

**Patent Prosecution
Tool Kit
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Introductory Message

Patent prosecution continues to evolve as rapidly as the innovations that patents protect. The America Invents Act of 2011 (AIA) ushered in the most significant changes to the U.S. patent system in over 50 years, and since then the courts are continuing to shape how the AIA should be interpreted. Recent court decisions on patent subject matter eligibility and biosimilar drug development have added further complexity to the landscape.

Indeed, preparing and prosecuting a quality patent application requires skill on many levels: a comprehensive technical understanding of the invention, a grasp of how it will be used in the business world, knowledge of how the U.S. Patent and Trademark Office (USPTO) examines applications, foresight to how courts interpret patent claims, awareness of the strategies used to avoid or design around a patent, and anticipation of possible enforcement efforts and invalidity challenges.

For more than four decades, Sterne Kessler has been preparing and prosecuting patent applications. We draft and prosecute utility, design and plant patents for companies with extensive, active patent portfolios, as well as smaller start-up companies that rely on the patent system to obtain funding and head off competition. We also apply our in-depth knowledge of the laws and workings of the USPTO to advise on complex patent issues such as strategic patent portfolio planning, freedom to operate and patentability assessment, patent infringement and invalidity analysis, and adversarial patent matters. In recent years, we have leveraged our leadership in post grant proceedings at the Patent Trial and Appeal Board to obtain strong and defensible patents for our clients.

This Tool Kit was created as a desk reference to highlight just some of the aspects of patent prosecution that Sterne Kessler's professionals are practicing day in and day out. Please let us know if you need more detailed information, and we will be happy to assist you.

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Table of Contents



Capturing After-Discovered Embodiments in Biotech Patents By Careful Prosecution	Tab 1
Patenting The Product Label	Tab 2
Implications of the BPCIA on the IP Strategies of Brand Companies and Biosimilar Developers	Tab 3
Summary of Subject Matter Eligibility: Biotech/Pharma Inventions	Tab 4
Update on Patent Subject Matter Eligibility and Abstract Ideas	Tab 5
Information Disclosure: Avoiding Common Pitfalls	Tab 6
Fast Track Patent Examination	Tab 7
The Changing Face of Non-Obviousness	Tab 8
Invoking an AIA Exception to Prior Art, 1.130 Declarations	Tab 9
1.132 Declarations For Traversing Rejections	Tab 10
Obviousness-Type Double Patenting	Tab 11
Patent Term Adjustment	Tab 12
Patent Term Extension	Tab 13
Federally Funded Inventions and Compliance with the Bayh-Dole Act	Tab 14
When to Obtain Foreign Filing and Export Licenses	Tab 15
Global Design Patent Guide	Tab 16
Medical Device Considerations	Tab 17

Tab 1: Capturing After-Discovered Embodiments in Biotech Patents by Careful Prosecution



Capturing After-Discovered Embodiments in Biotech Patents by Careful Prosecution

By: Jorge A. Goldstein, Ph.D.



A Maddening Habit

Biotechnology is an unpredictable science. When its practitioners wish to enforce their patents, they often run into a serious problem. Unlike chemists or pharmacologists, who for a century or so have used chemical formulas to describe their inventions, biotechnologists, who claim new biological molecules or their uses, have a maddening habit of giving them proper names, such as “interferon,” “CD20,” or “antiretroviral agent.” The problem is that the names they use today to describe and claim their entities may well—due to rapid scientific developments—acquire a different meaning years from today, when the patent holders are ready to assert their rights. Frequently, the proper name used at filing to denote a *specific* molecule has become, at infringement time, a *category* of molecules.

The classic example is the term “interferon,” which, on the 1958 priority date of his patent application, Dr. Isaacs, the inventor, thought to be one antiviral molecule found in chicken and mice; today, the same word, “interferon,” is used to denote a genus of over 35 *different molecules* classified into three different types (alpha, beta and gamma) and multiple subtypes. So, what happens to a claim that was filed in 1958, that says, “A method of treating viral infections which comprises administering to a patient in need thereof an antivirally-effective amount of interferon”? What if (assuming an extremely long patent life) such a claim is asserted today against some “interferon” that was not even known to exist on the priority date? Is the claim literally infringed? Is it invalid for lack of enablement? Something in between?

Short of being all-prescient seers and predicting that the name given a species at filing will become a *genus* at infringement, are there any strategies that patent applicants (and their prosecution counsel) can use, that will give them some hope of dominating later discovered (yet highly similar) embodiments at infringement time? Is there any way to draft patent applications and prosecute their claims, so as to convince a court years later to interpret the claims broadly enough to capture embodiments discovered after the priority date? Those are the questions we will try and answer in this article.

The Case Law on After Discovered Embodiments

Before we get going, it is worth a quick detour to explain the basic case law on capturing After-Discovered Embodiments (ADEs). Historically, and depending on the foreseeability of the ADE on the priority date, the decisions split into two branches, and one of these further into two more sub-branches.

- **First Branch. ADE is foreseeable on the priority date: claim held invalid.** In cases where the ADE is foreseeable but neither enabled nor described on the priority date and the language of the claim (as construed on the *infringement* date) is broad enough to literally read on the accused ADE, the claim is held invalid under 35 USC § 112(a). Examples are *Plant Genetic Systems v. DeKalb* (Fed. Cir. 2003); *Monsanto v. Syngenta* (Fed. Cir. 2007); and *AbbVie Deutschland v. Janssen* (Fed. Cir. 2014).

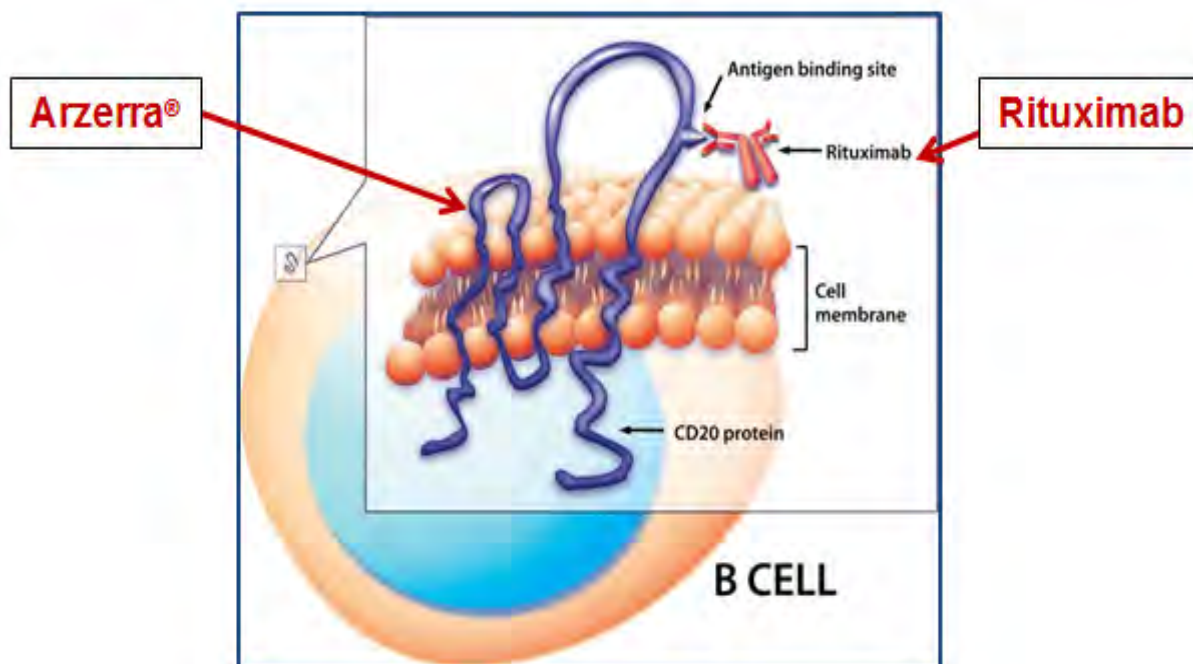
AbbVie Deutschland is illustrative of this First Branch. The main claim was, “A neutralizing isolated human antibody... that binds to human IL-12 and disassociates from human IL-12 with a k_{off} rate constant of $1 \times 10^{-2} s^{-1}$ or less...” The CAFC held the claim invalid based on insufficient written description of the broad genus of antibodies with the claimed k_{off} rate constant. There was only sufficient description of one subgenus of 300 human antibodies (V_H3 -type), but it was not representative of another foreseeable subgenus (V_H5 -type, also within the claim) that encompassed the accused, after-discovered antibody. The broad claim in *AbbVie Deutschland* was held invalid for being broader than the written description.

- **Second Branch. ADE is unknown or unforeseeable on priority date: claim saved.**

In these circumstances, where the patent applicant is unknowing, the courts are more forgiving than in the First Branch, and generally do not invalidate the claim. This branch splits into two sub-branches:

- ◊ **Second Branch, Sub-branch (1): Claim construed narrowly and no literal infringement.** In most cases where the ADE is not known or foreseeable on the priority date and the language of the claim (as it might be construed on the *infringement* date) is broad enough to read on an accused ADE, the claim is construed narrowly and limited in scope to the embodiments that are enabled and described at the priority date; in consequence, the courts find no literal infringement. Examples are *Genentech v. Wellcome* (Fed. Cir. 1994); *Schering v. Amgen* (Fed. Cir. 2000); *Amgen v. Hoechst Marion Roussell* (Fed. Cir. 2003) and *Biogen IDEC v. Glaxo* (Fed. Cir. 2013)).

Biogen IDEC v. Glaxo is illustrative. The claim was for a method of treating chronic lymphocytic leukemia (CLL) in a patient, including the limitation “...administering to the patient an anti-CD20 antibody...” The invention was based on using, as therapy, an anti-CD20 antibody, Rituximab, which, at the filing date, was known to bind the antigen CD20 that appeared on the cell membranes of lymphoma cells. It was later discovered that Rituximab bound to just one of at least two different epitopes on CD20, the one now known as the “large loop”; no other epitope was known at the filing date or described in the specification. The claim was asserted against the ADE antibody Arzerra®. The accused Arzerra® is also an anti-CD20 antibody but it binds to a different epitope, the so-called “small loop” epitope, discovered after the filing date. The following Figure illustrates both antibodies binding to the same antigen, although to different epitopes:



While Biogen IDEC, alleging literal infringement, relied on their broad claim language, “anti- CD20 antibody,” the CAFC held that “anti-CD20” meant “rituximab and antibodies that bind to the same epitope of the CD20 antigen with similar affinity and specificity as rituximab,” basing its conclusion on prosecution history disclaimer. The narrowly construed claim survived but was not literally infringed by Arzerra®.

- ◊ **Second Branch, Sub-Branch (2): Claim construed broadly and literal infringement.** Rare are the decisions where the ADE is not known or foreseeable on the priority date, the language of the claim (as construed on the *infringement* date) is broad enough to read on the ADE, and yet the court finds literal infringement. Examples are *U.S. Steel v. Phillips* (Fed. Cir. 1989); *Scripps v. Genentech* (Fed. Cir. 1991); and *Stanford v. Roche* (D. Ct. ND CA. 2007)). These cases may hold lessons for us.

Stanford v. Roche, although a decision of a District Court, is illustrative. The claim here was for a method of evaluating the effectiveness of anti-HIV therapy using a broad “antiretroviral agent.” The court found the claim term “antiretroviral agent” to be generic, even though the only such agents known on the 1992 filing date were *reverse transcription* inhibitors. It held that the claim captured the accused ADE *protease* inhibitors, whose use

was invented in 1995–1996. Roche’s argument that “antiretroviral agent” should be defined as limited to agents available for the treatment of AIDS/HIV infected patients in 1992, was rejected. The claim term was held to read on a broader *genus* of agents, not just on the subgenus of reverse transcription inhibitors.

A Multi-Million Dollar Question

The multi-million dollar question to inventors and their lawyers is: How do you avoid invalidity of the claim (as in the First Branch), save it (as in the Second Branch), and get it construed broadly so as to capture the ADE as literally infringed (as in the Second Branch, Sub-Branch (2))? Put differently, how do you avoid *AbbVie Deutschland* and *Biogen IDEC*, yet catch the golden ring of *Stanford v. Roche*? While this is not easy, it may be doable with careful drafting and prosecution. Here are some lessons gleaned from the case law.

Lesson Number 1. Even after the first filing date, an objectively unknowing inventor should stay up on developments in the technology and re-file as necessary.

Obviously, if an inventor or her attorney do not know of or cannot foresee ADEs, they will be spared the sting of patent invalidity for lack of enablement. The inventors in *Biogen IDEC* did not lose their claims, even though they failed to describe and enable antibodies to the small loop of CD20. Their claims survived, although in narrow, not literally infringed, fashion. However, even narrow survival means the possibility of asserting the Doctrine of Equivalents in litigation. Thus, while objective ignorance leads to claim survival, it is with a *major qualification*: One cannot be *willfully* ignorant, putting one’s head in the sand like an ostrich. When the court asks what was known or foreseeable on the priority date, it will always use an objective standard: that of the POSITA, the person of ordinary skill in the art. An inventor will be charged with knowing everything there is to know on the filing date, so she might as well actually know it. Then, as the technology develops further and ADEs appear in the literature, she can update every subsequent re-filing, as in a new provisional or CIP. If, say, a new epitope has been discovered, it may be worthwhile filing a CIP to describe it as another example within the broad genus claim; this may allow a judge at *infringement time* to broadly interpret a term like “CD20 antigen” so as to encompass both epitopes. (A claim to the *specific* new ADE will have a new priority date; we are discussing here preserving the original date for the *generic* claim.)

Lesson Number 2. If, at the priority date, an inventor foresees other embodiments, especially of a different type than the ones exemplified, he should mention them as part of the first filed generic description, try and reduce at least one example to practice, and file a subsequent application.

If, at the priority date, the inventor can foresee the existence of not yet discovered embodiments, such as the different antibody chains of the V_H5-type in *AbbVie Deutschland*, he should at least mention this in the patent application as a prophetic description of a broader genus. Ideally, the inventor should later try and reduce such embodiment to practice and add it in a new provisional or CIP application. This addition would be a means to *confirm* his earlier prediction of a broad genus, and support a generic claim without losing the earlier priority date.

Lesson Number 3. An inventor should always try and use in her original specification language of category, not of species or narrower subgenus.

Even if an all-knowing and prescient inventor stays up on the literature but is not able to foresee any future embodiments, she should always assume that she has invented a *group* of molecules, not just one. As in *Stanford v. Roche*, she should use language of broad category at the filing date: not “reverse transcription inhibitors” but “antiretroviral-agents.”

Lesson Number 4. The attorney should include claims of different scope and not drop them during prosecution.

The applicant in *AbbVie Deutschland* failed to include and maintain a dependent claim drawn to the distinct class of 300 V_H3-type human antibodies that he had made. All he did was claim the broadest genus functionally, by k_{off} rate. Had he included a dependent claim drawn to the V_H3-type he fully described, such a claim would have survived invalidity for lack of written description. Then, during litigation, it may have been held to be infringed by the accused V_H5 antibodies under the Doctrine of Equivalents. There was no such claim in the *AbbVie* patent and it never happened.

Lesson Number 5. Both inventor and attorney should try and glean a “principle of the invention” and include it in the specification.

There is a great case, *U.S. Steel Corp. v. Phillips Petroleum Co.* (Fed. Cir. 1989), that should help unknowing biotech inventors who have made pioneering inventions. The claim was, “Normally solid polypropylene, consisting essentially of recurring propylene units, having a substantial crystalline polypropylene content.” The CAFC looked beyond the literal words of the claim, focused on the so-called “principle of the invention” (which it decided was “high crystallinity”), and held that an ADE of even higher crystallinity (unforeseeable at the priority date), infringed literally. Both the claimed and accused polymers shared the same “high crystallinity” principle said the court, and it remained unchanged in the accused product.

Given the advantage of relying on a “principle,” and even if it may be difficult to glean one from the discovery of a single biological species, we recommend describing such a principle in the specification. If a smart scientist or attorney can understand a principle (e.g. “crystallinity” or “CLL sensitivity to anti-CD20 antibodies”), they should describe it. Invoking a principle may lead to broad claim construction and allow the capture of ADEs by literal infringement. Even if the claim is construed narrowly, the description of a principle may assist in achieving success under the Doctrine of Equivalents (which, in its modern three- part test, is but a refinement of its 19th Century form, i.e., “comparing the principles of the claimed and accused devices”).

Lesson Number 6. Use Means-plus-function and Think Outside The Box

Let us propose one more rather unconventional approach to capturing ADEs by careful claim drafting: the use of means plus function claims under 35 U.S.C. § 112 (f) (previously known as 6th paragraph). In 2014, in *Williamson v. Citrix Online, LLC*, the CAFC held that the absence of the words “means for” does not preclude applying means plus function analysis; there is no longer a strong presumption to that effect. This development may help biotechnology holders - who rarely, if ever, use claims in means plus function format - achieve a generic interpretation of its claims. This is especially the case when the situation is one where the “means” described in the specification at the filing date has changed by the time of infringement. And, if the prosecuting attorney can include a means plus function claim, the better.

Assume that the *Biogen IDEC* inventors had obtained a claim as follows, “A method for treating CLL in a human patient, comprising the step of administering to the patient an effective amount of antibody means to bind to CD20, so as to treat the CLL...” The term “administering antibody means...” could (and should) be construed to cover the “corresponding... material...described in the specification and *equivalents thereof*.” The material described in the specification is Rituximab, the existing antibody against the large loop epitope of CD20. The focus then is on the statutory phrase “and equivalents thereof.” The claim construction argument to be made in court is that the claim term “antibody means” should be construed to cover all manners of antibodies that bind to CD20 that act in an equivalent manner to Rituximab. Under established case law from the CAFC, the structural equivalency test under 35 U.S.C. § 112 (f) is a “way-result” two-part test; the function of the accused structural equivalent needs to be identical to that of the “corresponding...material... described in the specification...” Thus, the alleged structural equivalent of the described Rituximab (i.e., the accused antibody Arzerra®), while performing the identical function, must do so in substantially the same manner, and must achieve substantially the same result as Rituximab. If Biogen IDEC could convince the court that the claim should be construed broadly enough to read on antibodies that bind to different epitopes of CD20, including some to the small loop, and provided that the two-way test is met, the patentee would have a claim that is *literally* infringed. *That* is the golden ring of capturing ADEs.

A more in-depth analysis of this topic can be found in Goldstein, J.A., 25 Fed. Cir. Bar J. No. 3, 401-451 (2016).

Tab 2: Patenting the Product Label



Patenting the Product Label

By: Marsha Rose Gillentine, Ph.D. and Eric K. Steffe



When the U.S. Food and Drug Administration approves a new drug, it also approves a package insert of the drug, known as a “product label.” A pharmaceutical company marketing a generic product is required to package their product with a product label. The generic product label is typically substantially similar to the brand product label. Rarely does a generic company perform a step recited in a method of use patent, such as “treating a patient.” Therefore, to establish patent infringement, a patentee must demonstrate the company induced a third party, *e.g.* the doctor or patient, to perform the claimed method.

Overview of Inducement as Applied in the Pharmaceutical Context

- A party “causes, urges, encourages, or aids” a direct infringement by another party.
- Must establish that the alleged infringer knowingly induced infringement and had specific intent to encourage the third party to infringe the patent.
- Pharmaceutical company has no intent to induce infringing use if the product label does not instruct a third party to use the product in an infringing manner.

What Constitutes an “Instruction for Use” in an Infringing Manner in the Product Label?

- It is not sufficient that the product label describes an infringing mode. The label must “recommend,” “encourage,” or “promote” the infringing use.
- Vague label language cannot be combined with speculation about how physicians may act.

Prosecution Strategies Regarding the Product Label?

