated with filing a Prioritized Examination application, and therefore few additional preparation costs.

On the other hand, USPTO fees for filing an Accelerated Examination Application are significantly lower than those for filing an application under Prioritized Examination. Accelerated Examination requires only a $130 fee in addition to the regular filing, search, and examination fees.[7] Prioritized Examination requires a special $4800 fee and the up-front payment of the $300 publication fee (regardless of whether or not non-publication is requested) as well as the regular fees.[8]

Thus, despite the significantly lower cost of filing an application under Accelerated Examination, the total cost of preparing an application for Accelerated Examination could equal or, in some cases, exceed the total cost of preparing and filing an application under Prioritized Examination. Accordingly, when deciding between Accelerated Examination and Prioritized Examination, applicants should weigh the preparation costs involved in Accelerated
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Examination against the USPTO fees for Prioritized Examination.

On the other hand, Accelerated Examination may result in lower overall prosecution costs, as the process of preparing the Statement of Pre-Examination Search and Accelerated Examination Support Document may result in applicants seeking more focused claims. Consequently, fewer office actions and responses may be required before an application is allowed, resulting in an overall prosecution cost that may be commensurate with that of a non-expedited application.

Claim Requirements

Accelerated Examination applications are limited to 3 independent claims and 20 total claims.[9] Prioritized Examination applications are allowed up to 4 independent claims and up to 30 total claims.[10] Depending on the nature of the application, some applicants may desire the higher number of claims allowed by Prioritized Examination.

Requests for Continued Examination and Notices of Appeal

Another significant difference between applications filed under Accelerated Examination and those filed under Prioritized Examination are the options to file a Request for Continued Examination (RCE) and a Notice of Appeal.

For applications filed under Accelerated Examination, expedited examination of the application will continue after an RCE is filed and if prosecution is re-opened after a Notice of Appeal is filed.[11] By contrast, in Prioritized Examination the filing of an RCE or Notice of Appeal results in loss the application's status under Prioritized Examination.[12] That said, it is possible to pay another Prioritized Examination fee of $4800, as noted above, to reinstate the application's status under Prioritized Examination after the filing of an RCE (but not after the filing of a Notice of Appeal).[13]

Time-to-Allowance and Examiner Cooperation

A number of attorneys and agents at MBHB have successfully prosecuted Accelerated Examination applications to allowance.

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An unlimited number of cases can be filed under Accelerated Examination in any year. However, the Prioritized Examination program is limited to 10,000 applications per fiscal year.

We have observed a very short time-to-allowance for this type of application, including a number of first-action allowances. Additionally, we have observed a high level of Examiner cooperation. In particular, many Examiners seem eager to work with the applicant to find allowable subject matter.

We do not yet know whether a similarly favorable time-to-allowance and level of examiner cooperation will exist for Prioritized Examination applications. However, in a recently-released report on the Prioritized Examination program, the USPTO has indicated that on average, a first Office Action is mailed 66.4 days after a Prioritized Examination application is filed.[14]

As a practice note, it is important to remember that the filing receipt of a Prioritized Examination application will not indicate whether the application has been approved for the program, or whether it is in the program at all. Instead, an additional "Decision for Granting Request for Prioritized Examination" will be mailed approximately 30 days after the filing receipt is mailed.

Number of Applications

Still another notable difference between Accelerated Examination and Prioritized Examination is the number of applications the USPTO allows to be filed under each program. An unlimited number of cases can be filed under Accelerated Examination in any year. However, the Prioritized Examination program is limited to 10,000 applications per USPTO fiscal year, which runs until October 1.[15] That said, as of January 4, 2012, only 980 cases have been filed under Prioritized Examination for the current fiscal year.[16] At this rate, the limit is not likely to be met.

Insight from MBHB's Accelerated Examination Practice

As noted above, attorneys and agents at MBHB have prosecuted a number of Accelerated Examination applications. Based on this experience, we have compiled the following pointers for the preparation and filing of Accelerated Examination applications.

We have observed that USPTO Examiners can be inconsistent in their adherence to the Accelerated Examination procedures outlined in the Examiner's Checklist for Accelerated Examination. In particular, we've observed that some Examiners will strictly review the Pre-Examination Search Statement and Accelerated Examination Support Document, which can result in petitions for Accelerated Examination to be rejected for seemingly minor reasons. Applicants have only one chance to correct these documents and remain under Accelerated Examination. A second rejection will cause an application to lose its status as an Accelerated Examination application. Below is a sampling of pitfalls to avoid in preparing these documents.

Pre-Examination Search

The Examiner's checklist specifies that the Pre-Examination Search must "be directed to the claimed invention and encompass all of the features of the claims, giving the claims the broadest reasonable interpretation" and further must "encompass the disclosed features that may be claimed." Some Examiners have interpreted this language to require that the applicant search not only the limitations of all of the independent claims, but also the limitations of all of the dependent claims. For this reason, it is perhaps advisable to perform a Pre-Examination Search after finalizing the claim listing for an application, to ensure that all of the claims, and the exact language of the claims, is the subject of the search.

Accelerated Examination Support Document

Additionally, the Examiner's checklist specifies that the Pre-Examination Search must include a "detailed explanation of how each claim is patentable over the references cited with particularity ...." Some Examiners have interpreted this language to require that the applicant argue for the patentability of each dependent claim as well as each independent claim. Thus, the Accelerated Support Document may generate more prosecution history estoppel than a typical Office Action Response. For this reason, we believe that Prioritized Examination is a better choice for most applications.

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Illinois MCLE Board Grants MBHB Accredited CLE Provider Status Effective January 1, 2012

McDonnell Boehnen Hulbert & Berghoff LLP ("MBHB") has been granted Accredited Continuing Legal Education ("CLE") Provider status in Illinois by the Minimum Continuing Legal Education ("MCLE") Board of the Supreme Court of Illinois. As an Accredited CLE provider, all of the firm's CLE programs are presumptively approved for general credits. MBHB was retroactively granted this status as of January 1, 2012.

By way of background, when establishing the MCLE Rules, the Illinois Supreme Court created the MCLE Board of the Supreme Court of Illinois to administer the MCLE program. On September 29, 2005, the Supreme Court of Illinois ordered MCLE under Supreme Court Rules 790 through 798. With certain exceptions set forth under Rule 791(a), MCLE is required for "every attorney admitted to practice in the State of Illinois." The rules cover the administration of the program for MCLE, what education is actually required and what programs can be accredited for such education.

Every Illinois attorney subject to the MCLE Rules is required to complete a certain number of hours each two-year reporting period (Rule 794). An attorney's two-year reporting period depends on the first letter of the attorney's last name as it appeared on the master roll of attorneys when the individual attorney was admitted to the Illinois bar. The CLE reporting period is broken down for attorneys with last names beginning A-M and, separately, N-Z. Beginning with the July 1, 2010 through June 30, 2012 two-year reporting period for attorneys with last names beginning A-M, and all two-year reporting periods thereafter, 30 CLE activity hours are required. Of these total hours, at least 6 must be in the area of professional responsibility.

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Table 1: Comparison of Accelerated and Prioritized Examination