- If possible, draft claims with the exact language included in the “Indications and Usage” and/or “Dosage and Administration” sections of the product label.
- Draft claims to match “warnings” included in the product label.
- File applications directed to new indications and patient subpopulations, especially if there is a difference in efficacy in a particular patient subpopulation.
- File applications to combination therapies, especially if the combination impacts the safety and efficacy of the original patient population.
- File applications with claims directed to the pharmacokinetic parameters *e.g.*, C_{max} , T_{max} , and AUC, included on the product label.
- If must prosecute mechanism of action claims, try to tie the mechanism of action to the approved indication.
- Draft claims with divided infringement defense in mind. All steps must be performed by a single party or under the direction of that party.

Tab 3: Implications of the BPCIA on the IP Strategies of Brand Companies and Biosimilar Developers



Implications of the BPCIA on the IP Strategies of Brand Companies and Biosimilar Developers



By: Timothy J. Shea, Jr. and Paul A Calvo, Ph.D.

The enactment of the Biologics Price Competition and Innovation Act (“BPCIA”) in 2010 established for the first time ever in the US an abbreviated pathway for obtaining FDA approval of a new biological product that is deemed biosimilar to an already licensed biological. Although the BPCIA became law in 2010, the first biosimilar product approved under the new abbreviated pathway did not hit the market until five years later. Since the introduction of Sandoz’s Zarzio® in 2015, the US biosimilar industry has grown rapidly. The US biosimilar market was \$436M in 2018, but it is projected to reach nearly \$18B by 2026.

Key Differences Between the BPCIA and Hatch-Waxman

From the outset, it was clear that the BPCIA’s abbreviated pathway for biosimilars is fundamentally different from the abbreviated pathway for small molecule drugs established by the Hatch-Waxman Act in 1984. Although both statutes provide a mechanism by which patent disputes can be litigated and resolved prior to the actual launch of the biosimilar or generic product, there are few other similarities between the two statutes. Importantly, whereas Hatch-Waxman established the “Orange Book,” which provides a publicly-available listing of patents covering the brand product, no equivalent public patent listing is provided under the BPCIA. Instead, the BPCIA provides for a complicated mechanism involving the private exchange of information and patent lists between the biosimilar applicant and the reference product sponsor (known colloquially as the “Patent Dance”) which is designed to enable the parties to jointly identify and agree on the patents that will be the subject of the statutory litigation. Further, although the Hatch-Waxman Act prohibits process/manufacturing patents from being listed in the Orange Book, and consequently included in the ANDA litigation, the BPCIA contains no such restriction. This, combined with the significantly more complex nature of biological molecules and the fact that they are generally covered by many more patents, has led to a dramatic increase in the number and variety of patents that are asserted in the typical BPCIA litigation as compared to ANDA suits.

An Illustrative Case - Humira®

Indeed, a review of the BPCIA litigations to date related to antibody products showed that on average 20 patents are asserted in such litigations. In Abbvie’s BPCIA litigation with Amgen related to Amgen’s application to market Amjevita™, a biosimilar of Humira®, currently the world’s top selling drug, Abbvie identified a total of 61 patents that it said were infringed by Amjevita™. Only one of the 61 patents claimed the antibody itself. The other 60 patents were directed to dosing regimens (12 patents), indications (12 patents), formulations (8 patents), pharmaceutical compositions (9 patents), and manufacturing processes (19 patents). Moreover, only one of the 61 patents identified by Abbvie as infringed by Amgen was even in force on the date Humira was first approved by the FDA in 2002. The other patents were either pending applications at that time or were filed after Humira’s approval.

The case of Humira® illustrates two key implications of the BPCIA for brand companies. First, the importance of the core patents directed to the biological molecule itself is diminished under the BPCIA as compared to Hatch-Waxman. Because these patents are almost always filed very early in the development of the biologic product, they are often expired by the time the 12-year exclusivity period provided by the BPCIA has passed, which is the earliest point at which the FDA can approve a biosimilar. Conversely, the value of patents directed to other aspects of the reference product, such as methods of treatment, dosing regimens, manufacturing processes, etc., are significantly increased under the BPCIA as they are more likely to be the patents still in force at the time the biosimilar is approved.

Second, an innovator is wise to implement a robust patent-life cycle management strategy and consider patenting the full spectrum of innovations that occur throughout the development and commercial life of the biological product. In addition to the core biological molecule and the primary indication, consideration should be given to filings patent applications directed to:

- New indications
- Routes of administration (e.g., subcutaneous)
- Manufacturing processes
- Mechanisms of action
- Formulations
- Combination products
- Combination therapies
- Biological profiles
- Delivery devices (e.g., prefilled syringe)
- Companion diagnostics

Insights from the FDA’s Guidance Documents for Biosimilars

Additional IP implications can be gleaned from the “Guidance for Industry” documents that the FDA has issued for biosimilars since the BPCIA was enacted. The FDA issued several important Guidance documents in 2012, including: (1) Scientific Considerations in Demonstrating Biosimilarity to a Reference Product; (2) Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product; (3) Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product; and (4) Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 Guidance for Industry.

The guidance documents emphasize that the FDA will use a *totality of the evidence approach* to review applications for biosimilar products, and encourage a *stepwise approach to demonstrating biosimilarity*, which with rare exceptions will include a comparison of the proposed biosimilar product with the reference product in terms of structure, function, animal toxicity, human pharmacokinetics (PK) and pharmacodynamics (PD), clinical immunogenicity, and clinical safety and effectiveness. This stepwise approach is intended to better address residual uncertainty about biosimilarity that might remain at each step of the approval process.

The guidance documents also give some indication of which characteristics of the reference product the FDA will analyze most closely in determining whether an aBLA meets the standard for demonstrating biosimilarity. Thus, the brand company should consider pursuing patent protection around these critical parameters to better ward off a biosimilar challenge. The Guidances identify the following aspects as particularly important to the agency’s biosimilarity analysis:

Structural Identity

- *Guidance:* “In general, FDA expects that the expression construct for a proposed product will encode the same primary amino acid sequences as the reference product. . . .However, minor modifications such as N- or C- terminal truncations that will not effect safety and effectiveness may be justified. . . .” (Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, April 2015, at 9.)
- *Implication:* Exact structural identity (at AA level) may not be required to show biosimilarity – raising the possibility that patents reciting specific sequences of the reference product might be avoided (at least literally) by a biosimilar having minor sequence differences. This increases the importance of brand companies not relying too heavily on the core composition of matter patents to fend off biosimilar challenges. The brand company should pursue multiple layers of protection by patenting manufacturing methods, formulations, dosing regimens, etc.

Environmental Conditions

- *Guidance:* “Protein modifications and higher order structures can be affected by environmental conditions, including formulation, light, temperature, moisture, packaging materials, container closure systems and delivery device materials.” (Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, April 2015, at 5.)
- *Implications:* Because these are all factors that could impact demonstrating biosimilarity, innovators should consider obtaining patents on these aspects of their product to increase the burden on biosimilar competitors. For example, patents directed to pre-filled syringes containing the reference biologic product increasingly are sought by brand companies.

Comparative Assays/Devices

- *Guidance:* “The stepwise approach should start with extensive structural and functional characterization of both the

proposed product and the reference product. . . . It may be useful to further quantify the similarities or differences between the two products using a meaningful *fingerprint-like* analysis algorithm that covers a large number of additional product features and their combinations with high sensitivity using orthogonal methods.” (Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, April 2015, at 7.)

- *Implications:* Brand companies should consider patenting “fingerprints” and unique assays for characterizing their product.

Post-Translational Modifications

- *Guidance:* “Differences in certain post-translational modifications. . . *might not* preclude a finding of biosimilarity if data and information provided by the sponsor show that the proposed product is highly similar to the reference product.” (Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, April 2015, at 8.)
- *Implications:* This language suggests that there is a presumption that at least some differences in PTMs between the reference product and the proposed biosimilar will likely prevent a finding of biosimilarity. Thus, brand companies should consider patenting important PTMs, such as glycosylation profiles, as part of the overall patent life cycle management strategy for the reference product.

Formulations

- *Guidance:* “Differences in formulation between the proposed product and the reference product are among the factors that may affect the extent and nature of subsequent animal or clinical testing.” (Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, April 2015, at 10.)
- *Implications:* To the extent differences in formulation will result in additional clinical testing, which would increase both the cost and length of trials, biosimilar manufacturers will have a strong incentive to match the formulation of the reference product as closely as possible. This increases the value to the brand company of formulation patents covering the reference product.

Companion Diagnostics

- *Guidance:* “When selecting the study population for a comparative safety and effectiveness study, a sponsor should consider, for example, whether its study population has characteristics consistent with those of the population studied for the licensure of the reference product for the same indication”
- *Implication:* This illustrates the value of companion diagnostics to the brand company. If it is necessary for the biosimilar developer to use a companion diagnostic to recruit a similar study population as the reference product, then the sponsor’s patent on the CDx would be an additional hurdle that the biosimilar developer must overcome to get their product on market.

Thus, the FDA’s Guidance for Industry documents provide valuable insight into the factors the agency considers particularly important in assessing whether an aBLA submission meets the standard for biosimilarity required by the BPCIA. A reference product sponsor that is able to obtain additional patent protection around these key aspects of the brand product will increase the burden on companies seeking approval to market a competing biosimilar.

Protecting the Biosimilar Developer’s Innovation

Due to the complex nature of biological molecules, a considerable amount of innovation can be involved in developing a biosimilar product. This was illustrated in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012). The product at issue there was enoxaparin, an anticoagulant comprising low molecular weight heparin. It is made by cleaving raw heparin, which consists of sugar chains, into smaller chains. Lovenox®, marketed by Sanofi, was the reference product. Although not a typical biological product, the complexity of enoxaparin makes it more analogous to a complex biological than the usual small molecule drug. Indeed, the FDA cited the case of enoxaparin as instructive of how the agency would approach its review of aBLAs. *See, Lee, S. et al., Nature Biotech* 31:220-226 (2013).

Momenta and Sandoz both filed ANDAs to market generic Lovenox®. Due to the biochemical complexities of enoxaparin, it was difficult for ANDA filers to show the “sameness” required under Hatch-Waxman. Sanofi filed a Citizen’s Petition with the FDA to prevent the approval of generic enoxaparin until the reference product could be further characterized. The FDA denied Sanofi’s petition, but enumerated a list of criteria that had to be met for a generic applicant to show sameness to enoxaparin, including the nature and arrangement of components that constitute enoxaparin. To meet this criterion,

Momenta developed a new manufacturing control process to ensure each batch of its generic product included the same array of sugar chains characteristic of enoxaparin. Momenta sought and obtained patent protection for its proprietary process.

Momenta's ANDA was ultimately approved and it started marketing generic enoxaparin. The FDA also approved Amphastar's ANDA for enoxaparin. But Momenta immediately sued Amphastar for infringement of its process patent. The district court granted Momenta a preliminary injunction to prevent Amphastar from marketing its generic version of enoxaparin, finding a likelihood of success on the merits that Amphastar infringed Momenta's process patent. So, while the complexity of the reference product increased the difficulty for Momenta to show sameness, it compelled Momenta to develop an innovative assay that resulted in patents Momenta then asserted against another generic to keep competing generic products off the market. The preliminary injunction was ultimately vacated by the Federal Circuit on other grounds (*i.e.* that the district court had applied the wrong standard in rejecting Amphastar's defense under 35 U.S.C. §271(e)(2)). The court found that post-approval activity, such as batch testing, was not categorically outside the scope of the FDA safe harbor exemption from infringement. *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).

Similarly, in *Coherus Biosciences, Inc. v. Amgen, Inc.*, No.1:19-cv-00139 (D. Del. Filed January 24, 2019), Coherus received FDA approval to market its adalimumab biosimilar and then immediately sued Amgen, which had previously been approved to market biosimilar adalimumab, for patent infringement. Specifically, Coherus asserted that Amgen's biosimilar infringed three patents Coherus had obtained on adalimumab formulations. Coherus alleged that Amgen's manufacture in the U.S. of Amjevita for sale in Europe infringed the patents. The parties subsequently settled the case before any substantive decision by the court on the merits.

The *Momenta* and *Coherus* cases show that the techniques and strategies used by aBLA applicants in developing their product and demonstrating that it meets the standard for biosimilarity required by the BPCIA can involve a significant level of innovation that creates patenting opportunities for the biosimilar developer that can in some instances can be asserted against companies seeking to market competing biosimilar products.

Tab 4: Summary of Subject Matter Eligibility: Biotech/Pharma Inventions



Summary of Subject Matter Eligibility: Biotech/Pharma Inventions

By: Daniel K. Choo, Ph.D. and Carla Ji-Eun Kim



It has nearly been ten years since the Supreme Court's landmark *Mayo v. Prometheus* (132 S.Ct. 1289 (2012)) decision, in which the Court established a two-prong test for determining patentable subject matter under 35 U.S.C. § 101. And, yet, the law regarding patent eligibility for biotech/pharma inventions remains unsettled. In part, this is due to the paucity of appellate court decisions confirming the eligibility of claims under 35 U.S.C. §101. As highlighted in the court's opinion in denying *en banc* rehearing of *Athena v. Mayo*¹, intervention from either the Supreme Court or Congress will likely be required to provide clarity on the matter. However, based on the Court's reluctance in taking up such cases² and Senator Tillis' recent comments³, significant modification to the existing legal framework for determining patentable subject matter under 35 U.S.C. § 101 is unlikely to take place any time soon.

Under *Mayo's* two-prong test, the first step asks whether a claim is directed to a judicially recognized exception, *i.e.*, natural product, natural phenomenon, or abstract idea. If the answer is no, the claimed subject matter is patent eligible. If the answer is yes, however, the claim is further examined in step two to determine whether the additional elements recited in the claim, considered both individually and as an ordered combination, "transform the nature of the claim" into a patent eligible application by reciting an "inventive concept" that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself" (*i.e.*, not well-understood, routine, conventional activity). *Mayo* at 1294. For step two of the analysis, the judicially recognized exception is treated as if it was part of the prior art base.

To facilitate examination and to help fill the void left by the Supreme Court and Congress, the USPTO has released Interim Guidance documents with example claims (*see, e.g.*, Eligibility Examples) that it considers eligible under current case law⁴. A revised Guidance was published on January 7, 2019 ("January Guidance")⁵, with further updates (*e.g.*, Examples 43-36) and clarification provided more recently on October 17, 2019⁶. The January Guidance differs from the earlier Guidance in several ways. First, the January Guidance provides that all "abstract ideas" should fall into one of three categories⁷: (1) mathematical concepts (*e.g.*, mathematical relationships, mathematical formulas or equations, mathematical calculations), (2) certain methods of organizing human activities (*e.g.*, fundamental economic principles or practices, commercial or legal interactions, managing personal behavior or relationship or interactions between people), and (3) mental processes (*e.g.*, concepts performed in the human mind)⁸. Next, the January Guidance breaks step one of the above-described two-prong test into two sub-steps⁹: (i) whether the claim recites a judicial exception; and (ii) if the claim recites a judicial exception, whether the judicial exception is integrated into a practical application. In assessing this latter sub-step, the January Guidance expressly provides that "whether the additional elements represent well-understood, routine, conventional activity" should be excluded¹⁰. Such analysis should be reserved for step two of the two-prong test, which is only conducted if step one of the test is satisfied. Accordingly, claims reciting a judicial exception may be directed to patentable subject matter even where the additional elements that integrate the judicial exception into a practical application are well-understood, routine, and/or conventional.

To help understand when additional elements recited in a claim integrates a judicial exception into a practical application, the January Guidance provides several non-limiting examples: (i) "additional element reflects an improvement in the functioning of a computer, or an improvement to other technology or technical field" (*e.g.*, *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016)); (ii) "additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition" (*e.g.*, *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited*, 887 F.3d 1117 (Fed. Cir. 2018)); (iii) "additional element implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim" (*e.g.*, claim directed to a delivery device comprising a natural product (*e.g.*, denveric acid); *see* Example 44 in Appendix 1 of October 2019 Patent Eligibility Guidance Update); (iv) "additional element effects a transformation or reduction of a particular article to a different state or thing"; and (v) "additional element applies or uses the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment, such that the claim as a whole is more than a drafting effort designed to monopolize the exception." Non-

limiting examples of additional elements that do not integrate a judicial exception into a practical application include: (i) “additional element merely recites the words ‘apply it’ (or an equivalent) with the judicial exception, or merely includes instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea; (ii) additional element adds insignificant extra-solution activity to the judicial exception; and (iii) additional element does not more than generally link the use of a judicial exception to a particular technological environment or field of use.”

In biotech/pharma, claims can often recite a naturally occurring product or a variant thereof. Drafting these claims so that they are not “directed to a judicially recognized exception” under step one offers the safest path to patent eligibility as it altogether avoids the step two analyses. One way to achieve this goal is by ensuring that the composition recited in the claim is “markedly different” from its naturally occurring counterpart. In cases where the composition used is a product of nature, method/process claims using that composition in a non-natural way can offer a path to eligibility without the step two analyses.

In 2013, the Supreme Court held that a man-made isolated polynucleotide comprising the BRCA1 gene sequence constitutes a product of nature exception because it is not “markedly different” from the naturally occurring BRCA1 gene. *Ass’n for Molecular Pathology v. Myriad*, 133 S.Ct. 2107, 2111 (2013). The Court found, however, that a cDNA encoding BRCA1 is a patent eligible composition because it is markedly different from the naturally-occurring polynucleotides. *Id.* Similarly, the Federal Circuit in *Natural Alternatives International, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1348 (Fed. Cir. 2019), concluded that a claim directed to a human dietary supplement comprising a beta-alanine (a natural product) “in a unit dosage of between about 0.4 grams to 16 grams” is patent eligible, where the “claimed dosage forms can be used to increase athletic performance in a way that naturally occurring beta-alanine cannot.” The court also noted that a claim directed to a composition comprising a beta-alanine in combination with glycine (also natural product) can be patentable where “the claimed combination of glycine and beta-alanine could have synergistic effects allowing for outcomes that the individual components could not have.” *Id.* The court reasoned that the claims at issue “incorporate natural products, but they have different characteristics and can be used in a manner that beta-alanine as it appears in nature cannot.” *Id.*

Moreover, the Eligibility Examples mentioned previously further provide useful insight into USPTO’s view on what would be considered a “marked difference” for the purpose of eligibility. They include structural differences (*e.g.*, difference in molecular structure, crystal forms, amino acid sequence, and genetic composition) as well as functional ones (*e.g.*, increased stability, increased solubility, or new activity/function). When drafting the claims, however, care must be taken to ensure that the recited composition does not encompass a product of nature in addition to the otherwise patent eligible “markedly different” embodiments. *See, e.g., In re Roslin Institute*, 750 F.3d 1333, 1338 (Fed. Cir. 2014) (holding that claims directed to a “live-born clone of a pre-existing, non-embryonic, donor mammal” were ineligible because any differences between the clones and their donor mammals were unclaimed).

Cellzdirect, a recent Federal Circuit decision emphatically confirms that claims directed to a “method of producing a desired preparation of multi-cryopreserved hepatocytes” are patent eligible, even if the process uses a product of nature and even if the transformation is governed by the laws of nature. *Rapid Litigation Management v. Cellzdirect*, 827 F.3d 1042 (Fed. Cir. 2016) (“This type of constructive process, carried out by an artisan to achieve ‘a new and useful end,’ is precisely the type of claim that is eligible for patenting.”). The Court further found that the claims were not “directed to” a patent-ineligible concept, and therefore need not be analyzed under step two of the *Mayo/Alice* framework.

The patent eligibility of method of treatment claims was affirmed in *Vanda Pharmaceuticals* in which the Federal Circuit held that claims directed to a method of treating schizophrenia was patent eligible. 887 F.3d 1117 at 1134. The Court reasoned that the claims were not directed to a law of nature (*i.e.*, relationship between iloperidone, CYP2D6 metabolism, and QTc prolongation) and instead “directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.” *Id.* at 1136.