	Prioritized Examination[17]	**Accelerated Examination**[18]
Timeline for Final Disposition	Final Disposition in 12 months. Final Disposition entails: (a) Applicant files a petition for extension of time to extend the time period for filing a reply; (b) Applicant files an amendment to amend the application to contain more than four independent claims, more than thirty total claims, or a multiple dependent claim; (c) Applicant files an RCE; (d) Applicant files a Notice of Appeal; (e) Applicant files a request for suspension of action; (f) A Notice of Allowance is mailed; (g) A Final Office Action is mailed; (h) The application is abandoned; or (i) Examination is completed as defined in 37 CFR 41.102.	Final Disposition in 12 months. Final Disposition entails: (a) A Notice of Allowance is mailed; (b) A Final Office Action is mailed; (c) Applicant files an RCE; or (d) The application is abandoned.
Claim Limits	4 independent claims; 30 total claims.	3 independent claims; 20 total claims.
Timeline for Examination	Standard timeframe for responses set forth by MPEP 710.02(b), *e.g.*, 3 months to respond to an office action.	1 month to respond to an office action.
Effect of Applicant Taking an Extension of Time	Available, but results in removal of special status.	Not available; failure to timely reply will result in abandonment.
Pre-Examination Search	Not Required.	Required.
Maximum Number of Applications	10,000 per fiscal year.	No maximum.
Eligible Applications	Any original utility non-provisional applications (including continuing and divisional applications). Not available for international, design, reissue, provisional, and reexamination applications.	Any non-reissue utility or design application (including continuing and divisional applications). Not available for international, plant, reissue, provisional, and reexamination applications.
Effect of RCE	Special status is withdrawn when an RCE is filed. However, an applicant can pay an additional Prioritized Examination fee to keep the RCE on prioritized Examination.	Special status is retained when an RCE is filed.
Effect of Appeal	Special Status withdrawn when Notice of Appeal filed. Applicant can*not* pay for Prioritized Examination again on the application.	Standard appeal process. If examination is re-opened then Accelerated Examination procedures still apply.

	Prioritized Examination[17]	Accelerated Examination[18]
Carry Over to Continuations	Status as Prioritized Examination application does *not* carry over to child.	Status as Accelerated Examination application does *not* carry over to child.
Filing Requirements	Must: (i) file complete application under 37 CFR 1.51(b); (ii) file via EFS-Web; (iii) file with oath or declaration; and (iv) file with all applicable fees.	Must: (i) file complete application under 37 CFR 1.51(b); (ii) file via EFS-Web; (iii) file with oath or declaration; (iv) file with all applicable fees; (v) file with petition to make special; (vi) file with combined pre-examination search statement and accelerated examination support document; and (vii) file an IDS.[19]
Petition Dismissal	Applicant can file a petition under 37 CFR 1.181 if applicant believes that a decision dismissing the request for prioritized examination is not proper. Applicant should review the reason(s) stated in the decision dismissing the request and make a determination that an error was made by the Office in not granting the request before filing such a petition under 37 CFR 1.181.	Applicant is allowed one chance to fix a dismissed petition with a one month response period.
Fees	$6,480, plus any excess claims fees (includes: (i) $4,800 prioritized examination fee, (ii) $1,250 filing fees, (iii) $130 processing fee, and (iv) $300 publication fee.[20]	Standard application fees, plus $130 fee for petition to make special.
Interviews	Encouraged.	Applicant must agree to an interview with the examiner to discuss any outstanding issues arising in the examination process. Any pre-first action interview should be held within two weeks of initial contact by the examiner.
Restriction Practice	Standard restriction practice applies.	Applicant agrees to elect without traverse a single invention for examination.
Non-Publication Request allowed?	Yes.	Yes.

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Endnotes

1 Leahy-Smith America Invents Act, Pub. L. No. 112-29, http://www.gpo.gov/fdsys/pkg/PLAW-112publ29/pdf/PLAW-112publ29.pdf.
2 Changes To Implement the Prioritized Examination Track (Track I) of the Enhanced Examination Timing Control Procedures Under the Leahy-Smith America Invents Act, 76 Fed. Reg. 59050-55 (Sep. 23, 2011) [hereinafter Prioritized Examination].
3 Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 Fed. Reg. 36323-27 (June 26, 2006) [hereinafter Accelerated Examination].
4 *Id.* at 36324.
5 *Id.* at 36324-25.
6 Prioritized Examination, *supra* note 2, at 59051.
7 U.S. Patent and Trademark Office, Accelerated Examination FAQs 5, http://www.uspto.gov/patents/process/file/accelerated/ae_faq_091207.pdf (last visited Jan. 28, 2012); 37 C.F.R. § 1.17(h).
8 U.S. Patent and Trademark Office, Frequently Asked Questions, Prioritized Examination (Track 1), Question PE4, http://www.uspto.gov/aia_implementation/faq.jsp#heading-9 (last visited Jan. 28, 2012).
9 Accelerated Examination, *supra* note 3, at 36324.
10 Prioritized Examination, *supra* note 2, at 59051.
11 Accelerated Examination FAQs, *supra* note 7, at 9 ("In the very rare circumstance where an examiner might re-open prosecution after the filing of an appeal brief, the application would still be examined under the accelerated examination program.").
12 Frequently Asked Questions, Prioritized Examination (Track 1), *supra* note 8, at Question PE15.
13 Changes To Implement the Prioritized Examination for Requests for Continued Examination, 76 Fed. Reg. 78566 (Dec. 19, 2011).
14 U.S. Patent and Trademark Office, USPTO Track I: The Agency's Self-Report on Implementation Performance Through Year-End 2011, http://www.uspto.gov/blog/director/entry/uspto_track_i_the_agency (last visited Jan. 28, 2012).
15 Frequently Asked Questions, Prioritized Examination (Track 1), *supra* note 8, at Questions PE11 and PE13.
16 U.S. Patent and Trademark Office, Patents Examination, Prioritized Examination, http://www.uspto.gov/aia_implementation/patents.jsp#heading-5 (last visited Jan. 28, 2012).
17 See, *e.g.*, Prioritized Exam*ination, supra note 2; Frequently Asked Questions, Prioritized Examination (Track 1), supra note 8.*
18 See, *e.g.*, Accelerated Exam*ination, supra note 3; Accelerated Examination FAQs, supra note 7.*
19 An applicant typically needs to file two IDSs with the application – one "full" IDS and another IDS with the "most closely related" reference(s).
20 The publication fee is required even if a non-publication request is filed, but is refundable if the application issues and the application has not published (the assumption is that this applies if the application is abandoned without publishing, but this is not explicitly stated).

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Now What? Strategies for Responding to Final Office Actions

"THIS ACTION IS MADE FINAL."

No practitioner likes seeing this phrase in an Office action. But what does this phrase mean, and how does it affect prosecution? Because the possible responses and strategies for responding to a final Office action are often taken for granted, this article reviews the "first principles" of after-final practice. Specifically, this article explains (i) the "final" Office action, (ii) when an Examiner is allowed to designate an Office action as final, (iii) strategies for challenging the prematurity of a final designation of an Office action, (iv) the types of responses allowed to a final Office action, and (v) how to instruct prosecution counsel to respond to a final Office action.

What is a Final Office Action?

During patent prosecution, the U.S. Patent Office will issue an examination report of the patent application, referred to as an "Office Action." A number of Office Actions may be issued during prosecution of a patent application, and an Applicant may file a response to the Office Action rebutting any objection/rejection set forth by the Office. Unfortunately, the Patent Rules[1] do not provide a concise definition of a "final" or "non-final" Office action. Rather, these Office actions are defined by the types of replies allowed by an Applicant to the respective type of Office action. Generally, there are no limitations on the types of replies allowed by an Applicant to non-final Office actions, and an Applicant is allowed to freely amend any pending claims.[2] In contrast, replies to a final Office action are generally limited to canceling claims, filing an appeal, and/or filing an RCE among a few other options.[3] These (and other) options are discussed in detail below. Generally, non-final Office actions are preferred over final Office actions because they allow the Applicant a full range of responses.

Is the Final Office Action Premature?

The Patent Rules state that any second or subsequent Office action "may be made final,"[4] however, the M.P.E.P. places limitations on when an Examiner is allowed to designate as final any second or subsequent Office action. Nonetheless, Examiners often prematurely designate an Office action as final.

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In a response to a Final Office Action, an Applicant generally cannot make claim amendments other than to cancel claims; therefore, such a response should generally be limited to arguments as to why the pending claims are nevertheless allowable over the Examiner's rejections.