However, when drafting method of treatment claims that incorporate a judicial exception, it is important that the treatment aspect is the focus of the claims. In *INO Therapeutics LLC v. Praxair Distribution Inc.*, 782 Fed.Appx. 1001, 1005 (Fed. Cir. 2019) (not precedential), the Federal Circuit held that claims directed to a “method of treating patients who are candidate for inhaled nitric oxide treatment” were “directed to [a] natural phenomenon” and not patent eligible. The Court noted that, unlike the claims at issue in *Vanda*, when analyzed as a whole, the claim is not directed to “a new way of actually treating the underlying condition of hypoxic respiratory failure,” but instead the focus is directed to “screening for a

particular adverse condition that, once identified, requires iNO treatment be withheld.” *Id.* at 1007.

Thus, cases such as *Cellzdirect*, *Vanda*, and *Endo* confirm the USPTO’s position expressed in the Eligibility Examples that process claims, including method of treatment claims, are generally patent eligible unless the true focus of the claims are to claim a judicially recognized exception itself, such as was the case in *INO Therapeutics*.

Patents directed to diagnostic assays were the hardest hit by the post-*Mayo* changes in § 101 jurisprudence. All appellate decisions involving a claim directed to a diagnostic assay found it to be directed to a judicially recognized exception and not eligible after step two analysis. See, e.g., *Myriad Genetics; In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755 (Fed. Cir. 2014); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (*en banc petition denied*) (*cert. denied*); *Genetic Tech. Ltd. v. Merial LLC*, 818 F.3d 1369 (Fed. Cir. 2016); *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017); *Roche Molecular Systems, Inc. v. CEPHEID*, 905 F.3d 1363 (Fed. Cir. 2018); *Genetic Veterinary Sciences, Inc. v. Laboklin GmbH & Co. KG*, 933 F.3d 1302 (Fed. Cir. 2019); *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 760 Fed.Appx. 1013 (Fed. Cir. 2019); *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, 915 F.3d 743 (Fed. Cir. 2019). In each of these cases, the claims were drawn broadly to capture all diagnostic uses of the underlying natural phenomena regardless of the reagents employed or the starting samples used. And, in each of these cases, the courts found the claims not eligible because once the newly discovered natural phenomenon is removed from the claims, the remaining elements merely recite routine, conventional, and well-understood steps that cannot provide the inventive concept needed to transform the methods into patent eligible subject matter.

Recently the Federal Circuit in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 2019-1419 (Fed. Cir. Mar. 17, 2020) provided a potential option to avoid patent eligibility issues. The Federal Circuit reversed the district court’s grant of summary judgment, holding that the claims of U.S. Patent Nos. 8,580,751 and 9,738,931 were directed to patent-eligible subject matter and were not invalid under 35 U.S.C. § 101. The representative claim of the ’931 patent is provided below:

1. A method, comprising:

- ◇ (a) extracting DNA comprising maternal and fetal DNA fragments from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female;
- ◇ (b) producing a fraction of the DNA extracted in (a) by:
 - » (i) size discrimination of extracellular circulatory fetal and maternal DNA fragments, and
 - » (ii) selectively removing the DNA fragments greater than approximately 300 base pairs, wherein the DNA fraction after (b) comprises extracellular circulatory fetal and maternal DNA fragments of approximately 300 base pairs and less and a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA fragments; and
- ◇ (c) analyzing DNA fragments in the fraction of DNA produced in (b).

Reversing the district court’s grant of summary judgement that the claims lack patent eligibility, the Federal Circuit remanded the case for further proceedings. The Court noted that “[t]his is not a diagnostic case. And it is not a method of treatment case. It is a method of preparation case.” Applying step one of the *Alice/Mayo* test, the majority of the Court held that the claims were directed to a patent-eligible method that “exploit[s] that discovery in a method for preparation of a mixture enriched in fetal DNA.”

This decision is coherent with the USPTO’s Eligibility Examples: to be considered eligible, a diagnostic claim may need to recite the use of an assay or reagent that was not well known and in common use. If all elements of the claim were well known and in common use, it may need to recite a new, inventive combination of these elements.

While the above cases and the USPTO’s patent eligibility Guidance documents provide some guidance, there is still much uncertainty that need to be resolved. For instance, while the USPTO’s guidance provides many helpful examples, in *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, the court explicitly noted that it was “not bound by its guidance.” 760 Fed. Appx. 1013, 1020 (Fed. Cir. 2019). Therefore, it remains to be seen whether the Courts agree with the USPTO’s more recent eligibility analysis put forth in the January Guidance. Thus, IP practitioners developing a patent portfolio for biotech/pharma inventions must continue to carefully monitor the new developments in § 101 case law, or until Congress finally decides to step in and help resolve the issue.

¹*Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, 927 F.3d 1333, 1336 (Judge Lourie, concurring in declining en banc rehearing) (“Accordingly, as long as the Court’s precedent stands, the only possible solution [to patent eligibility of diagnostic claims] lies in the pens of claim drafters or legislators. We are neither.”)

²See *Athena Diagnostics*, 927 F.3d (Fed. Cir. 2019), cert. denied, No. 19-430, 2020 WL 129579; *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited*, 887 F.3d 1117 (Fed. Cir. 2018), cert. denied, No. 18-817 2020 WL 129534.

³Michael Borella, *The Zombie Apocalypse of Patent Eligibility Reform and a Possible Escape Route*, http://www.patentdocs.org/patent_legislation/ (last visited Feb. 10, 2020) (“Tilis stated ‘[g]iven the reasonable concerns that have been expressed about the draft as well as the practical realities of the difficulty of passing legislation, absent stakeholder consensus I don’t see a path forward for producing a bill—much less steering it to passage—in this Congress.’”)

⁴<https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility>

⁵The 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (January 7, 2019).

⁶October 2019 Patent Eligibility Guidance Update, available at <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility>

⁷84 Fed. Reg. 52 (January 7, 2019)

⁸The January Guidance provides six additional examples relating to abstract ideas (Examples 37-42).

⁹*Id.* at 53

¹⁰*Id.* at 55

Tab 5: Update on Patent Subject Matter Eligibility & Abstract Ideas



Update on Patent Subject Matter Eligibility & Abstract Ideas

By: Lestin L. Kenton, Jr. and Michelle K. Holoubek



Since the U.S. Supreme Court's decision in *Alice v. CLS Bank*, patent stakeholders have faced many difficulties navigating the world of patent-eligibility. Through many Federal Circuit decisions and Guidance given by the U.S. Patent and Trademark Office (USPTO) since *Alice*, there is some, but not complete, clarity on what is patent-eligible subject matter, especially for the financial services industry and any industry where **software** or **computing** forms a core part of its technology (e.g., diagnostics, analytics, data transmission, cloud-based computing, etc.).

Many are still calling for further clarity on the patent eligibility of software claims and are still questioning the ability to obtain software-based patents in multiple industries. But, there are some steps that a patent applicant or owner can take to place their cases in the best posture for overcoming a §101 challenge.

Background

On June 19, 2014, the U.S. Supreme Court issued its decision in *Alice Corp. Pty Ltd. v. CLS Bank International*, holding that computerized abstract patent ideas are not patent eligible. Specifically, the Supreme Court determined that the claims at issue "simply instruct[ed] the practitioner to implement the abstract idea of intermediated settlement on a generic computer," and were thus abstract. Subsequently, the Federal Circuit has issued several pro-eligibility decisions. However, while these pro-eligibility decisions have provided positive data points for pro-patent-eligible claims, they are far outnumbered by decisions holding claims ineligible, and thus there continues to be uncertainty among stakeholders.

USPTO Guidelines

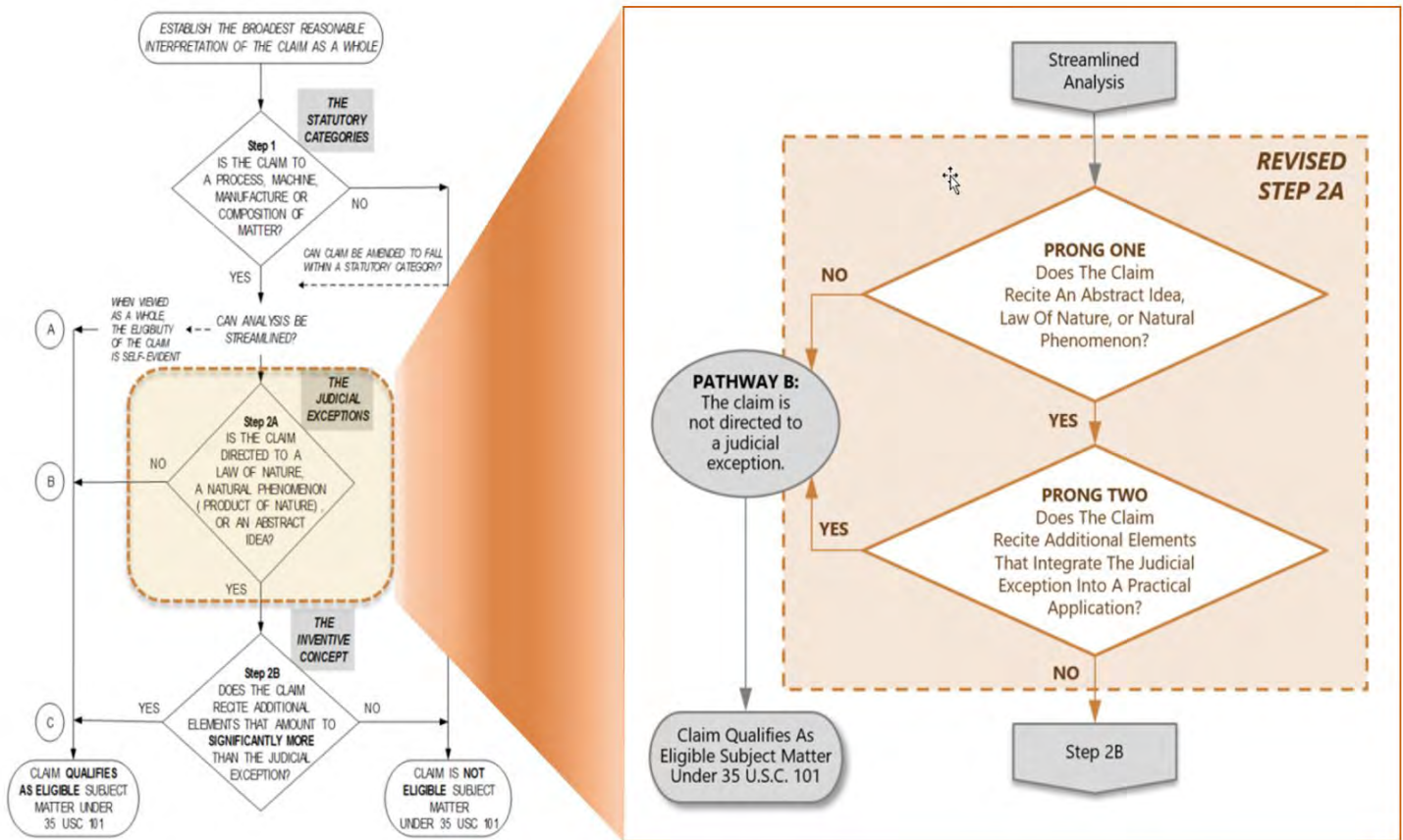
The USPTO has issued various guidelines on subject matter eligibility in an effort to bring some consistency to examination of computer-implemented innovation. The first set, issued March 4, 2014, was a response to the Supreme Court's decisions in *Mayo v. Prometheus* and *Myriad*. This guidance was specific to claims involving laws of nature/natural principles, natural phenomena and/or natural products. On June 25th, 2014, the day after the Supreme Court's decision in *Alice*, the USPTO issued guidance specific to claims involving abstract ideas. Further guidance was issued on April 19, 2018 (the Berkheimer memo). The most recent guidance was issued on January 7, 2019, with a clarifying update issuing on October 17, 2019.

In general, the 2019 revised patent subject matter eligibility guidance revamped the procedures for determining patent eligibility in the following key ways:

- The first step of the *Alice/Mayo* test was revised—providing three categories of subject matter that are considered abstract ideas: mathematical concepts, certain methods of organizing human activity, and mental processes. Only concepts that fall into those groupings can be rejected as "abstract ideas."
- Even if a claim recites an abstract idea, the claim is not "directed to" the abstract idea if the idea is integrated into a practical application.
- A claim that recites an abstract idea, but is not integrated into a practical application, is considered "directed to" the abstract idea under Step 2A and must then be evaluated under Step 2B (inventive concept) to determine the subject matter eligibility of the claim.

Combined, the UPSTO's guidance set out the following required process for any claim directed to a judicial exception:

Subject Matter Eligibility Test for Products and Processes



The combined guidance further:

- Provides examples of both statutory (patent-eligible) and non-statutory (not patent-eligible) claims, along with accompanying analysis.
- Includes a requirement that Examiners address each and every claim element, and each individual claim. Specifically, the guidance notes that “claims do not automatically rise or fall with similar claims in an application.”
- Paves a smoother path toward patenting computer-implemented innovation. Examiners must (1) Identify the specific limitation(s) in the claim under examination (individually or in combination) that the examiner believes recites an abstract idea and (2) Determine whether the claimed subject matter falls into one of the enumerated categories:
 - ◊ Mathematical concepts — mathematical relationships, mathematical formulas or equations, mathematical calculations;
 - ◊ Certain methods of organizing human activity — fundamental economic principles or practices (including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations); managing personal behavior or relationships or interactions between people (including social activities, teaching, and following rules or instructions); and
 - ◊ Mental processes — concepts performed in the human mind (including an observation, evaluation, judgment, opinion).
- Claims that do not recite matter that falls within one of these groupings should pass the eligibility test, and the analysis should end, except in very rare circumstances.

The 2019 Guidance further provides the following guidance for Examiners and Practitioners:

- When an examiner identifies an abstract idea and proceeds to Prong 2, they must evaluate whether the claim integrates the abstract idea into a practical application.

- Examiners should evaluate integration into a practical application by:
 - ◊ Identifying whether there are any additional elements recited in the claim beyond the judicial exception(s); and
 - ◊ Evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application.
- Claims integrate the abstract idea into a practical application when:
 - ◊ An additional element reflects an improvement in the functioning of a computer, or an improvement to another technology or technical field;
 - ◊ An additional element implements the abstract idea with a particular machine or manufacture that is integral to the claim;
 - ◊ An additional element effects a transformation or reduction of a particular article to a different state or thing; and
 - ◊ An additional element applies or uses the abstract idea in some other meaningful way beyond generally linking the use of the abstract idea to a particular technological environment, such that the claim as a whole is more than a drafting effort designed to monopolize the exception.
- Claims do not integrate an abstract idea into a practical application if:
 - ◊ The additional elements merely recite the words “apply it” (or an equivalent) with the judicial exception, or merely includes instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea;
 - ◊ The additional elements only add insignificant extra-solution activity to the judicial exception; and;
 - ◊ The additional elements do no more than generally link the use of a judicial exception to a particular technological environment or field of use.
- The “well-understood, conventional, and routine” analysis in Step 2B must consider all claim elements — even those previously deemed “insignificant.”
- The Examiner’s analysis during Step 2A specifically excludes consideration of whether the additional elements represent well-understood, routine, and conventional activity. Instead, this analysis is done in Step 2B.
- During Step 2A, examiners are to give weight to all additional elements, whether or not they are conventional, when evaluating whether a judicial exception has been integrated into a practical application.
- Elements found in Prong 1 to be part of the abstract idea, or elements found in Step 2A to be insignificant (or not contribute to the integration of the abstract idea into a practical application) are considered anew in determining whether the claim is “well-understood, conventional, and routine.”
 - ◊ The office gives a helpful example of a data gathering step that may be considered as “insignificant extra-solution activity” under Step 2A, yet contribute the unconventionality (and thus, the overall inventive concept) of the claim.

Practice Tips

Given the case law and current USPTO posture, we provide the following practice tips for mitigating the applicability of §101 to a claim:

Application status: Pre-filing

- Thoroughly articulate the state of the art in the background section. Then in the detailed description, **clearly articulate the improvement relative to the state of the art**. This will help you argue later that the claims recite “significantly more” than what was known in the state of the art at the time of the invention.
 - ◊ Conduct a **patentability search** to ensure improvement is accurately defined, and to ensure you understand the **technical contribution** provided by the invention.
 - ◊ Consider in advance how you would argue the **technical problem/technical solution** test for inventive step in Europe – it is possible that the U.S. is headed in that direction for eligibility.
- **Include alternative embodiments** in the specification, or discuss other methods known in the art. This will help you demonstrate that the inventive concept does not have a preclusive effect on all approaches of an abstract idea.
- **Support all claims in equal detail**, in case you need to rely on your dependent claims. Provide **detailed algorithms** for all method steps claimed, in case they are interpreted under §112(f) as means/step-plus-function claims. This is especially applicable for software claims.
- Take advantage of the limitations inherent to **means-plus-function claims**. If fully supported in your specification, means-plus-function claims may provide enough of a specific implementation to overcome a §101 challenge. Plus, such claims may be viewed favorably outside the U.S.

- Integrate **hardware** or **specialized computing devices** into the steps of the claims. Demonstrate why the steps cannot be performed by humans.
- Draft claims to avoid classification into **Tech Center 3600**, which has an extremely low allowance rate compared to other software/electronics tech centers.

Application status: Pending

- Take advantage of the **First Action Interview Pilot Program** (FAIPP). For appropriate claims, you may want to argue that your claims do not preempt all uses of the abstract idea, such that the claims qualify for “streamlined analysis.” But if the Examiner issues an office action that does not use the streamlined analysis, the weight of your preemption argument is lessened. Use the FAIPP to argue for the stream-lined analysis early on, so that the Examiner can hear your arguments before he or she performs the full analysis.
- Recognize when the Examiner has not analyzed **each and every claim** as required by the Guidelines, or has not **clearly identified the abstract idea(s)** recited in the claims. Push back against the incompleteness of a rejection when appropriate. Use this to argue that a future rejection be made non-final.
- If the abstract idea is identified as a **fundamental economic practice**, present evidence showing that the concept is not fundamental. Argue that the claimed practice only exists because of the particular technical implementation.
- If the abstract idea is identified as a **method of organizing human activity**, argue that the claims cannot be performed by a human and/or require a specific machine implementation to operate.
- Introduce **expert declarations** rebutting the Examiner’s positions. Focus on the scope of the abstract idea, or the inventiveness of the “something more.” This also has the benefit of entering expert evidence into the record during prosecution, which is generally easier than trying to enter expert evidence during an *inter partes* process.
- If an abstract idea has been identified by the examiner, confirm that the examiner is identifying an appropriate abstract idea category. Moreover, even when an abstract idea is found, ensure that the examiner is properly giving weight to all claim limitations when determining whether the abstract idea is integrated into a practical application.
- Novelty of the alleged “abstract idea” and any other extra-solution activity can now contribute to the unconventionality of the claim as a whole, such that the claim survives a patent-eligibility challenge.
- §101 law is in great flux. **Keep a continuation pending** to update the claims as the law changes.

Application status: Issued Patent

- Analyze claims for §101 issues **prior to enforcement**.
- File a narrowing (or broadening, within 2 years) **reissue** to revise claims through the USPTO.
 - ◊ Must argue that the patentee claimed more or less than he or she had the right to claim. Possibly argue that the claim amendments remove a potential preemption of an abstract idea.
- Enter an **ex parte reexamination** using **supplemental examination**. While §101 is usually not a valid ground for filing an *ex parte* reexam, there is a special carve-out for *ex parte* reexams resulting from supplemental examination. If a patentee requests supplemental examination based on §101, the USPTO will determine whether a substantial new question of patentability (SNQ) exists. If so, the USPTO will institute an *ex parte* reexamination to address the SNQ.