M.P.E.P. 706.07(a) states that an Examiner may not designate an Office action as final if the Examiner introduces a "new ground of rejection" of a non-amended claim (and the Applicant did not submit an information disclosure statement (IDS) after the Examiner mailed the previous Office action).[5] This is true even if the Examiner introduces a new ground of rejection for just a single non-amended claim—in that case, the entire Office action must nevertheless be designated as non-final.[6]

So what is a new ground of rejection? First, a rejection relying upon a new statutory basis is a new ground of rejection.[7] Second, a rejection relying on a new prior art reference is almost always a new ground of rejection.[8] One case recognized an exception for a prior art reference that is a "standard work" (*e.g.*, a dictionary) cited "only to support a fact judicially noticed."[9] This exception, however, has not been extended beyond standard works.[10]

Third, the Federal Circuit has stated that a rejection relying on "new facts and rationales" raises a new ground of rejection.[11] Such new facts and/or rationales give rise to a new ground of rejection even if the rejection relies upon the same statutory basis or upon the same prior art references.[12] The new facts could be "facts concerning the scope and content of the prior art," as an example.[13]

If a previous Office action response introduced claim amendments, or if the Applicant untimely filed an IDS subsequent to receiving the previous Office action, then the Examiner is prohibited from designating the Office action as final if the new ground of rejection was not "necessitated" by the amendment or the IDS.[14] An exception to this rule exists if the "new ground of rejection" was necessitated by information submitted by an Applicant in an untimely IDS.[15] Under such circumstances, the Examiner may properly designate the Office action as final, even if the claim was not amended.[16]

Challenging the Prematurity of a Final Office Action

Practitioners wanting to obtain review of the prematurity of a final Office action may petition the Director of the U.S. Patent and Trademark Office.[17] The time

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for appeal is not stayed while the petition is pending before the Director,[18] and the Board of Patent Appeals and Interferences lacks jurisdiction over the finality of Office actions. Therefore, petitioning the finality of Office actions may not be the best option in a number of cases.

The best course of action for dealing with a premature holding of finality is often to bring the issue up directly with the Examiner. The Examiner may decide, at Applicant's request, to withdraw the finality of the Office action.[19]

Responding to a Final Office Action

In a response to a Final Office Action, an Applicant *generally* cannot make claim amendments other than to cancel claims; therefore, such a response should generally be limited to arguments as to why the pending claims are nevertheless allowable over the Examiner's rejections.[20] Responses to amendments after final are generally fast—the Office tries to respond within one month of a response after final.[21]

In response to a Final Office Action, an Applicant may file claim amendments (in addition to arguments) in conjunction with a request for continued examination (an "RCE") under Patent Rule 1.114.[22] Claim amendments filed with an RCE generally achieve the same result as claim amendments filed with a continuation application (discussed below).[23] However, an RCE may have two important advantages over filing a continuation. First, RCEs tend to be acted upon sooner than a continuation application. While USPTO procedures give the same examination priority to RCEs as continuation applications,[24] in practice, the total time from filing an RCE to receiving an Office action is, on average, only 4.9 months.[25] Second, the USPTO charges Applicants less to file an RCE than to file a continuation application.[26]

An Applicant may respond to a Final Office Action by initiating an Appeal to present arguments in the Appeal to the Board of Patent Appeals and Interferences.[27] An advantage of the appeal process is that a Board of Administrative Patent Judges, rather than the Examiner, decides whether the arguments have merit.[28] This approach is good for those situations where the Examiner is simply unwilling to be persuaded and the Applicant needs a second opinion. To date, the entire appeal process is more expensive than filing an RCE, but less expensive than filing a continuation application.[29] A disadvantage, however, is the amount of time taken for the appeal process. At the end of 2011, the average pendency of decided appeals from the time the notice of appeal was filed was thirty-three months, or nearly three years.[30]

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If Applicant's goal is to minimize the fees associated with any response associated with a reply to a final Office action, then prosecution counsel should avoid the appeal process and continuation applications.

Rather than pursuing a full appeal, an Applicant may initially pursue a pre-appeal brief conference request, in which a panel of examiners (including the Examiner of record) will consider the merits of an Applicant's appeal and issue a summary decision indicating that the appeal should be maintained, that prosecution should be reopened, or that the application should be allowed to issue as a patent.[31] An advantage of this approach is that the USPTO does not charge any extra fees for requesting a pre-appeal brief conference beyond the fees for filing an appeal.[32] Further, 38% of all requests result in the panel reopening prosecution.[33] Another advantage is that, like a full appeal, a pre-appeal brief conference reduces the influence of the Examiner of record over the decision to maintain the rejection. A conference decision is usually received within the same time period that an Applicant would expect to receive an Office action response.

Lastly, an Applicant may file a continuation application, which is "a second application for the same invention claimed in a prior nonprovisional application and filed before the original prior application becomes abandoned or patented."[34] As noted above, a continuation application is slower and more expensive than filing an RCE.[35] However, Applicants may prefer to file a continuation application to delay examination of the application in order to, for example, increase the chances that a different examiner will examine the application.

If no response is filed, the application will go abandoned. This is the least expensive

option since neither USPTO fees nor attorney fees will be required to respond to the Office action.[36] Of course, this option also ends any chance of receiving a patent.

Instructing Your Prosecution Counsel on What Course of Action to Take

The instructions provided to prosecution counsel will likely depend on the goals that an Applicant is seeking to achieve. A few of those goals are described below.

Minimize Pendency of Application

An Applicant desiring review of the Examiner's rejection may consider instructing counsel to file a pre-appeal brief conference request along with a notice of appeal since an Applicant can usually expect to receive a conference decision in about the same amount of time as it would take to receive an Office action response. If the conference decision is adverse to the Applicant, counsel can file an RCE rather than maintaining the appeal.

If an Applicant wants to make claim amendments after receiving a final Office action, then counsel should file an RCE. If the Applicant simply wants to present arguments in response to receiving a final Office action, then counsel should file an amendment after final.

Minimize USPTO Fees

If Applicant's goal is to minimize the fees associated with any response associated with a reply to a final Office action, then prosecution counsel should avoid the appeal process and continuation applications. Prosecution counsel should instead present arguments and requests for reconsideration in an amendment after final, which does not require any fee. While an Examiner generally will not enter claim amendments made in an amendment after final, the Examiner will usually indicate (via an advisory action) whether the claim amendments would overcome the current rejection and advance prosecution, perhaps saving the Applicant the cost of filing an RCE with ineffective claim amendments.[37]

To further minimize costs, amendments after final should be filed within two months of the mailing date of the final Office action. By filing within this time period, any extension of time fees necessary for filing an RCE (among other options) are reduced according to the amount of time it took the Examiner to respond (though the Applicant is still required to file an RCE within six months of receiving the final Office Action).[38]

Maximize Patent Term

If Applicant's goal is to maximize the term of the patent, then prosecution counsel should avoid filing RCEs. The USPTO will grant Patent Term Adjustment and extend the term of a patent if the Office does not expeditiously examine and grant a patent.[39] For example, the USPTO will extend the term of a patent by one day for each day beyond three years that the patent application is pending before it becomes a patent. However, that delay will no longer accrue after the filing of an RCE.[40] Accordingly, counsel should instead respond to a final Office action with an amendment after final, a pre-appeal brief conference request, and/or a notice of appeal, which will not *per se* negatively affect PTA.

Conclusion

By understanding the circumstances under which an Examiner is allowed to designate an Office action as final, an Applicant can determine whether (and how) to challenge the prematurity of a final designation. Further, an Applicant can better instruct prosecution counsel on how to respond to the final Office action by understanding the types of responses allowed to a final Office action (and the pros and cons of each).