Tab 6: Information Disclosure: Avoiding Common Pitfalls



Information Disclosure: Avoiding Common Pitfalls

By: Michele A. Cimbala, Ph.D.



An essential part of U.S. patent prosecution is the duty of disclosure, which requires the disclosure of all known information that is material to patentability. 37 C.F.R. § 1.56.

Who Has a Duty of Disclosure?

- Anyone substantively involved in preparation or prosecution of an application, including:
 - ◊ Inventor(s)
 - ◊ Attorneys, agents, and paralegals
 - ◊ In-house patent counsel

Suggested Composition of an IDS Filing

- Information Disclosure Statement (IDS) pleading;
- Form PTO/SB/08a and/or PTO/SB/08b;
- Certifications (37 C.F.R. § 1.97(e)) and/or PTA safe harbor statements (37 C.F.R. § 1.704(d));
- Copies of the cited documents, if required;
- Fee payment, if required; and
- Other requests or petitions, if required (*e.g.*, request for continued examination, petition to withdraw from issue).

Special Considerations for an IDS Pleading

- *Explain:*
 - ◊ Materials that may be relevant to patentability are being submitted.
 - ◊ The prosecution status of the application (Before examination? After first Office action? After final rejection?) and under which rule the IDS is filed.
 - ◊ What copies of the cited documents are/are not being submitted.
 - ◊ No need to submit:
 - » U.S. patents and published applications. 37 C.F.R. § 1.98(a)(2)(ii);
 - » Documents cited by or submitted to the U.S. Patent and Trademark Office (PTO) in an IDS filed in an earlier U.S. nonprovisional application to which the current application claims benefit; or
 - » Unpublished U.S. applications stored in the PTO's Image File Wrapper system. Official Gazette, October 19, 2004.
 - ◊ Any related information or matters that you desire the examiner consider:

Examiner is expected to review the prosecution and cited art of parent applications.	MPEP 2001.06(b)
Inform examiner of any related litigation, reexamination or appeal proceeding and "material information arising therefrom."	MPEP 2001.06(c)

Special Considerations for Form PTO/SB/08a

- Form PTO/SB/08a = for citing patents and published applications
- When a patent or published application is in a foreign language, it is preferable to provide an **English language translation**.
 - ◊ Human translations are preferred if possible.
 - ◊ Machine translations are often available otherwise - check website of WIPO, EPO, JPO, KIPO, SIPO, etc.
 - ◊ **Tip:** Is the foreign language document the foreign national phase of a PCT application that was published in English?

- » **If so**, then also submit the publication of the English language PCT publication since that is either a human translation or the original language of the application.
- » Explain the relationship between the foreign language patent document and the PCT publication in the IDS pleading.
 - For example, state that the PCT publication is believed to be a translation of “at least” the specification and figures of the foreign language patent document.
 - **Note:** The claims in the foreign language patent document may be different than they are in the PCT publication.
- » List the foreign language patent document and the PCT publication separately on the IDS forms.
- ◇ **Tip:** Is the foreign language patent document the foreign national phase of a PCT application that was not published in English, but which entered national phase in a country in which it was published in English (e.g., the U.S.)?
 - » **If so**, then also list and/or submit the English language publication.
 - » Explain the relationship between the foreign language patent document and the English publication in the IDS pleading.
 - For example, state that the English publication is believed to be a translation of “at least” the specification and figures of the foreign language patent document.
 - **Note:** The claims in the foreign language patent document may be different than they were in the English publication.
 - Explain that the foreign language patent document and the English publication are national phase applications that arose from the same PCT application
 - » List the foreign language patent document and the English publication separately on the IDS forms.
 - » If the English publication is a U.S. application, attach a copy to the foreign language patent document as a courtesy to the examiner, even though it isn’t required.
- If no translations of the foreign document are available, a **statement of relevance** must be submitted.
- Alternatively, if the foreign language document was cited in a search report by a foreign patent office in a counterpart foreign application, you can submit an English language version of the search report that indicates the degree of relevance of the document.
 - ◇ A copy of the English language version of the search report must be submitted. MPEP 609.04(a)(III).

Special Considerations for Form PTO/SB/08b

- Form PTO/SB/08b = for citing all other documents or other information, including unpublished U.S. patent applications.
- The citation should include author, title of the article, title of the item (book, journal, etc.), date, page(s), volume-issue number(s) and, for books, the publisher.
- Foreign language documents must be submitted with an English language translation and/or a statement of relevance.
 - ◇ You can prepare your own statement of relevance, or you can submit an English language version of a search report that lists the foreign document, as explained above.

Timing of Filing an IDS

For an IDS Filed	Fee Required?#	Statement Under 37 C.F.R. § 1.97(e) (1)* or (e)(2)+ Required?
*Within (i) three months of the date of filing, (ii) three months of the date of national stage entry, (iii) prior to a first Office action on the merits, or (iv) before the mailing of a first Office action after the filing of a request for continued examination (RCE) <u>37 C.F.R. § 1.97(b)</u>	No	No

*More than three months after the U.S. filing date and after the mailing date of the first Office action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. <u>37 C.F.R. § 1.97(c)</u>	Pay fee or file statement	
*More than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. <u>37 C.F.R. § 1.97(d)</u>	Yes	Yes
*After payment of the issue fee, but before issuance		
1. Filed with an RCE, petition to withdraw from issue, and other required fees	No	No

For an IDS Filed	Fee Required	Statement Under 37 C.F.R. § 1.97(e)(1)* or (e)(2)+ Required?
2. <u>Quick Path Information Disclosure Statement pilot program</u> Filed with a “conditional” RCE, petition to withdraw from issue, and other required fees. If no item of information in the IDS necessitates reopening examination, the PTO will issue a corrected notice of allowability. <u>This is a pilot program. Before using it, check the PTO’s website to ensure it is still active.</u>	Yes	Yes

– \$240 for a large entity applicant, \$120 for a small entity applicant, and \$60 for a micro entity applicant.

* – “I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.” 37 C.F.R. § 1.97(e)(1).

+ – “I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.” 37 C.F.R. § 1.97(e)(2).

Special Considerations for a Statement Under 37 C.F.R. § 1.97(e)

- Statement refers to a “**counterpart**” foreign application.
 - ◊ Be careful when making this statement because not all “related” foreign applications are counterpart foreign applications.
 - ◊ A counterpart foreign application has a specific meaning:
 - » “The term counterpart foreign patent application means that a claim for priority [the PTO means foreign priority] has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (*e.g.*, an application filed

in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application).” (MPEP 609.04(b) (V)).

- A U.S. or English language counterpart of a foreign patent or application cited by a foreign patent office can qualify the IDS for certification under 37 C.F.R. § 1.97(e)(1).
 - ◇ “Some applicants submit information disclosure statements to the PTO which list and include copies of both the particular patent cited in the foreign patent office communication and the related United States or other English language patent from the family list. Since this is to be encouraged, the United States or other English language patent will be construed as being cited by the foreign patent office for purposes of a statement under 37 CFR 1.97(e)(1).” (MPEP 609.04(b)(V)).
 - » **For example,**
 - You have a counterpart application in Japan.
 - The Japanese examiner cites a published Japanese application, JP 2010-xxxxx, against your Japanese application.
 - JP 2010-xxxxx is the publication of the Japanese national phase application that arose from PCT/US2010/YYYYYY.
 - PCT/US2010/YYYYYY was published in English.
 - You are after final rejection in the counterpart U.S. application.
 - You can file the IDS and certify under 37 C.F.R. § 1.97(e)(1) not only JP 2010-xxxxx but also PCT/US2010/YYYYYY.
 - A machine translation of an office action from the EPO, SIPO, KIPO and the JPO may be available on the application’s Global Dossier (which can be reached through PAIR). However, especially with foreign search reports, always check the original language document to ensure the machine translation correctly lists all the cited art. For example, we have noticed that with supplemental search reports from CNIPA (formerly SIPO), that are on the Global Dossier (GD), the search report often shows only the patent documents that were on the search report. The non-patent documents do not show up on the GD version of the search report. Obtain a copy of the office action/search report from your foreign associate and confirm that you have a list of all the documents cited by the foreign patent office.

Establish an IDS Process

- Docket reminders to consider filing an IDS:
 - ◇ With or shortly after the filing of any new nonprovisional application;
 - ◇ When a new search report or Office action is received in a related application; and
 - ◇ Before payment of the issue fee.
- Keep a well-organized spreadsheet of cited documents in all related applications for more complex matters.
- When replying to an Office action, check that the examiner considered all previously submitted IDS’s and consider whether any new documents should be cited.
- When filing an IDS in the U.S., consider whether the documents should also be cited in any related applications in foreign countries having a duty of disclosure.

Special Considerations for Patent Term Adjustment

- Avoid filing an IDS by itself during examination.
 - ◇ Considered “failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application,” which is counted against a patent term adjustment (PTA) to which a case may be entitled. 37 C.F.R. § 1.704.
- An IDS filed alone after a reply to a restriction requirement and before a first Office action on the merits **is considered applicant delay** counted against PTA. *Gilead Sciences Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015). But, an IDS filed alone after a restriction requirement is issued and before a reply to the restriction requirement is filed, **is not considered applicant delay** counted against PTA.
- An IDS filed by itself before the mailing of a first office action after the filing of an RCE did not count against PTA from the date of filing of the RCE until the filing of the IDS. *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351 (Fed. Cir. 2019). The cited documents were related to an EP opposition that was not filed at the EPO until 546 days after the RCE was filed at the USPTO. Supernus filed an IDS citing the opposition documents 646 days after the RCE was filed. The USPTO

subtracted 646 days of PTA. *Supernus* argued that it was entitled to at least 546 of the 646 days of PTA reduction because the IDS citing the opposition documents could not have been filed before that time. The Federal Circuit agreed and found that the USPTO may not count as applicant delay a period of time during which there was no action that the applicant could take to conclude prosecution of the patent.

- **Request PTA Reconsideration:** In view of the *Supernus* decision, The USPTO published a “Notice” that, effective May 9, 2019, a patentee who disagrees as to whether the USPTO’s calculation of the period of PTA reduction exceeds the period of time during which the patentee failed to engage in reasonable efforts to conclude prosecution must raise the issue and provide relevant information in a timely request for reconsideration of the PTA (84 Fed. Reg. 20343 (May 9, 2019)). The problem is that the event from which the Federal Circuit measured the beginning of the PTA reduction in *Supernus* was a notice from a foreign authority. That type of event is not recorded in the USPTO PALM system. Therefore, the burden is on the applicant to bring such events to the USPTO’s attention and request reconsideration of the PTA calculation.
- The USPTO published a **Notice of Proposed Rulemaking** to align PTO rules with the decision in *Supernus* (84 Fed. Reg. 53090 (October 8, 2019)). The comment period closed December 3, 2019. The proposed rule revises the period of reduction of PTA in 37 C.F.R. § 1.704 for the following events: deferral of issuance of a patent, abandonment of an application, submission of a preliminary amendment, submission of papers after a PTAB or Federal court decision and submission of papers after a notice of allowance. The proposed rule specifies a period of reduction corresponding to “the period from the beginning to the end of the applicant’s failure to engage in reasonable efforts to conclude prosecution.”
- **Safe Harbor Provisions: 37 C.F.R. § 1.704(d)(i) and (d)(ii)**
PTA is not subtracted if the information:
 - ◇ Was first cited in a communication from the PTO or a patent office in a counterpart foreign or international application, and this communication was not received more than **30 days** prior to the filing of the IDS (37 C.F.R. § 1.704(d)(i)); or
 - ◇ Is a communication that was issued by the PTO or a patent office in a counterpart foreign or international application, and this communication was not received more than **30 days** prior to the filing of the information disclosure statement. (37 C.F.R. § 1.704(d)(ii))
 - ◇ To take advantage of these safe harbor provisions, be sure to clearly label the pleading as including a statement under 37 C.F.R. § 1.704(d)(i) or (d)(ii) (or use the USPTO forms below) and actually make the appropriate statement(s).
- **USPTO safe harbor forms**
To make an IDS “safe harbor” statement and to request PTA recalculation based on the safe harbor statement
 - ◇ Use the USPTO’s “Interim Procedure” for requesting recalculation of PTA with respect to IDS’s that are accompanied by a safe harbor statement under 37 C.F.R. § 1.704(d)(i) or (d)(ii). (83 Fed. Reg. 55102 (November 2, 2018)).
 - ◇ Use form **PTO/SB/133** to make a safe harbor statement under 37 C.F.R. § 1.704(d). **Important:** this form will not satisfy the requirement of 37 CFR 1.97(e).
 - ◇ Use form **PTO/SB/134** to request recalculation of PTA in view of having made a safe harbor statement under 37 CFR 1.704(d). This form must be filed within the time period set forth in 37 C.F.R. § 1.705(b).
 - ◇ Both forms are available at (<https://www.uspto.gov/patent/patents-forms>). The USPTO PALM system is being updated to automatically include these forms when calculating PTA (still in the future).

Special Considerations for Continuing Applications

- The examiner **will consider information** considered by the PTO in a parent application when examining a continuation, divisional or continuation-in-part application. MPEP 609.02.
- This information need not be resubmitted, unless the applicant desires the information to be **printed on the patent**.
- However, when filing a continuing application that claims benefit to an international application, documents cited in the international search report (ISR) and/or international preliminary report on patentability (IPRP) should be submitted.

Special Considerations for National Phase Applications

- Documents cited in an ISR should be considered when Form PCT/DO/EO/903 indicates that the ISR and copies of the cited documents are present in the national stage file. MPEP 609.03.
- **ISR, IPRP and their translations**
 - ◇ English language translations of the ISR and IPRP/Written Opinion are available for download directly from WIPO’s

website.

- ◇ If the English language translation of the IPRP/Written Opinion is not available when the IDS is filed, docket to obtain it and submit it in a supplemental IDS as a courtesy to the examiner if WIPO has not automatically sent it to the PTO.
- ◇ Be sure to check the ISR and IPRP translations to ensure they are accurate.
 - » We have found errors in the listings of the documents.
 - » For example, in the listing of the cited documents in two highly related applications, the foreign language ISRs cited different documents, but both translations cited the same documents.
 - » If you only looked at the translations of the ISRs, you would have missed important documents cited in the original ISRs.

- **Chapter II prosecution during PCT phase**

- ◇ If Chapter II was entered, check the IPRP to determine if additional documents were cited by the examiner.
- ◇ Includes:
 - » Affirmative misrepresentations of material fact;
 - » Failure to disclose material information; or
 - » Submission of false material information;
 - » With an intent to deceive.
- ◇ If you consider a document, but ultimately do not cite it in an IDS:
 - » Place a memo in the file that indicates why you decided not to cite it (*e.g.*, document is not material or is cumulative). MPEP 2004(18).
 - » Could serve as evidence of no intent to deceive.
 - » In *Therasense*, the Federal Circuit established that the materiality of a withheld reference is assessed using a “but-for” materiality test (*Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011)). The court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.
 - » The USPTO published a proposed rulemaking to amend 37 C.F.R. § 1.56 to adopt the *Therasense* but-for materiality test (81 Fed. Reg. 74987; October 28, 2016). The comment period closed in December, 2016.

Tab 7: Fast Track Patent Examination



Fast Track Patent Examination

By: Joseph E. Mutschelknaus and Peter A. Jackman



Building a patent portfolio is an important part of new product development. For many startups, patents help credential their technology and attract investment. However, backlogs at the U.S. Patent and Trademark Office (USPTO) can delay the grant of a patent by years. To deal with this delay, mechanisms to fast track patent examination have become important tools to rapidly build a patent portfolio in the U.S.

Options Prior to Examination

1. Track One - Prioritized Examination

(<http://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program>)

- The Leahy-Smith America Invents Act (AIA) established a new expedited patent review program called Track One or Prioritized Examination. Unlike prior initiatives, Track One has a lower burden on applicants, essentially only requiring that they pay an additional fee for the opportunity to receive a final disposition of an application (e.g., a Final Rejection or Notice of Allowance) within the USPTO’s goal of 12 months from the grant of prioritized status. Current statistics from the USPTO show that the Track One program far exceeds this goal.

Requirements	<ul style="list-style-type: none"> • Track One Request Form PTO/AIA/424 • Payment of all application filing fees and Track One fees • Must be filed electronically by EFS-Web if a utility application or by paper if a plant application • Request can be filed at the time of filing or with a Request for Continued Examination (RCE) • Can be made in an original or continuation utility application filing, but cannot be submitted with a national stage filing from a Patent Cooperation Treaty application • May not contain or be amended to contain more than 4 independent claims, more than 30 total claims, or any multiple dependent claims • Annual limit of 12,000 accepted requests
Cost	<p><u>Application Filing Fees</u></p> <ul style="list-style-type: none"> • \$300 basic filing fee (\$70 for electronic filing by small entity) • \$660 search fee (\$330 for small entity) • \$760 examination fee (\$380 for small entity) <p><u>Track One Fees</u></p> <ul style="list-style-type: none"> • \$4,000 Track One examination fee (\$2,000 for small entity) • \$140 Track One processing fee (\$70 for small entity) <p>Total Fees = \$5,860* (\$2,850 for small entity) *Plus any additional application size fees</p>

Advantages	<ul style="list-style-type: none"> • Can be used to receive a Notice of Allowance or first Office Action on the merits quickly <ul style="list-style-type: none"> ◊ Average time from filing Track One request to grant of request = 1.2 months ◊ 94% of requests are granted ◊ Average time from grant of Track One request to first Office Action on the merits = 1.7 months ◊ Average time from grant of Track One request to Notice of Allowance = 5.4 months ◊ Average time from grant of Track One request to Final Disposition = 6.6 months ◊ On the average, final dispositions are approximately 50% Notices of Allowance and 50% Final Rejections • No need to conduct a prior art search
Disadvantages	<ul style="list-style-type: none"> • Limited to 4 independent claims, 30 total claims and no multiple dependent claims • Can only request at the time of application filing or with a RCE • Not available for design applications or national phase applications at the time of filing • Prioritized status is lost if an extension of time is taken • Number of accepted requests is limited to 12,000 per fiscal year

2. Patent Prosecution Highway (PPH) – Global / IP5 PPH Pilot Program

(<https://www.uspto.gov/patents-getting-started/international-protection/patent-prosecution-highway-pph-fast-track>)

Requirements	<ul style="list-style-type: none"> • <u>U.S. application is eligible for PPH if:</u> <ul style="list-style-type: none"> ◊ An indication of allowable subject matter in a related application from a partnering PPH office has been received; ◊ The application with the indication of allowable subject matter and the U.S. application share a common earliest priority date; and ◊ Examination has not begun in the U.S. application. • Submit a PPH Request Form • If not available from certain websites, evidence of the positive examination results, the cited references in the related application, and their English translations may need to be submitted • A statement that the claims “sufficiently correspond” to the allowed claims serving as the basis for the request, along with an “explanation regarding the correspondence” • Must be filed by EFS-Web
Costs	<ul style="list-style-type: none"> • No additional fee required
Advantages	<ul style="list-style-type: none"> • Ability to leverage positive examination results in one country to reach a final disposition of a corresponding application in other countries more quickly and efficiently than standard examination processing • Can be used in conjunction with fast track programs available in the U.S. or elsewhere to build a global patent portfolio quickly • <u>An international PCT application or application from the following patent offices can form the basis for PPH:</u> <ul style="list-style-type: none"> ◊ Argentina, Australia, Austria, Brazil, Canada, Chile, China, Colombia, Czech Republic, Denmark, Estonia, Eurasia, Europe, Finland, Germany, Hungary, Iceland, Israel, Japan, Korea, Mexico, Nicaragua, New Zealand, Nordic Patent Institute, Norway, Peru, Philippines, Poland, Portugal, Romania, Russia, Saudi Arabia, Singapore, Spain, Sweden, Taiwan and United Kingdom, Visegrad Patent Institute • Average time from filing request in USPTO to decision on request = 72 days • 77% of petitions in USPTO are granted • High allowance and first action allowance rates compared to non-PPH applications • Prioritized status is not lost if an extension of time is taken • Lowers prosecution costs • See statistics: <ul style="list-style-type: none"> https://www.uspto.gov/sites/default/files/documents/PPH%20Quarterly%20Statistics%20Data_Year%202018.pdf