Endnotes

1 37 C.F.R. § 1.1 *et seq.* (2010).
2 37 C.F.R. § 1.111.
3 *Id.*; 37 C.F.R. § 1.116; U.S. Patent & Trademark Office, Manual of Patent Examining Procedure 714.12 (8th ed., rev. 8, 2010) [hereinafter M.P.E.P.].
4 37 C.F.R. § 1.113.
5 M.P.E.P. 706.07(a).
6 *Id.*
7 *In re Meyer*, 599 F.2d 1026, 1031 (C.C.P.A. 1979).
8 *In re Boon*, 439 F.2d 724, 727-28 (C.C.P.A. 1971).
9 *Id.*
10 *Id.*
11 *In re Stepan Co.*, 660 F.3d 1341, 1344-45 (Fed. Cir. 2011); s*ee also In re Leithem*, 661 F.3d 1316, 1319 (Fed. Cir. 2011) (stating that "The thrust of the Board's rejection changes when, as here, it finds facts not found by the examiner regarding the differences between the prior art and the claimed invention, and these facts are the principal evidence upon which the Board's rejection was based").
12 *In re Stepan Co.*, 660 F.3d at 1345.
13 *In re Leithem*, 661 F.3d at 1320.
14 M.P.E.P. 706.07(a).
15 *Id.*
16 *Id.*
17 *See* 37 C.F.R. § 1.181(a)(1); *see also* M.P.E.P. 706.07(c).
18 37 C.F.R. § 1.181(f).
19 M.P.E.P. 706.07(d).
20 *See* 37 C.F.R. § 1.114.
21 M.P.E.P. 714.13 ("The U.S. Patent and Trademark Office goal is to mail the examiner's action on the reply within 1 month from the date on which the amendment or reply is received by the U.S. Patent and Trademark Office.").
22 *Id.*
23 *C.f.* M.P.E.P. 706.07(h) ("35 U.S.C. § 132(b) provides for continued examination of an application at the request of the applicant (request for continued examination or RCE) upon payment of a fee, without requiring the applicant to file a continuing application under 37 CFR § 1.53(b)").
24 Both continuing applications and RCEs

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are placed on an Examiner's "special new" docket. David J. Kappos, U.S. Patent and Trademark Office, Notice of Change to Docketing of Requests for Continued Examination (Sept. 19, 2009), http://www.uspto.gov/web/offices/com/sol/og/2011/week52/TOCCN/item-102.htm.

25 U.S. Patent and Trademark Office, USPTO Data Visualization Center, http://www.uspto.gov/dashboards/patents/main.dashxml (last accessed Feb. 20, 2012).

26 USPTO Fee Schedule, available at http://www.uspto.gov/web/offices/ac/qs/ope/fee092611.htm.

27 37 C.F.R. §§ 41.33(a)-(c), 41.37(c)(1)(vii) (2010).

28 35 U.S.C. § 6(a).

29 USPTO Fee Schedule, *supra* note 26.

30 U.S. Patent and Trademark Office, B.P.A.I., FY 2011 Performance Measures, http://www.uspto.gov/ip/boards/bpai/stats/perform/FY_2011_Performance.jsp (last accessed Feb. 20, 2012).

31 Joseph J. Rolla, U.S. Patent and Trademark Office, New Pre-Appeal Brief Conference Pilot Program (June 20, 2005), http://www.uspto.gov/web/offices/com/sol/og/2005/week28/patbref.htm.

32 USPTO Fee Schedule, *supra* note 26.

33 75 Fed. Reg. 69831 (Nov. 15, 2010), *available at* http://edocket.access.gpo.gov/2010/pdf/2010-28493.pdf.

34 M.P.E.P. 201.07.

35 *Id.*

36 *See* USPTO Fee Schedule, *supra* note 29.

37 M.P.E.P. 706.07(f).

38 M.P.E.P. 714.13.

39 37 C.F.R. § 1.702(a)-(e).

40 37 C.F.R. § 1.703(b)(1).

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MBHB Opens New Office in Heart of Research Triangle Park Region of North Carolina

McDonnell Boehnen Hulbert & Berghoff LLP ("MBHB") is pleased to announce the opening of a new office in the heart of the Research Triangle Park ("RTP") region of North Carolina. Opening February 1, 2012 in Durham, the new office is located in close proximity to the state's world renowned Research Triangle Park, an area widely regarded as one of the most prominent high-tech research and development centers in the United States. Surrounded by North Carolina State University, Duke University, University of North Carolina at Chapel Hill, and the cities of Raleigh, Durham, and Chapel Hill respectively, RTP is home to numerous high-tech companies and enterprises.

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