Disadvantages	<ul style="list-style-type: none"> • Substantive examination will still occur - the USPTO could identify new prior art and make new rejections • Allowed claims from a utility model or innovation patent from a country other than Korea cannot be used as the basis for the request • Developing U.S. claims that “sufficiently correspond” to the allowed claims serving as the basis for the request could be challenging in view of the differences in claiming style between countries • The allowed claims serving as the basis for the request could be broader or narrower than the desired scope for the U.S. • Provisional applications, plant applications, design applications, reissue applications, reexamination proceedings, and applications subject to a secrecy order are not subject to participation in the PPH program
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3. Full First Action Interview Pilot Program

(<http://www.uspto.gov/patent/initiatives/first-action-interview/full-first-action-interview-pilot-program>)

- Promotes personal interviews between the applicant and examiner before a first Office Action is issued
- After a request is filed, the examiner will conduct a prior art search and issue a Pre-Interview Communication, setting a one month (30 day) time period to request or decline an interview. This deadline is extendible for one additional month (30 days) with the payment of an extension of time fee of \$200 (\$100 for small entity, \$50 for micro entity)
- If agreement is not reached at the interview, the applicant will receive an Office Action and interview summary

Requirements	<ul style="list-style-type: none"> • Request to participate must be filed at least one day before a first Office Action, Notice of Allowance or Ex Parte Quayle action is mailed • Application must contain 3 or fewer independent claims, 20 or fewer total claims, and no multiple dependent claims • Must be filed by EFS-Web
Cost	<ul style="list-style-type: none"> • No additional fee required
Advantages	<ul style="list-style-type: none"> • Advances examination of applications once taken up in turn • Facilitates resolution of issues for timely disposition of an application • Program is open to all technology areas and application filing dates • Has a first action allowance rate of 29% versus 14% for applications not in the program
Disadvantages	<ul style="list-style-type: none"> • <u>Applicant agrees to:</u> <ul style="list-style-type: none"> ◊ Make an election without traverse if the USPTO determines the claims are not directed to a single invention ◊ Not request a refund of the search fee or any excess claims fee paid after the mailing or notification of the Pre-Interview Communication ◊ Not expressly abandon the application after the mailing or notification of the Pre-Interview Communication • Reissue applications are not eligible

4. Collaborative Search Pilot Program

(<http://www.uspto.gov/patents-getting-started/international-protection/collaborative-search-pilot-program-csp>)

- Purpose is to provide search results from two patent offices (USPTO and JPO or KIPO) early in the examination process so the applicant can determine their next steps in patent prosecution

Requirements

- Applicant consents to permit the USPTO and its partner Offices (JPO and KIPO) to share information
- Claims limited to 3 independent/20 total, and directed to a single invention

- Claims must correspond between Offices
- Earliest priority date must be post-AIA (March 16, 2013)
- Application must be unexamined in both Offices
- Granted Petition in both Offices
- Expires in November 2020, but may be extended
- **Potential Benefits According to the USPTO**
 - ◊ Greater consistency in examination across patent offices, leading to more certainty of intellectual property rights
 - ◊ Application is taken out of turn, resulting in expedited search results and final disposition
 - ◊ No additional fee required
- **The JPO-USPTO Pilot Program**
 - ◊ The USPTO and Japanese Patent Office (JPO) will exchange search and evaluation results identifying the best prior art and provide a work product that incorporates the efforts of the two patent offices
 - ◊ Limited to 200 applications per year, per patent office

<https://www.uspto.gov/sites/default/files/documents/JPOUSPTO%20Pilot.pdf>

- **The KIPO-USPTO Pilot Program**
 - ◊ The USPTO and Korean Intellectual Property Office (KIPO) will conduct two independent searches and provide both work products to the applicant for consideration
 - ◊ Limited to 200 applications for each patent office

<https://www.uspto.gov/sites/default/files/documents/KIPOUSPTOCSP.pdf>

5. Petition to Make Special

“Special” status and fast track examination are granted where Applicant (i) is at least 65 years old or (ii) has poor health.

(<http://www.uspto.gov/patents-application-process/petitions/23-make-special-age-and-health>)

- **Requirements:**
 - ◊ File a petition and submit evidence showing that (i) the state of health of the applicant is such that he or she might not be available to assist in the prosecution of the application if it were to run its normal course, such as a doctor’s certificate or other medical certificate, or (ii) the applicant is 65 years of age or more
 - ◊ **Note:** Any personal/medical information submitted as evidence to support the petition will be available to the public, unless submitted in compliance with MPEP 724.02
 - ◊ Not available to international applications that have not entered the national stage, design applications, reissue applications, provisional applications, or reexamination proceedings
 - ◊ No additional fee required
 - ◊ See MPEP 708.02
 - ◊ Timelines are similar to PPH, roughly 6-7 months to First Action

6. Accelerated Examination

(<http://www.uspto.gov/patent/initiatives/accelerated-examination>)

- Fast examination is also granted for performing a pre-examination prior art search
- USPTO’s goal is to complete examination within 12 months
- **Requirements**
 - ◊ File petition and fee
 - ◊ Must conduct a pre-examination search that meets certain requirements and provide an accelerated examination support document that discusses the results and patentability of the claims
 - ◊ Must agree to an interview with the examiner and elect a single invention without traverse, if needed
 - ◊ Application must contain no more than 3 independent claims and 20 total claims
 - ◊ Must be filed by EFS-Web
- **Recommendations**
 - ◊ Generally not recommended in view of the other available options that do not require a prior art search and

Options After Examination

1. After Final Consideration Pilot 2.0

(<http://www.uspto.gov/patent/initiatives/after-final-consideration-pilot-20>)

- Designed to enhance communication between the USPTO and applicant after issuance of a Final Rejection closing examination
- Authorizes additional time for examiners to search and/or consider applicant responses
- To be eligible, must file a response to a Final Rejection that includes a request for consideration under the pilot and an amendment to at least one independent claim that does not broaden its scope
- Must agree to have an interview
- Must be filed by EFS-Web
- No additional fee required
- Currently projected to end September 30, 2020, but may be extended

2. Pre-Appeal Brief Conference Programs

(https://www.uspto.gov/web/offices/pac/mpep/s1204.html#ch1200_d1fc9d_147da_3d)

- When a notice of appeal is filed in an application, the appellant may also request a Pre-Appeal Brief Conference
- Intended for applications where there are either (1) clear errors of fact in the examiner's rejections or (2) omissions of one or more essential claim elements that are needed to establish a prima facie rejection of the claims
- Once filed, the request is reviewed by a panel that consists of a supervising examiner, another examiner and the examiner of record
- Appellant must file a short memo (no more than 5 pages) in support of their request which is reviewed by the panel at the conference
- No additional fee required
- The panel can (1) allow the appeal to proceed to the Patent Trial and Appeal Board ("PTAB"), (2) allow the application, or (3) reopen examination
- Program may avoid the expense of a lengthy appeal process

3. Quick Path Information Disclosure Statement Pilot Program

(<http://www.uspto.gov/patent/initiatives/quick-path-information-disclosure-statement-qpids>)

- Eliminates the requirement for processing of an RCE with an information disclosure statement (IDS) filed after payment of the issue fee in order for the IDS to be considered by the examiner
- No additional fee required
- If no item of information in the IDS necessitates reopening examination, the USPTO will issue a corrected notice of allowability
- Must include a statement that the references in the IDS were first cited in a communication from a foreign patent office in a counterpart foreign application not more than 3 months prior to the filing of the IDS

4. Ombudsman Pilot Program

(<http://www.uspto.gov/patent/ombudsman-program>)

- Application-specific prosecution assistance when the normal channels have not provided the timely assistance needed (e.g., a communication barrier between applicant/attorney and examiner or when there is prolonged prosecution)
- A request is made by submitting an electronic form on USPTO's website
- An ombudsman assigned to the technology center for the application will then contact the requestor by telephone within one business day
- Telephone communication is encouraged, as written communications regarding the merits of an application will be placed in the application file
- No additional fee required

Other Tips on When to Use Fast Track Examination

- Fast and efficient patent portfolio creation
 - ◇ Startups seeking investment
 - ◇ Shield against known competitors
 - ◇ Sword for entry into new space
 - ◇ Meet in-house or investor expectations on numbers of patents
- Tool for patent litigation
 - ◇ Obtain additional patents to assert against competitor
 - ◇ Increase leverage during settlement negotiations
- If parent patent(s) is involved in an *Inter Partes* Review
 - ◇ Obtain additional claims before any patent owner estoppel attaches
 - ◇ Easier to amend claims during prosecution

Sterne Kessler has filed over:

268 – Track One Original Applications
310 – Other Track One Applications (includes CONs, DIVs, and CIPs)
147 – First Action Interview Requests
214 – Track One RCEs (Track One applications that include an RCE in the file history)
115 – PPH Requests (USPTO PPH decisions)
1000+ – After Final Consideration Pilot 2.0 Requests

[Source: Juristat]

Tab 8: The Changing Face of Non-Obviousness



The Changing Face of Non-Obviousness

By: Lori M. Brandes, Ph.D. and Eric K. Steffe



It is difficult to think of a case that has had more influence on patent practice than *KSR v. Teleflex* (550 U.S. 398 (2007)). In *KSR*, the U.S. Supreme Court rejected the established practice that an invention could not be obvious unless there was a teaching, suggestion or motivation in the prior art to make the invention. After *KSR*, it is unquestionably easier to establish a *prima facie* case of obviousness. As such, patent applicants and patentees are increasingly relying on secondary considerations of non-obviousness (*e.g.*, unexpected results, commercial success, or long-felt need) to overcome *prima facie* obviousness. Moreover, obviousness has become the go-to argument for many patent challengers, particularly in post-grant proceedings before the Patent Trial and Appeal Board (PTAB).

How are secondary considerations faring for patentees in post-grant proceedings?

- **Overall not well.** Out of post-grant proceedings decided from January 2018-January 2020 where secondary considerations of non-obviousness were raised, only about **15%** found the secondary considerations persuasive. For example:
 - ◇ *Lectrosonics v. Zaxcom*, IPR2018-00129, Paper 33 (PTAB Jan. 24, 2020) (evidence of industry praise and long-felt need, but not evidence of failure of others, weighed heavily in favor of non-obviousness of proposed substitute claims)
 - ◇ *Hytera Communications v. Motorola Solutions*, IPR2018-00128, Paper 47 (PTAB May 9, 2019) (evidence of competitor's copying and marketing efforts "modestly supports a conclusion that the claims would not have been obvious")
 - ◇ *Fox Factory v. SRAM*, IPR2017-01440, Paper 62 (PTAB Dec. 6, 2018) (evidence of commercial success, licensing, copying, praise by others, long-felt, unresolved need and failure by others weighed "significantly" in favor of non-obviousness)
 - ◇ *Argentum Pharmaceuticals v. Alcon Research*, IPR2017-01053, Paper 52 (PTAB Sep. 20, 2018) (evidence of "considerable" commercial success and long-felt need "tip the scales further" in favor of Patent Owner, in contrast to the "relatively weak" evidence of obviousness)
 - ◇ *Campbell Soup Company v. Gamon Plus*, IPR2017-00094, Paper 84 (PTAB Apr. 11, 2018) ("strong" evidence of commercial success, industry praise and copying by competitors supported the ultimate determination of non-obviousness)
 - ◇ *Paint Point Medical Systems v. Blephex*, IPR2016-01670, Paper 44 (PTAB Feb. 28, 2018) (copying by competitors and industry praise given weight in determination of non-obviousness)
 - ◇ *Polygroup v. Willis Electric*, IPR2016-01610 and IPR2016-01612, Paper 187 (PTAB Feb. 26, 2018) (a "remarkable amount of evidence" suggesting non-obviousness, including industry praise, copying and commercial success)
 - ◇ *Telebrands v. Tinnus Enterprises*, PGR2016-00031, Paper 88 (PTAB Feb. 7, 2018) (evidence of commercial success and industry praise, but not evidence of copying and long-felt need, was entitled to "significant" weight and supported an "overwhelming showing" of non-obviousness)
- Historically, the U.S. Patent and Trademark Office (USPTO) has been wary of secondary considerations, possibly because of the examinational nature of prosecution and reexamination.
 - ◇ In contrast, post-grant proceedings give the PTAB truth-revealing benefits of the adversarial process, including cross-examination.

What can patent applicants and patentees do?

- **Have an evidence-based narrative that explains non-obviousness.** The threshold for making a *prima facie* case of obviousness is lower post-*KSR*, but it can be attacked with evidence.
 - ◇ Even *KSR* recognized that secondary considerations are important to avoid the problem of "hindsight bias" – when a USPTO examiner or patent challenger uses what the inventor has taught to arrive at a determination of obviousness, rather than what the prior art has taught.

- ◇ Evidence supporting why a person of ordinary skill in the art (POSITA) would not have combined prior art references to arrive at the invention often dovetails with secondary considerations.
 - » For example, a POSITA would not reasonably have combined X and Y because the result was thought to be toxic. Unexpectedly, however, X+Y not only proved to be non-toxic but increased Z tenfold. The industry had been searching for a non-toxic agent with large amounts of Z for many years. X+Y received industry recognition and praise as a result.
- **Develop the narrative early.** Prosecution of an application should be undertaken with an eye towards possible appeal of an examiner's obviousness rejection or post-grant obviousness challenge.
 - ◇ Putting secondary consideration evidence on record during prosecution could deter potential patent challengers. However, it also alerts patent challengers of the patentee's best arguments for overcoming an obviousness challenge.
 - ◇ While the specific prior art grounds of a possible post-grant challenge may not be foreseeable, the patentee probably at least has an idea of why the invention is significant.
 - ◇ Developing secondary consideration evidence early allows patentees to use it early in a post-grant proceeding, when it could make the most difference.
 - » Because anticipation is a tougher standard to satisfy, patent challengers (and the PTAB) tend to pursue grounds based on obviousness in post-grant proceedings.
 - » A patent owner's preliminary response to a post-grant challenge is due within *three months* from when the challenge was filed. This is simply not enough time to develop substantial evidence of secondary considerations, especially when experimental data needs to be collected or expert declarations need to be prepared.
 - » After the patent owner's preliminary response, the PTAB decides whether or not to institute a post-grant proceeding and on which claims.
 - » **Avoiding the institution of valuable claims is often the best defense** because the odds of saving an instituted claim are not good once the PTAB decides to institute a proceeding.
 - **81%** of proceedings to date with a final written decision have resulted in some or all of the instituted claims being found unpatentable. (Data current as of Dec. 31, 2019; https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_20191231.pdf)

Ten years ago, *KSR* forever changed the face of patent obviousness. While USPTO examiners and patent challengers can now more readily establish a *prima facie* case of obviousness, all is not lost for patent applicants. Recent trends show that the PTAB can find evidence of secondary considerations persuasive to overcome *prima facie* obviousness. Therefore, a strategy of proactively developing evidence of secondary considerations of non-obviousness early in the patent process can place applicants in the best position to face obviousness rejections by the USPTO as well as post-grant obviousness challenges.

Tab 9: Invoking an AIA Exception to Prior Art, 1.130 Declarations



Invoking an AIA Exception to Prior Art, 1.130 Declarations

By: Michele A. Cimbala, Ph.D.



Arguably, no other provision of the America Invents Act (AIA) is more important than 35 U.S.C. § 102. It defines what activities preclude patentability and what documents are available as prior art. Applications having an effective filing date that is on or after March 16, 2013 are subject to the new AIA § 102. As more AIA applications are being examined, granted and involved in post-grant proceedings, it is increasingly important to understand AIA § 102 and what conditions can create an exception to its rules.

AIA § 102 differs from the pre-AIA § 102 in several significant aspects, indicated below:

Pre-AIA 35 U.S.C. § 102 (Before March 16, 2013)	AIA 35 U.S.C. § 102 (On/after March 16, 2013)
A person shall be entitled to a patent unless - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or	Corresponds to § 102(a)(1)
(c) he has abandoned the invention, or	No corresponding provision
(d) <i>(Invention was first patented in a foreign country)</i>	
(e) the invention was described in - 1. an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or 2. a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or	Corresponds to § 102(a)(2)
(f) he did not himself invent the subject matter sought to be patented, or	Corresponds to § 291
(g) <i>(Prior invention by another)</i>	No corresponding provision

Prior art is defined in 35 U.S.C. § 102(a)(1) and § 102(a)(2)

- According to § 102(a)(1), prior art includes **public disclosures** that are (i) available before the effective filing date of the claimed invention, and (ii) patented, described in a printed publication, in public use, on sale, or “otherwise available

to the public.”

- ◇ AIA did not change the pre-AIA “on-sale” bar. In reaching its decision in *Helsinn Healthcare*, the Supreme Court applied a presumption “that when Congress reenacted the same “on sale” language in the AIA, it adopted the earlier judicial construction of that phrase. *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 586 U. S. ____ (2019).
- According to § 102(a)(2), prior art also includes **issued or published U.S. patent documents** that (i) name another inventor, and (ii) were effectively filed before the effective filing date of the claimed invention.
- The availability of a disclosure as prior art depends upon the **effective filing date** of the claimed invention. See 35 U.S.C. § 100(i).
 - ◇ Unlike pre-AIA law, the AIA provides that a foreign priority date can be the effective filing date of a claimed invention if:
 - » The foreign application supports the claimed invention under § 112(a), and
 - » The applicant has perfected the right of priority by providing a certified copy of the priority application, and a translation of the priority application (if not in English).

35 U.S.C. § 102(b) provides exceptions to the prior art defined in 35 U.S.C. § 102(a)

Prior Art 35 U.S.C. 102(a) (Basis for Rejection)	Exceptions 35 U.S.C. 102(b) (Not Basis for Rejection)	
102(a)(1) Disclosure with Prior Public Availability Date	102(b)(1)	(A) Grace Period Disclosure by Inventor or Obtained from Inventor
		(B) Grace Period Intervening Disclosure by Third Party
102(a)(2) U.S. Patent, Published U.S. Patent Application, and Published PCT Application with Prior Filing Date	102(b)(2)	(A) Disclosure Obtained from Inventor
		(B) Intervening Disclosure by Third Party
		(C) Commonly Owned Disclosures

*Reproduced from https://www.uspto.gov/sites/default/files/aia_implementation/FITF_card.pdf

Prior art exceptions under 35 U.S.C. § 102(b)(1)

- § 102(b)(1)(A) provides a grace period for a disclosure made by an inventor, or obtained from an inventor that prevents the disclosure from being used as the basis for rejection.
 - ◇ For the § 102(b)(1)(A) exception to apply to a public disclosure under § 102(a)(1), the disclosure must be:
 - » Made one year or less before the effective filing date of the claimed invention, and
 - » Made by the inventor or joint inventor or by “another” who obtained the disclosed subject matter directly or indirectly from the inventor or joint inventor (*i.e.*, an “inventor-originated” or “shielding” disclosure).
- § 102(b)(1)(B) provides a grace period for an intervening disclosure by a third party that prevents the disclosure from being used as the basis for rejection.
 - ◇ For the § 102(b)(1)(B) exception to apply to a third party’s public disclosure under § 102(a)(1) of subject matter X:
 - » The third party’s disclosure must have been made one year or less before the effective filing date of the claimed invention,
 - » An inventor-originated disclosure must have been made prior to the third party’s disclosure, and
 - » Both must have disclosed subject matter X.
- An exception under § 102(b)(1)(A) or § 102(b)(1)(B) may apply when:
 - ◇ The authorship/inventorship of the public disclosure only includes one or more joint inventor(s) or the entire

inventive entity of the application under examination, or

- ◇ The specification of the application under examination identifies the potential prior art disclosure as having been made by or having originated from one or more members of the inventive entity, in accordance with 37 C.F.R. § 1.77(b)(6). See https://www.uspto.gov/sites/default/files/aia_implementation/2014_aia_fitf_roadshow_slides.pdf

Prior art exceptions under 35 U.S.C. § 102(b)(2)

- § 102(b)(2)(A), § 102(b)(2)(B) and § 102(b)(2)(C) provide exceptions for a disclosure by a third party in a U.S. patent or published application that prevents the disclosure from being used as the basis for rejection.
 - ◇ Disclosure obtained from the inventor - For the § 102(b)(2)(A) exception to apply, the subject matter disclosed by the third party must have been obtained directly or indirectly from the inventor or a joint inventor.
 - ◇ Intervening disclosure by a third party - For the § 102(b)(2)(B) exception to apply:
 - » The third party's U.S. patent document must have been effectively filed before the effective filing date of the claimed invention,
 - » An inventor-originated disclosure must have been made prior to the effectively filed date of the third party's U.S. patent document, and
 - » Both the third party's U.S. patent document and the inventor-originated disclosure must have disclosed the same subject matter.
 - ◇ An exception under § 102(b)(2)(A) or § 102(b)(2)(B) may apply when:
 - » The inventive entity of the disclosure only includes one or more joint inventor(s), but not the entire inventive entity, of the application under examination, or
 - » The specification of the application under examination identifies the potential prior art disclosure as having been made by or having originated from one or more members of the inventive entity, in accordance with 37 C.F.R. § 1.77(b)(6). See https://www.uspto.gov/sites/default/files/aia_implementation/2014_aia_fitf_roadshow_slides.pdf
 - ◇ Commonly owned disclosures - For the § 102(b)(2)(C) exception to apply, the subject matter disclosed in the U.S. patent document and the claimed invention must have been:
 - » Owned by the same person, subject to an obligation of assignment to the same person, or deemed to have been owned by or subject to an obligation of assignment to the same person, in view of a joint research agreement, and
 - » Not later than the effective filing date of the claimed invention.
 - » A statement is sufficient to invoke the common ownership exception. A declaration is not needed.

The burden of proof in characterizing a reference as prior art

- Unless the record is clear by a preponderance of the evidence that an exception applies, the Examiner must make or maintain any applicable rejection.
- Recall that for § 102(a)(2) prior art, the authorship of the patent reference must be different from the inventorship of the subject application.
 - ◇ **Tip:** the Examiner is looking for references having authorship that does not include all of the inventors and includes at least one author that is not listed as an inventor.

Overcoming a rejection under § 102(a) by filing a declaration under 37 C.F.R. § 1.130

- An applicant may overcome a rejection under § 102(a) by filing a declaration under 37 C.F.R. § 1.130 to invoke a prior art exception under § 102(b).
 - ◇ 37 C.F.R. § 1.130 - "When any claim of an application or a patent under reexamination is rejected, the applicant or patent owner may submit an appropriate affidavit or declaration to disqualify a disclosure as prior art by..."
 - ◇ 37 C.F.R. § 1.130(a) - Affidavit or declaration of attribution
 - » "...establishing that the disclosure was made by the inventor or a joint inventor, or the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor."
 - ◇ 37 C.F.R. § 1.130(b) - Affidavit or declaration of prior public disclosure
 - » "...establishing that the subject matter disclosed had, before such disclosure was made or before such subject matter was effectively filed, been publicly disclosed by the inventor or a joint inventor or another who obtained

the subject matter disclosed directly or indirectly from the inventor or a joint inventor.”

- If the prior disclosure is a printed publication, a copy of that disclosure must accompany the declaration.
- If the prior disclosure is not a printed publication, the declaration must describe the subject matter “with sufficient detail and particularity” to determine what subject matter was publically disclosed on that date and by whom.

“That is my/our work!” - invoking an attribution exception using a § 1.130(a) declaration

- § 1.130(a) declarations are used to invoke a § 102(b)(1)(A) or § 102(b)(2)(A) attribution exception, and thereby disqualify a reference as prior art.
- A successful § 1.130(a) declaration must show that the cited reference or subject matter originated with the inventor(s):
 - ◇ It provides an unequivocal statement from the inventor(s) that they invented the subject matter (not necessary if the inventor’s declaration has been filed), and
 - ◇ Provides a reasonable explanation of the presence of authors who are not listed as inventors:
 - » Explain that the disclosure was not by the inventor(s) but the cited subject matter therein was obtained from the inventor(s) (e.g., a collaborator), or
 - » Explain that the non-inventor author(s) were merely working under the direction and supervision of the inventor(s) (i.e., *In re Katz*). See MPEP 717.01(a)(1).
 - ◇ It is not necessary to show that the inventor-originated disclosure was an enabling disclosure within the meaning of 35 U.S.C. § 112(a). See MPEP 717.01(a)(1) and 2155.04.

“I/we made it public first!” - invoking an prior (shielding) disclosure exception using a § 1.130(b) declaration

- § 1.130(b) declarations are used to invoke a § 102(b)(1)(B) or § 102(b)(2)(B) prior (shielding) disclosure exception, and thereby disqualify a reference as prior art.
- A successful § 1.130(b) declaration must show that the same subject matter within the cited reference was previously and publicly disclosed in an inventor-originating disclosure. See MPEP 717.01(b)(1). Specifically, it must:
 - ◇ Describe, with sufficient detail and particularity, the subject matter in the inventor-originating prior public disclosure,
 - » **Tip:** A mere statement of “sameness” will not likely be enough. Provide a nexus between the subject matter cited by the Examiner and what was previously disclosed by the inventor. Show specific facts to establish that the potential prior art subject matter disclosed was previously publicly disclosed in an inventor-originated disclosure.
 - ◇ Provide the date of the inventor-originating prior disclosure, and
 - ◇ Be accompanied by a copy of the inventor-originating prior disclosure (if it is a printed publication).
 - ◇ IT is not necessary to show that the inventor-originated disclosure was an enabling disclosure within the meaning of 35 U.S.C. § 112(a). See MPEP 717.01(a)(1).
- The prior, public, inventor-originating disclosure must have disclosed **the same** subject matter to be shielding, and a shielding reference is only effective against that same subject matter.
 - ◇ It is possible that only a portion of a third party’s intervening reference will be disqualified as prior art and that other portions of that same reference may be used.
- What is “the same” subject matter?
 - ◇ A prior disclosure of the claimed species **will** shield a third party disclosure of the genus. However, a prior disclosure of the genus **will not** shield a third party disclosure of the claimed species, unless the claimed species is also disclosed.
 - ◇ A prior inventor disclosure does not disclose the same subject matter if it would only render the cited subject matter obvious. See MPEP 717.01(b)(2).
- Disqualifying prior art under § 102(a)(1) or § 102(a)(2) does not remove that reference from use for other patentability considerations such as 35 U.S.C. §§ 101, 112(a), 112(b) and obviousness-type double patenting.

Formal Requirements of Rule 130 Declarations

- The formal requirements of Rule 130 declarations are the same as pre-AIA requirements.
 - ◇ The declaration must be timely. See MPEP 717.01(f).
 - ◇ The declaration must include the required statements for declarations. See MPEP 717.01(c).

- ◇ If exhibits are included, they must comply with 37 C.F.R. § 1.91.
- ◇ The person who signs the declaration must be someone with knowledge of the facts addressed.
- ◇ The person who files the declaration must be someone who may sign a paper under 37 C.F.R. § 1.33(b) [patent practitioner or applicant].

Remember:

- When a declaration states that a disclosure by another is an inventor-originated disclosure, it must be clear on the record that the subject matter was both obtained from a person named as an inventor and invented by a person named as an inventor. This can be accomplished by
 - ◇ Stating that the declarant is the inventor of the subject matter in the declaration; or
 - ◇ Filing a Rule 63 inventor's declaration naming the declarant as an inventor and signed by the declarant inventor.
 - ◇ An ADS naming the declarant as an inventor is not sufficient.
- For 130(a) declarations:
 - ◇ When the inventor attributes a reference to himself and the reference names someone else in addition to the inventor, a reasonable explanation of the other person's involvement is required. The other person does not need to provide a declaration or statement.
- For 130(b) declarations:
 - ◇ The inventor-originated prior public disclosure must be compared to the potential prior art disclosure, not to the claimed invention.
 - ◇ The examiner should mark the proper box in item 1 on the office action summary sheet and on the Notice of Allowability, to indicate that a Rule 130(b) declaration was filed. This information will also appear on the face of the patent.
- Review of the declarations.
 - ◇ A primary examiner decides whether the declaration is sufficient as to formal matters. If the applicant disagrees with the examiner's opinion, review is by way of a petition under 37 C.F.R. § 1.181.
 - ◇ A primary examiner also decides whether the declaration is sufficient on the merits. If the applicant disagrees with the examiner's opinion, review is by way of an appeal of the rejection to the PTAB.

Tab 10: 1.132 Declarations for Traversing Rejections



1.132 Declarations for Traversing Rejections

By: Bonnie W. Nannenga-Combs, Ph.D., Tyler C. Liu , and Eldora L. Ellison, Ph.D.



Long before the AIA, declarations were a tool that was available during patent prosecution to put evidence, *e.g.*, post-filing data and expert opinions, in front of an Examiner to rebut obviousness or lack of enablement rejections. However, unless essential to obtain allowance, such declarations were often used only as a last resort. Indeed, some practitioners avoided declarations unless absolutely necessary out of concern for seeding the prosecution record with expert or inventor testimonial statements that could potentially be used against the patent owner during a future litigation.

Even still, since arguments of counsel cannot take the place of evidence in the record, certain evidence submitted to the U.S. Patent and Trademark Office (USPTO) must be supported by a declaration. Such evidence can include, for example, expert statements supporting unexpected results, commercial success, solution to a long-felt need, inoperability of the prior art, or evidence supporting attribution of a reference to the Applicant or prior public disclosure of subject matter derived from an inventor. Furthermore, a response to an obviousness rejection including a well-written 37 C.F.R. § 1.132 Declaration can be more persuasive to an Examiner than well-written legal and/or technical arguments by the patent attorney alone.

Decisions from the Patent Trial and Appeal Board (PTAB) suggest that 1.132 Declarations can also be persuasive to the Board when considering whether to institute or not institute an *Inter Partes* Review (IPR) or Post-Grant Review (PGR). The overall number of cases before the PTAB where objective evidence has been found to be persuasive is fairly low. However, lessons from Board decisions seem to be driving a trend to submit objective evidence during prosecution in an effort to strengthen the record. And failure to address objective evidence of record can be fatal to IPR or PGR institution. *See, e.g., Coalition for Affordable Drugs V LLC v. Hoffman-LaRoche, Inc.*, IPR2015-01792 (PTAB Mar. 11, 2016) (Paper 14) and *Merial Ltd. v. Virbac*, IPR2014-01279, Paper 13 (PTAB Jan. 22, 2015) (denying institution for failure to address objective evidence considered by examiner during original prosecution); *Omron Oilfield & Marine Inc. v. MD/TOTCO*, IPR2013-00265, Paper 11 (PTAB Oct. 31, 2013) (denying institution for failure to address objective evidence successfully argued during reexamination). Furthermore, recent Board decisions have found objective evidence sufficient to overcome a *prima facie* case of obviousness. *See, e.g., Xactware Solutions, Inc. v. Eagle View Techs., Inc.*, IPR2016-00592 (Paper 50) (PTAB August 25, 2017); *InnoPharma, Inc. et al. v. Bausch & Lomb Incorporated et al.*, IPR2015-00903, Paper 82 (PTAB July 28, 2016); *Leapfrog Product Development, LLC v. Lifefactory, Inc.*, IPR2015-00614, Paper 31 (PTAB Aug. 17, 2016).

As practitioners look for ways to help protect patents from institution of IPR or PGR, prosecution practices are evolving. Thought should still be put into statements made in declarations during prosecution that might be used against the patent owner in a future litigation, but the benefit of strengthening the prosecution record to help avoid IPR or PGR institution and having objective evidence in the record to support a non-obviousness position, provides an incentive to consider submitting 1.132 Declarations during prosecution. Such declarations are no longer considered a last resort.

1. Types of Declarations Post-AIA

Pre-AIA and Post AIA Declarations		
Purpose of Declaration	37 CFR Rule	
	Pre-AIA (First-to-Invent) Applications	AIA (First-to-File) Applications
Traversal of rejection or objection (<i>e.g.</i> , unexpected results, commercial success, etc.)	1.132	1.132
Other Declarations		
Show earlier date of invention	1.131(a)	No longer available
Attribution (Katz-type Declaration)	1.132	1.130(a)

Prior public disclosure	Not available	1.130(b)
Common ownership declaration filed with terminal disclaimer	1.131(c) (formerly pre-AIA 1.130(a)) (more frequently used common ownership statement under pre-AIA 103(c))	No longer available (frequently used common ownership statement under AIA 102(b)(2)(c))

Table is adapted from USPTO's "Effective Use of AIA (FITF) Evidentiary Declarations under Rule 130," Slide 54 (Sept. 18, 2015).

2. When can you file a 1.132 Declaration?

- Prior to a final rejection;
- Before appeal in an application not having a final rejection;
- After final rejection, but before or on the same date of filing an appeal, upon a showing of good and sufficient reasons why it was not earlier presented; or
- After prosecution is closed if filed with a Request for Continued Examination (RCE).

3. What kind of evidence can you submit in a 1.132 Declaration?

- Any evidence submitted to traverse a claim rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under section 37 CFR 1.132. See MPEP §716.
- Evidence can include post-filing data accompanied by factual statements from a declarant with first-hand knowledge of the data, *e.g.*, to show enablement or differences in the claims compared to the prior art. Factual evidence is preferable to opinion testimony. See MPEP 716.01(c), Section III.
- Evidence can also include expert opinions based on facts in view of the expert's knowledge, *e.g.*, in support of no reasonable expectation of success. While an expert opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive. *In re Chilowsky*, 306 F.2d 908, 134 USPQ 515 (CCPA 1962).
- Declarations are commonly used to submit objective evidence of inoperability of the cited references or of non-obviousness, *e.g.*, evidence of criticality or unexpected results, commercial success, long-felt but unmet need, failure of others, copying, skepticism of experts, etc.

4. Standards for objective evidence of non-obviousness:

- The objective evidence must be reasonably commensurate in scope with the claims.
- To be of probative value, any objective evidence must have a causal relationship to merits of the claimed invention (nexus requirement). For example, commercial success or industry praise must be related to the merits of the claimed invention, not the prior art. Determining nexus is fact dependent, and the Federal Circuit has indicated that a patentee can demonstrate nexus for a claimed combination "as a whole" in the sense that proof of nexus is not limited to so-called "novel elements." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016).
- 1.132 Declarations to rebut a *prima facie* case of obviousness, *e.g.*, showing unexpected properties over the art, must compare the claimed subject matter with the closest prior art to be effective. See MPEP 716.02(e) citing *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979).

5. Post-AIA Considerations:

- Relevant and compelling evidence in the file wrapper or relevant public documents from related proceedings (*e.g.*, litigation or reexamination) can be used in arguments in a party's briefs, *e.g.*, a Patent Owner's Preliminary Response in an IPR or PGR petition.
- Well-drafted declarations addressing objective evidence in the prosecution record can tip the balance to non-institution by the PTAB. In particular, when the *prima facie* case is weak, objective evidence can be particularly persuasive. See, *e.g.*, *Hologic, Inc. v. Biomerieux, Inc.*, IPR2018-00567, Paper 9 (PTAB August 4, 2018); *Coalition for Affordable Drugs II LLC v. Cosmo Technologies Ltd.*, IPR2015-00988, Paper 55 (PTAB Oct. 5, 2016).
- But, objective evidence must be reasonably commensurate with the scope of the claims, and it needs a nexus to be persuasive. Final written decisions are made on a claim-by-claim basis; thus, objective evidence that is not

commensurate in scope with one or more claims will not help any non-commensurate claims. *See, e.g., Acrux DDS Pty Ltd. et al. v. Kaken Pharmaceutical Co., Ltd. et al.*, IPR2017-00190, Paper 80 at 42-52 (PTAB June 6, 2018); *Praxair Technology, Inc. v. Entegris, Inc.*, IPR2016-01845, Paper 20 at 34-38 (PTAB March 29, 2018).

- Parties and individuals involved in USPTO proceedings have “a duty of candor and good faith.” But inequitable conduct cannot be the basis for challenging a patent in an IPR or PGR; so there would likely be no estoppel precluding a losing IPR or PGR petitioner from raising inequitable conduct in any subsequent litigation.
- Establishing a legally and factually strong record of patentability—including non-obviousness—during prosecution can increase the likelihood of avoiding IPR or PGR institution.

6. Other considerations:

- Identify the declarant and any relationship to the applicant(s), assignee(s) or application in the declaration (*see, e.g., Ferring B.V. v. Barr Laboratories, Inc.* 437 F.3d 1181 (Fed. Cir. 2006), finding inequitable conduct because Applicants failed to disclose that individuals who submitted declarations in support of patentability had affiliations with the assignee).
- Have an agreement with the declarant in place to protect against disclosure of confidential information, discussions and/or draft documents.
- Continue to select experts and fact witnesses with the possibility of future litigation and possible deposition in mind.
- Do not prepare 1.132 Declarations in haste. Prepare concise and persuasive declarations that avoid statements that are unnecessary or could be considered inconsistent.

Tab 11: Obviousness-Type Double Patenting



Obviousness-Type Double Patenting

By: Gaby L. Longsworth, Ph.D. and Brian M. Dudley, Ph.D.



35 U.S.C. § 101 precludes a patentee from obtaining more than one patent on the same invention. Courts have extended this prohibition “to preclude a second patent on an invention which ‘would have been obvious from the subject matter of the claims in the first patent, in light of the prior art.’” *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985). Thus, obviousness-type double patenting (ODP) (also known as “nonstatutory double patenting”) is a judicially created doctrine intended to prevent an improper time-wise extension of a patent right by prohibiting the issuance to a single inventor of claims in a second patent which are not “patentably distinct” from the claims of a first patent. *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997).

1. Why should you worry about ODP?

- Filing a terminal disclaimer (TD) to obviate an ODP rejection can reduce the patent term by limiting Patent Term Adjustment (PTA) (the term cannot extend beyond that of the earlier patent). 35 U.S.C. §§ 154(b)(2) and 253. Patents having the same earliest effective filing date may have different patent terms due to different PTA. In some instances, PTA can be more beneficial than Patent Term Extension (PTE), as it extends the term of all the claims in the patent.
- If the first (earlier) patent has expired, a TD cannot be filed and the second (later) patent will be invalid for ODP.
- **Note:** Filing a TD does not affect PTE obtained under 35 U.S.C. § 156. *Merck & Co. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317 (Fed. Cir. 2007); *see also Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1373 (Fed. Cir. 2018). However, any PTA time awarded to a patent subject to a terminal disclaimer will be limited by the expiration date of the reference patent, and patent term that is extended by PTA may affect the double patenting analysis under *Gilead, infra*. 35 U.S.C. § 154(b)(2)(B); *see also Magna Electronics, Inc. v. TRW Automotive Holdings Corp.*, 2015 WL 11430786 (W.D. Mich. 2015).

2. When may ODP issues arise?

- **During prosecution** – The claims of an application can be rejected for ODP in view of claims of patents or applications that have at least one common inventor, that are commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. § 103(c)(2)(3). *See* MPEP § 804 and *In re Hubbell*, 709 F.3d 1140 (Fed Cir. 2013).
- **In litigation** – ODP is an affirmative defense as it is a ground for invalidating one or more claims of a patent. *See e.g., Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991); *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003).

3. Standard for ODP

- The claims of the second patent or application are not distinct (anticipated or obvious) in view of the claims of the first patent or application.
- The “one way” and “two way” tests:
 - ◇ **The one way test (default):**
 - » Whether the claim at issue is patentably distinct over the earlier reference claim.
 - ◇ **The two way test (rare):**
 - » Applies only in cases where the applicant could not have filed the claims in a single application and there is administrative (U.S. Patent and Trademark Office) delay.
 - » Compares the patentable distinctness of both the later claim over the earlier claim and the earlier claim over the later claim.
- Obviousness analysis under ODP is analogous to an obviousness analysis under 35 U.S.C. § 103 except that:
 - ◇ The first patent or application is not considered prior art. But reference to the specification of the first patent or application may be appropriate, e.g., for claim construction. *In re Vogel*, 442 F.2d 438, 441-442 (C.C.P.A. 1970).

- ◇ Lead compound analysis is not required in cases involving claimed chemical compounds. *Otsuka Pharmaceuticals Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1298 (Fed. Cir. 2012).
- A later claim in a patent to a method of treatment using a compound is not patentably distinct from a claim to the identical compound in a first patent disclosing the identical use. See *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003); *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008); *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010).
- A patent that issues after but expires before another patent may qualify as a double patenting reference for that other, later expiring patent. See *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014).
 - ◇ The two patents can be from the same family and have a different expiration date due to PTA. *Magna Elecs., Inc. v. TRW Automotive Holdings Corp.* (W.D. Mich. December 10, 2015).
 - ◇ However, an earlier expiring post-GATT patent cannot be used as a reference against a later expiring pre-GATT patent. *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical, Inc.*, 909 F.3d 1355 (Fed. Cir. 2018) (applying “pre-URAA obviousness-type double patenting practice” and holding that “to require patent holders to truncate any portion of the statutorily-assigned term of a pre-URAA patent that extends beyond the term of a post-URAA patent would be inconsistent with the URAA transition statute”); but see *Janssen Biotech, Inc. v. Celltrion Healthcare Co. Ltd.*, (D. Mass. September 28, 2016), appeal dismissed, No. 17-1120, 2018 WL 2072723 (Fed. Cir. 2018) in view of *In re Janssen Biotech, Inc.*, 880 F.3d 1315 (Fed. Cir. 2018) (affirming the rejection of claims 1-7 of the subject patent under the doctrine of obviousness-type double patenting on other grounds).
- Case law appears to be settled regarding whether secondary indicia should be considered in an ODP analysis.
 - ◇ Evidence of secondary considerations should be considered, when offered, in an ODP analysis. See *Otsuka Pharmaceuticals Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1298 (Fed. Cir. 2012); *Eli Lilly and Company v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1378 (Fed. Cir. 2012); *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1372 (Fed. Cir. 2014).

4. How can you overcome ODP during prosecution?

- Argue that the claims are patentably distinct from each other.
 - ◇ File a TD.
 - ◇ Affirmatively disclaim any term of the second patent beyond the term of the first patent. 35 U.S.C. § 253 and 37 C.F.R. § 1.321; *In re Longi*, 759 F.2d at 894; *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 980 (Fed. Cir. 1992).
 - ◇ Patents linked by a TD will only be enforced while commonly owned.
 - ◇ Signed by an owner (in part or in entirety) or an attorney or agent of record. 37 C.F.R. § 1.321.
 - ◇ Filing a TD requires common ownership. *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013).
 - » At least one district court has held that patents assigned to two wholly owned subsidiaries are not commonly owned by the parent company for purposes of satisfying requirements of TD. See *Email Link Corp. v. Treasure Island, LLC*, No. 2:11-cv-01433-ECRGWF (D. Nev. Sept. 25, 2012).
 - » However, the U.S. Patent and Trademark Office appears to consider the above situation to be commonly owned. See MPEP §§ 1490, 706.02(I)(2).
 - ◇ Need to disclaim the entire patent, not just the claims at issue. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001).

5. How can you overcome ODP post-issuance or in litigation?

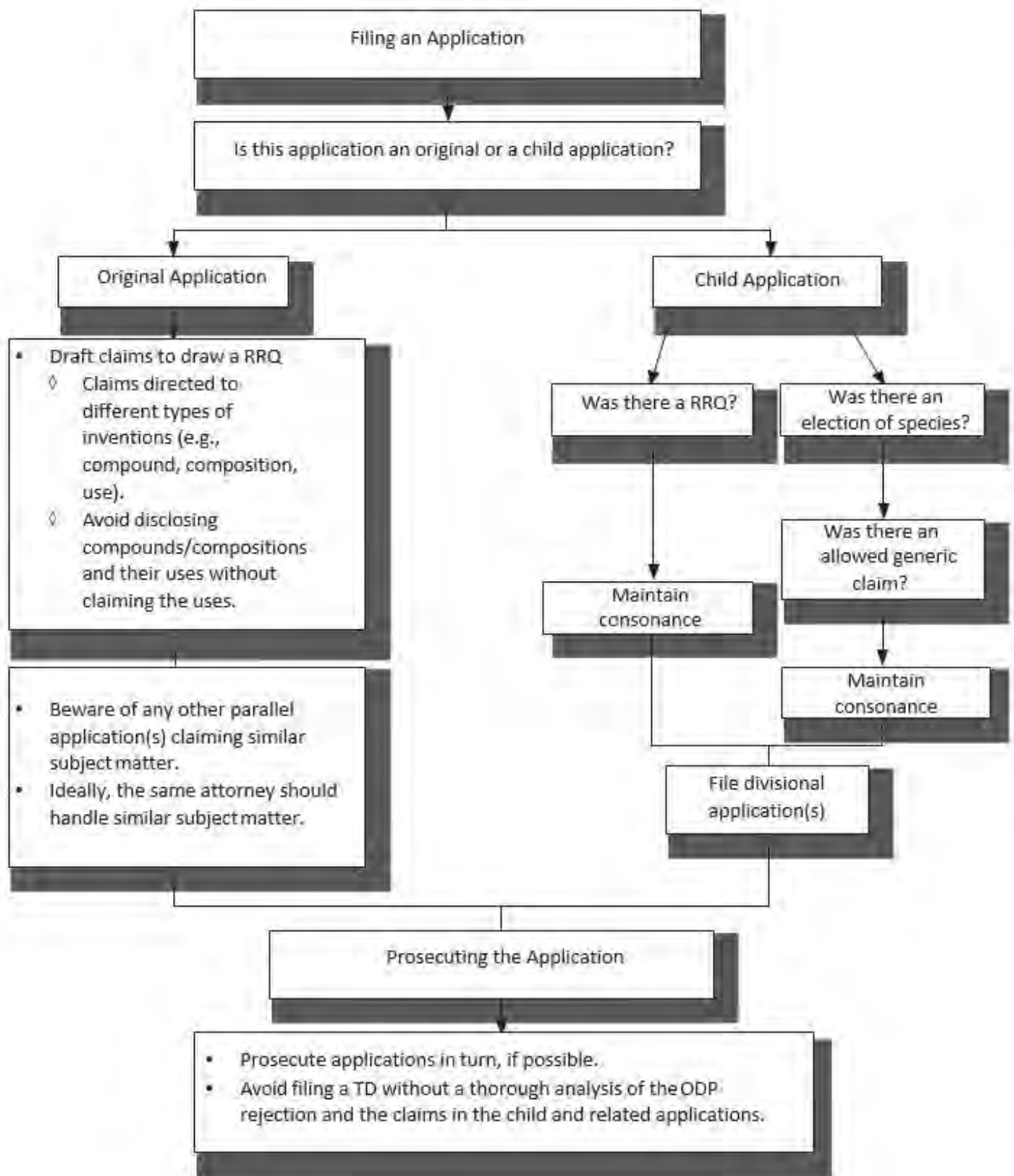
- If patents can trace their lineage back to a common parent which was subject to a restriction requirement (RRQ), then 35 U.S.C. § 121 (“safe harbor”) may prevent an ODP challenge.
 - ◇ Safe harbor is only available when there was a RRQ. *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1347 (Fed. Cir. 2004).
 - ◇ Safe harbor is only available to divisional applications, not continuations or continuations-in-part. *Pfizer Inc. v. Teva Pharmaceuticals Inc.*, 518 F.3d 1353 (Fed. Cir. 2008); *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009).
 - ◇ Consonance must be maintained (the line of demarcation between the inventions identified in the RRQ). *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1579 (Fed. Cir. 1991); *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990).
 - ◇ Requirement for election of species creates a restriction if no generic claim is found allowable. *St. Jude Medical*,

Inc. v. Access Closure, Inc., 729 F.3d 1369 (Fed. Cir. 2013).

- ◇ For safe harbor to apply, the actual filing date (instead of the effective filing date) of the divisional application must be before the issuance of the patent on the application that is subjected to the restriction requirement. *Ex parte Sauerberg*, decision of the Patent Trial and Appeal Board, Application No. 14/016,442 (Jan. 12, 2017).
- File a TD.
 - ◇ A TD can be filed at any time except after the earlier-issued patent has expired. *See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1347 (Fed. Cir. 2010).
- Consider filing a statutory disclaimer disclaiming only the claims challenged under ODP. 35 U.S.C. § 253(a).
 - ◇ 35 U.S.C. § 253(a) authorizes disclaiming “any complete claim.”
 - ◇ May not impact patent term.
- Consider filing a reissue application in the reference patent to cancel or otherwise amend the cited claims (reference patent must be eligible for reissue; *see Sanofi-Aventis U.S., LLC v. Dr. Reddy's Laboratories, Inc.*, Nos. 2018-1804; 1808; 1809 (Fed. Cir. 2019)).

6. ODP Best Practices

- Before filing a patent application:
 - ◇ Is this an original or a child application?
 - » Original application: draft claims to draw a RRQ.
 - » Child applications: file divisional applications before issuance of an original patent and maintain consonance; or, for serial continuing applications, consider filing claims identical to the full set of restricted claims in the parent application to induce an identical RRQ in each subsequent case.
- Filing the application:
 - ◇ Incorrectly calling a divisional a continuation may lead to a loss of safe harbor protection.
- Prosecuting the application:
 - ◇ Prosecute applications in turn, if possible.
 - ◇ Beware of later filed, earlier issued patents in related families.
 - » E.g., if the first patent has generic claims and the second patent has species claims, the second patent may issue earlier and create ODP issues. PTA may be shortened or lost.
 - ◇ Avoid filing a TD to overcome ODP without a thorough analysis of the relevant claims.
 - » If only some of the claims are rejected under ODP, consider splitting the claims. E.g. let the non-rejected claims issue and pursue the rejected claims in a separate application.
 - » A TD may not be nullified once it is filed (e.g., by arguing a TD was improper because the required fee was not paid). *President and Fellows of Harvard College v. Lee*, 589 Fed. Appx. 982 (Fed. Cir. 2014).
 - » An incorrectly filed TD is not an “error” correctable by reissue. *In re Dinsmore*, 757 F.3d 1343 (Fed. Cir. 2014).
- See the chart on the next page.



Tab 12: Patent Term Adjustment



Patent Term Adjustment

By: Lori M. Brandes, Ph.D. and Eric K. Steffe



In 1999, Congress created a system of patent term adjustment (PTA) that adds additional time to patent terms to remedy certain delays caused by the U.S. Patent and Trademark Office (PTO) in issuing a patent.

Why Review PTA?

More than half of all patents granted in December 2019 were entitled to PTA, with an average PTA of about 142 days. <https://www.uspto.gov/dashboards/patents/main.dashxml>.

PTA: The Basics

- Available for utility or plant applications, not reissue or design applications.
 - ◇ 35 U.S.C. § 154(b)(1)(A) – PTA granted if any of the following occur (“**A delay**”)
 - » PTO issues an office action or notice of allowance more than 14 months after the application is filed.
 - » PTO acts more than four months after applicants file a reply to office action.
 - » PTO acts more than four months after a decision on appeal or decision by a federal court finding at least one claim allowable.
 - » PTO issues a patent more than four months after payment of the issue fee.
 - 35 U.S.C. § 154(b)(1)(B) – PTA granted if the application is pending for more than three years, excluding time consumed by the following (“**B delay**”).
 - ◇ Continued examination.
 - ◇ Interference or derivation proceeding.
 - ◇ Imposition of a secrecy order.
 - ◇ Review by PTO on appeal or by federal court.
 - ◇ Delays in processing requested by the applicant.
 - 35 U.S.C. § 154(b)(1)(C) – PTA granted if issuance was delayed due to interference or derivation proceeding, imposition of a secrecy order, or appellate review by PTO or federal court that reversed an adverse determination of patentability (“**C delay**”).
 - PTA is the sum of A, B and C delays, excluding the following periods of time:
 - ◇ Overlap between A, B and C delays
 - ◇ Patent term specified in a terminal or statutory disclaimer
 - ◇ Applicant-caused delays such as:
 - » Taking longer than three months to reply to a PTO notice or office action.
 - » Abandonment of the application or late payment of the issue fee.
 - » Failing to file a petition to withdraw abandonment or revive an application within two months from issuance of a notice of abandonment.
 - » Converting a provisional application to a nonprovisional application.
 - » Submitting a preliminary amendment or other preliminary paper less than one month before issuance of an office action or notice of allowance that requires the issuance of a supplemental office action or notice of allowance.
 - » Submitting a reply having an omission.
 - » Submitting a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the PTO, after a reply has been filed.
 - » Submitting an amendment or other paper after a notice of allowance.

Challenging the PTO’s Calculation of PTA

- File a request for reconsideration of PTA at the PTO.

- ◇ Due **two months after patent issuance**, with extensions of time available for up to five additional months.
- ◇ However, a request to reinstate PTA deducted for periods of time in excess of three months taken to reply to a PTO notice or office action must be filed **prior to issuance**, with no extensions of time available.
- File a civil action within 180 days after issuance?
 - ◇ Applicants dissatisfied with the PTO's decision on a request for reconsideration have an "exclusive remedy" by **civil action within 180 days** after the date of the PTO's decision. 78 Fed. Reg. 19416; *Daiichi v. Lee* (Fed. Cir. 2015).
 - ◇ **Ordinary tolling** of the 180-day deadline is allowed while awaiting the PTO's decision on a request for reconsideration of PTA. *Novartis v. Lee* (D.D.C. 2012); *Bristol-Myers Squibb v. Kappos* (D.D.C. 2012).
 - ◇ But, courts have not allowed **equitable tolling** of the 180-day deadline, *e.g.*, when a significant new PTA decision is issued. *Novartis v. Lee* (Fed. Cir. 2014); *Actelion v. Kappos* (D.D.C. 2013); *Daiichi v. Rea* (D.D.C. 2013).

Best Practices and Other Tips

- Independently carry out a PTA calculation according to the current rules and regulations, and if there is an error, file a petition with the PTO to challenge the PTA calculation.
- Patentees can request reconsideration of PTA based on a deduction for "applicant delay" during a period of time when "there was no identifiable effort" the patentee could have taken to avoid the delay. *Supernus vs. Iancu* (Fed. Cir. 2019).
- Ensure responses to a final office action are proper.
 - ◇ Reply including "the same arguments that were previously found unpersuasive" for an obviousness rejection and claim amendments related to a different rejection was deemed a failure to engage in reasonable efforts to conclude processing or examination. *Mayo v. Iancu* (Fed. Cir. 2019).
- Avoid filing a paper containing only an information disclosure statement (IDS) after a reply has been filed.
 - ◇ IDS filed after a reply to a restriction requirement and before examination is considered applicant delay. *Gilead v. Lee* (Fed. Cir. 2015).
 - ◇ Review patent office communications from counterpart applications as soon as they are received, and instruct international associates to report such communications as quickly as possible.
 - ◇ Paper containing only an IDS will not be considered applicant delay if, *e.g.*, the documents cited in the IDS were first cited in a communication that was not received more than 30 days prior to the filing of the IDS. 37 C.F.R. § 1.704(d).
- When multiple inventions are claimed, consider making an oral election of species to the examiner.
 - ◇ Issuance of a written restriction requirement will likely end the period of A delay sooner than it would have ended if the first PTO action is a substantive office action.
- To maximize A and/or B delay, consider taking a one-month extension of time and replying to a pre-examination notice or restriction requirement at the three-month deadline.
- To maximize B delay, pay the issue fee on the deadline rather than before the deadline.
- Carefully consider the consequences of filing a terminal disclaimer.
 - ◇ May or may not negatively affect PTA.
 - ◇ Does not affect patent term extension granted for delays related to regulatory review by the U.S. Food and Drug Administration. *Merck v. Hi-Tech* (Fed. Cir. 2007).
 - ◇ Preserve the largest possible PTA in parent applications in the event a terminal disclaimer is filed in later child applications.
- Avoid filing a request for continued examination (RCE).
 - ◇ Time in "continued examination" is excluded from B delay, but only for the time before allowance. *Novartis v. Lee* (Fed. Cir. 2014).
 - ◇ The RCE period is not ended by an interference proceeding. *Mayo v. Iancu* (Fed. Cir. 2019).
 - ◇ May still be entitled to PTA for A or C delays.
 - ◇ Consider filing an appeal instead of an RCE to preserve B delay.
- Avoid filing a supplemental amendment or an amendment after allowance.
 - ◇ Considered applicant delay.
 - ◇ If possible, correct problems in the next reply or with an examiner's amendment.
 - ◇ Challenge PTA detracted for such amendments when made in reply to a PTO notice or request.

PTA Around the World

In addition to the U.S., the following countries also grant PTA for patent office delays.

Country	Requirements
Chile	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.
Colombia	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later. • Request must be filed within 2 months of grant. • Does not apply to pharmaceutical patents. • No fee is required.
Costa Rica	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later. • Maximum of 18 months granted.
Dominican Republic	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later. • Does not apply to applications filed before March 1, 2008.
El Salvador	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later. • Maximum of 550 days granted.
Guatemala	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.
Honduras	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later.
Nicaragua	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 5 years from the application filing date or 3 years after the request for examination, whichever is later. • Maximum of 550 days granted.
Singapore	<ul style="list-style-type: none"> • Available for “unreasonable” delay by Intellectual Property Office of Singapore in granting a Singapore patent or by a “prescribed” foreign patent office in granting a foreign patent on which a Singapore patent is based. • Available if grant of a patent is delayed more than 4 years from the application filing date or 2 years after the request for examination, whichever is later. • Subject to delays caused by the applicant (<i>e.g.</i>, extensions of time). • Request must be filed within 6 months of grant and include documentary evidence to support the application and an official fee. • Maximum of 5 years granted. • Does not apply to applications filed before July 1, 2004.
South Korea	<ul style="list-style-type: none"> • Available if grant of a patent is delayed more than 4 years from the application filing date or 3 years after the request for examination, whichever is later. • Subject to delays caused by the applicant (<i>e.g.</i>, extensions of time). • Request must be filed within 3 months of grant.

Tab 13: Patent Term Extension



Patent Term Extension

By: Tarja H. Naukkarinen and Lori M. Brandes, Ph.D.



Patent term extension (PTE) is available under the 1984 Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act (The Act). The Act allows the extension of the term of a patent claiming a product that requires regulatory approval prior to being sold, or a method of using or manufacturing the product. Such products include human and veterinary pharmaceuticals, food additives, color additives and medical devices. PTE aims to restore a portion of the patent term that is lost while the patent holder is awaiting regulatory approval of the product.

The determination as to whether PTE should be granted is made by the U.S. Patent and Trademark Office (PTO), in consultation with the regulatory agency responsible for approval of the product.

Requirements for PTE Application Under 35 U.S.C. § 156

- Deadline for filing is **within 60 days** of the mailing date of a marketing approval of the product (37 C.F.R. § 1.720(f))
 - ◇ Approval of New Drug Application (NDA), Biologics License Application (BLA) or Premarketing Approval Application (PMA)
 - ◇ The approval date is counted as **day 1**
 - ◇ Saturdays, Sundays and Federal Holidays are counted
- Applicant is the owner of record or its agent (37 C.F.R. § 1.730(a))
- Must comply with the requirements provided in 37 C.F.R. § 1.740:
 - ◇ Complete identification of the approved product (37 C.F.R. § 1.740(a)(1))
 - ◇ Complete identification of the Federal statute under which the regulatory review occurred
 - ◇ An identification of the date on which the commercial marketing approval was received
 - ◇ In case of a drug product, identification of each active ingredient and a statement that the product has not been previously approved
 - ◇ A statement that the PTE application is submitted within the 60-day period and an identification of the last day the application can be submitted
 - ◇ A complete identification of the patent for which extension is sought
 - ◇ A copy of the patent
 - ◇ A copy of any terminal disclaimer, certificate of correction, maintenance fee statement, or reexamination certificate
 - ◇ A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing for at least one claim how it reads on the product
 - » **Tip:** This showing can be conveniently provided as a claim chart
 - ◇ A statement of the relevant dates and information to enable the Secretary of Health and Human Services to determine the applicable regulatory review period
 - » An example of information for a human drug, antibiotic, or human biological product:
 - The effective date of an Investigational New Drug application (IND) for human drugs
 - **Note:** Substantiate the date as necessary. Was there a clinical hold?
 - The date of filing the NDA, BLA or PMA
 - The date on which the NDA, BLA or PMA was approved
 - » Has to begin on a new page
 - ◇ A brief description of the significant activities and dates during the regulatory review period
 - » Has to begin on a new page
 - » **Tip:** Conveniently submitted as an attachment of a chronology of events
 - » **Note:** This is to show due diligence of the applicant during the regulatory review period. Can be challenged by a third party.
 - ◇ A statement that in the applicant's opinion, the patent is eligible for extension, including the length of the extension

and how it was determined

- » Has to begin on a new page
- » Requirements for eligibility:
 - The patent claims a product, a method of using the product, or a method of manufacturing
 - The patent has not expired
 - The term of the patent has never been extended
 - The application is submitted by the owner of record or its agent
 - The product has been subject to a regulatory review period before its commercial marketing or use
 - No other patent has been extended for the same regulatory review period (i.e., only one patent can be extended per approved product)
- ◇ A statement that applicant acknowledges the duty to disclose any information material to the determination of entitlement of the extension sought
- ◇ Payment of fees
 - » Currently, \$1,120 for large, small and micro entities
- ◇ Information on the contact person
- ◇ Submitted as one original and two copies
 - » **Note:** Cannot be electronically filed
 - » **Tip:** Preferably hand-carried to the Office of Patent Legal Administration, Room MDW 7D55, Madison Building

Calculation of the Length of PTE

- PTE is the sum of the “testing period” and the “approval period,” less:
 - ◇ The number of days which were on or before the patent issued
 - ◇ The number of days during which the applicant did not act with due diligence
 - ◇ One-half the number of days of the testing period after the patent issued
- PTE cannot be more than 5 years
- PTE cannot extend the patent term over 14 years from the date of receipt of marketing approval
- The “testing period” starts on the IND effective date and ends on the date of NDA/BLA/PMA initial submission
- The “approval period” starts on the date of the NDA/BLA/PMA initial submission and ends on the date of approval of the NDA/BLA/PMA
 - ◇ **Note:** the FDA counts the NDA/BLA/PMA submission date in both the testing period and approval period

Interim Extension

- Available if the regulatory review period is reasonably expected to extend beyond the original expiration date of the patent
- Aims to maintain the patent term until regulatory approval is received
- Can be submitted during the period beginning 6 months before the patent term is due to expire and ending 15 days before the patent term is due to expire
- Available for not more than one year, but subsequent interim extensions can be filed
- Any interim extension terminates at the end of the 60-day period beginning the day on which the product receives a regulatory approval, unless the applicant submits a PTE application within this period

Best Practices and Other Tips

- A duty of disclosure exists during the PTE application process - remember to disclose information material to PTE determination (MPEP 2762)
 - ◇ In *in re Zetia* (Ezetimibe) Antitrust Litigation, defendants argued inequitable conduct because the patent owner withheld material information from the PTO during the PTE review period. 2019 WL 1397228, E. D. Va, Aug. 9, 2019
- Consider filing **more than one PTE application for different patents** based on a single regulatory review period
 - ◇ Postpones making the decision of which patent to extend, which may be helpful when there are:
 - » Differences in the projected patent terms of the different patents

- » Obviousness-type double patenting (ODP) considerations
 - Would a successful ODP challenge during litigation reduce a patent term adjustment (PTA) to which the patent may be entitled?
 - During the PTA extension period, the right to exclude with the patent reaches the **entire claim scope**
 - However, during the PTE extension period, the right to exclude with the patent only reaches, e.g., **the approved drug and approved indication**
 - The Federal Circuit held that obviousness-type double patenting did not invalidate an otherwise validly obtained patent term extension under 35 U.S.C. § 156. *Novartis AG v Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018)
 - The Federal Circuit held in *Novartis v. Breckenridge* that if a later patent expires earlier only because of the URAA's change in the patent term, the post-URAA patent is not an ODP reference against the pre-URAA patent. *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.*, 909 F.3d 1355 (Fed. Cir. 2018)
 - Having PTE granted on a patent is not a defense against an ODP challenge
 - Consider the following dicta from *Novartis v. Breckenridge* (D. Del. April 3, 2017): "The patent term extension provision of the Hatch-Waxman Act was intended to restore to a patent the time lost in seeking FDA approval for the drug claimed in the patent. I see no reason why such a patent term extension would protect a patent from a double patenting challenge."
- ◇ PTO will provide a period of time (usually one month) for the patent owner to elect the patent for which extension is desired
- Consider filing **more than one PTE application on the same patent** based on regulatory review periods of different products, if the products are covered by the same patent
 - ◇ Postpones making the decision of which product to extend, which may be helpful when there are:
 - » Differences in the markets of the different products
 - ◇ PTO will provide a period of time (usually one month) for the patent owner to elect the product for which extension is desired
- PTO has permitted an applicant under 37 C.F.R. § 1.103 to **suspend action** on a PTE application for up to 6 months upon showing good and sufficient cause
 - ◇ Useful when:
 - » An applicant wants the PTE extension to apply to a reissue patent that has not yet granted, rather than to the original patent
 - » There is an actual or impending litigation
- The filing of a **terminal disclaimer does not affect a PTE** to which a patent is entitled (*Merck v. Hi-Tech* (Fed. Cir. 2007))
- Make sure that at least one claim of the patent reads on the approved product
 - ◇ Angiotech sought to obtain PTE for U.S. Patent No. 5,811,447 (the '447 patent) based on FDA approval of Angiotech's drug-eluting stent. The claims of the '447 patent are directed to a method of biologically stenting a mammalian blood vessel that included administering a drug. The District Court agreed with the PTO's denial of Angiotech's PTE application because none of the claims recited any structure of a particular product and, therefore, did not specify that the drug was administered by a stent (*Angiotech v. Lee*, 191 F.Supp.3d 509 (E.D. Va. 2016))
- Special Considerations for Chemical Compounds
 - ◇ PTE determination turns on whether or not an "active ingredient" had previously been approved by the U.S. Food and Drug Administration
 - ◇ The Federal Circuit upheld PTE for a product containing the **enantiomer** levofloxacin, finding that it was different than a product containing its racemate ofloxacin (*Ortho-McNeil v. Lupin* (Fed. Cir. 2010))
 - ◇ However, the Federal Circuit has also upheld the denial of PTE for the **active methyl ester form** of a compound that had previously been approved for the same therapeutic use because it had the same "active moiety" as the previously approved product (*Photocure v. Kappos* (Fed. Cir. 2010))
- PTE could be available for **corresponding foreign patents** covering products approved in countries such as Australia, Canada, Chile, Europe, Israel, Japan, Malaysia, Singapore, South Korea, Taiwan, Vietnam, Russia and Ukraine, and also in Brunei, Costa Rica, Dominican Republic, El Salvador, Guatemala and Nicaragua
 - ◇ **Note:** The requirements and deadlines for foreign PTEs often vary from the U.S.
 - ◇ **Tip:** Once approval of a product in a foreign country is received, docket any deadlines to file PTE requests

- How do I know if a PTE request has been filed or granted?
 - ◇ Review the file history of the patent on the PTO's Patent Application Information Retrieval (PAIR) system (<http://portal.uspto.gov/pair/PublicPair>)
 - ◇ A list of extended patent terms is available at: <http://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156>
 - ◇ Check the issued patent for a certificate of correction indicating that a PTE has been granted

Tab 14: Federally Funded Inventions and Compliance with the Bayh-Dole Act



Federally Funded Inventions and Compliance with the Bayh-Dole Act

By: Bonnie W. Nannenga-Combs, Ph.D. and John M. Covert



Organizations that receive federal funds or that license technology from third parties that receive Federal funds need to be aware of Federal funding obligations under the Bayh-Dole Act. Any invention conceived *or* reduced to practice with the assistance of the Federal funding is subject to the Bayh-Dole Act. Bayh-Dole permits businesses and nonprofit organizations to elect to retain title of such inventions, if certain obligations are met. However, the government retains certain rights to the invention. To allow for a uniform patent policy among the funding agencies, specific obligations of the parties are set out in the Bayh-Dole Act and Federal agencies are required to use standard funding agreement clauses setting out such obligations. 37 C.F.R. §401.14(a). Furthermore, businesses and nonprofits that receive funding under a Federal government agreement (*e.g.*, contract, cooperative agreement, or grant) executed after May 14, 2018, are subject to the updated regulatory provisions of the Bayh-Dole Act. Certain Federal agencies, *e.g.*, NIH, have given notice that grant renewals will also be subject to the updated provisions (*see, e.g.*, NIH's ["Notice Regarding 2018 Bayh-Dole Act Final Rule - Rights to Federally Funded Inventions and Licensing of Government Owned Inventions"](#)).

The government established an electronic system ([iEdison](#)) for grantees and contractors to report inventions arising out of federal funding and to comply with other on-going reporting obligations, as required by the Bayh-Dole Act. Certain key obligations owed to the funding agency include:

- **Disclosure of the invention** to the funding agency within **two (2) months** after an inventor discloses it in writing to the contractor.
- **Election to retain title of the invention** (in writing) within **two (2) years** after disclosing the invention to the agency or within **60 days** prior to the end of any one year statutory period (*e.g.*, publication, on sale bar, public use, etc.), whichever is sooner.
- **Filing an initial patent application** on the invention within **one (1) year** of election of title or prior to the end of any statutory period, and filing in additional countries or international patent offices within **10 months** of filing the initial application.
- Extensions of time for disclosure, election, and filing may be granted *at the discretion of the agency*.

Disclosure

First, compliance with Bayh-Dole starts prior to the filing of a patent application. The standard funding agreement obligates a businesses or nonprofit organization (referred to in Bayh-Dole as a "contractor") to disclose each invention developed using government funds to the funding agency within **two months** after an inventor discloses it *in writing* to the contractor personnel responsible for patent matters. 37 C.F.R. § 401.14(c)(1). This allows the funding agency time to determine whether it has an interest in taking title to the invention if certain "exceptional circumstances" or other conditions apply.

- Disclosure is through iEdison and includes submission of a written description of the invention, *i.e.*, an "Invention Disclosure Document."
- iEdison submission includes reporting an "Invention Report Date," which is defined as "the date that the inventor discloses the subject invention in writing to the recipient institution."
- A disclosure report also includes the following: the applicable grant number(s), the inventor(s), and any publication, on sale or public use of the invention.
- If a manuscript describing the invention was submitted for publication and/or accepted for publication, it must also be reported. After disclosure, the contractor must also notify the agency of the acceptance of any manuscript describing the invention for publication or any on sale or public use planned by the recipient.

Election

Second, a contractor must also elect *in writing* to retain title to an invention within **two years** of disclosing the invention

to the agency or no more than 60 days prior to the end of any one year statutory period for excluding certain types of prior art. 37 C.F.R. § 401.14(c)(2). For example, if an action (*e.g.*, publication, on sale bar, public use, etc.) by an inventor has started a one year clock to file a patent application in the U.S., the agency may shorten the time period for election to be no more than 60 days prior to the end of the one year “grace period.”

- The “Title Election Date” entered into iEdison is the legally binding date that the contractor elected to retain title to an invention.
- The Title Election Date starts the one-year period during which the initial patent application must be filed, if a one year extension has not been requested.
- iEdison provides an option to request a one year extension of time to file the initial patent application.

Filing

Third, a contractor is obligated to file an initial patent application on the invention within **one year** of election of title or prior to the end of any statutory period, whichever comes first. U.S. 37 C.F.R. § 401.14(c)(3). Under the updated regulations, if the initial patent application is a provisional application, a non-provisional application must be filed within 10 months of filing the provisional application. The regulations also state that a request to extend the 10 months for filing a non-provisional application will automatically be granted for one year, unless the agency notifies the contractor to the contrary within 60 days of the request. 37 C.F.R. § 401.14(c)(5). In addition, the contractor must file patent applications in additional countries or international patent offices within either 10 months of the initial patent application or 6 months from the date the USPTO allows the invention to be filed if there was a Secrecy Order in place. However, the contractor will still retain title in a non-U.S. country even if an application was filed after the specified time as long as a written request (to take title) from the agency was not received prior to filing in that country. 37 C.F.R. § 401.14(d)(2). Furthermore, the updated regulations specify that if a government employee co-invents with a contractor, the agency may submit an initial patent application, but must consult with the contractor and the contractor retains the right to elect title under 35 U.S.C. 202(a). 37 C.F.R. § 401.14(c)(4).

- The patent application(s) must include a statement reciting the following: “This invention was made with government support under [*identify the contract*] awarded by [*identify the Federal agency*]. The government has certain rights in the invention.”
- Contractors must notify the Federal agency of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than **sixty days** before the expiration of the response period required by the relevant patent office. 37 C.F.R. § 401.14(f)(3). The updated regulation increased the notification time from 30 days to 60 days, reducing the decision-making time for the contractor to decide whether to proceed with prosecution or maintain a patent.
- If a contractor elects not to continue the prosecution of any *non-provisional* application, the government can obtain title upon request. 37 C.F.R. § 401.14(d)(3).

Other Obligations

- Contractors are also required to have clauses in employee agreements that provide for timely notification of new inventions to the employer/contractor, and an obligation of assignment of new inventions to the employer/contractor. 37 C.F.R. § 401.14(f)(2).
- Contractors must provide the government with a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the invention. 37 C.F.R. §401.14(b). The license should be recorded with the USPTO Assignment Branch.
- Contractors must submit periodic reports as requested (no more than annually) on the utilization of the invention or on efforts at obtaining such utilization.
- Contractor nor any assignee can grant to any person the exclusive right to use or sell any subject inventions in the U.S. unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the U.S.
 - ◊ Subject to any waiver granted by the Federal agency upon a showing that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

Failure to Comply

Businesses and non-profits should consider the on-going obligations associated with accepting government funds or licensing technology created using government funds. If federal funds are used, the recipient must exercise diligence in meeting the timelines under the Bayh-Dole regulations and abide by the terms of each funding agreement to reduce the risk of the government having a right to take title. If the government takes title, it takes all rights. The contractor will not even retain the right to practice the invention. Failure to meet the requirements of the funding agreement can cause a recipient to lose its patent rights even absent any particularized harm to either the funding agency or the public. See *Campbell Plastics v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004). Thus, all businesses and non-profits engaging in funding agreements should review the Bayh-Dole regulations and timely comply with all obligations. Licensees or purchasers of IP should make sure that the licensor or assignor of government funded IP complied with the appropriate regulations.

Of particular note, the 2018 update to Bayh Dole eliminated the previous sixty day objection period that allowed a fund recipient to retroactively correct defects in complying with disclosure and election of title obligations. Prior to this update, if a contractor failed to meet these disclosure or election obligations within the required time periods, the government had sixty days after discovery of the failure to object and request title. This allowed a contractor the opportunity to correct such a defect and if the government did not object within sixty days, the defect was cured. However, under the revised regulations, there is no longer an objection period. 37 C.F.R. § 404.14(d)(1). Instead, the government can object at any time and obtain title, presumably, even if an effort to correct the mistake was made. Thus, anyone receiving federal funding must timely notify the agency of any invention developed using the funding and timely elect to retain title to avoid a potential cloud over the invention title.

- If the funding agreement is dated after May 14, 2018 (or the renewed funding agreement was amended to incorporate the updated regulations), failure to timely meet the disclosure and election obligations may not be curable.
- If the funding agreement is dated before May 14, 2018 (and was not renewed under the updated rules), it may still be possible to remedy defects in complying with disclosure and election obligations under the old version of the regulations assuming correction is made and the government does not object within 60 days.
- An extension of time for meeting the disclosure obligation may be granted *at the discretion of the agency*. 37 C.F.R. § 401.14(c)(5). It is unclear whether retroactive extensions will be granted.

Practice Tips

- If your organization accepts or is contemplating accepting government funds, employment agreements should be reviewed to ensure the agreements require the employee to provide timely notification of new inventions to the employer, and an obligation of assignment, or a vesting of title, for new inventions to the employer/contractor.
- Invention disclosures and patent department workflow should be updated to allow for flagging inventions conceived or reduced to practice using government funds, and to provide time for reporting inventions to the funding agency.
- At the time of giving election notice to the agency, consider submitting a written request to extend the one year deadline to file the initial application. Requests can be made through iEdison.
- At the time of notifying the agency of a provisional application filing, consider submitting a written request to extend the 10 month non-provisional and foreign filing obligation. Requests can be made through iEdison.
- During due diligence, be sure to check that the potential assignee or licensor of government funded IP complied with all Bayh-Dole obligations.
- If any deadlines are missed, efforts to correct and request any available extensions should be made as soon as possible.
- [iEdison](#) provides useful information and tips including Q&A. Furthermore, specific questions and requests, *e.g.*, for disclosure extensions, can be emailed to edison@od.nih.gov.

Tab 15: When to Obtain Foreign Filing and Export Licenses



When to Obtain Foreign Filing and Export Licenses

By: Jason A. Fitzsimmons and Tracy-Gene G. Durkin



I. Summary

Two important, but sometimes overlooked issues in patent prosecution, particularly for companies with worldwide patent portfolios, are: 1) when a foreign filing license must be obtained; and 2) how to determine when an export license may be necessary. This information is also particularly relevant to multinational corporations, which may have employees—and potential inventors—that are residents and/or citizens of different countries.

Foreign filing licenses allow for the disclosure of technology to foreign jurisdictions for the limited purpose of filing patent applications abroad. However, it may also be necessary to obtain an export license prior to disclosing certain information to persons in foreign countries or to foreign nationals within the United States. Items that are not subject to the International Traffic in Arms Regulations (ITAR) may still be subject to export controls under the Export Administration Regulations (EAR). Therefore, if a company is concerned that technology may be subject to export controls, it is important to consult the EAR, and also possibly counsel specializing in export control law, prior to communicating information about any technology to company employees outside the United States, or even to company employees who are non-U.S. citizens living in the United States.

A. Foreign Filing Licenses

Foreign filing licenses are required by some countries in order to file a patent application in a foreign country prior to filing a domestic patent application for the same invention. The laws regarding foreign filing licenses vary from country to country, which can potentially cause conflicts for patent applications that include inventors from two or more countries. Accordingly, it is important to review the laws of *each* country in question with regard to inventorship and first filing requirements. By way of example, this discussion focuses on the laws in the United States and Germany¹. Similar considerations should be made for any country where a patent application will be filed.

1. Inventorship

In the United States, an inventor is anyone who “conceived” of any subject matter that is claimed in a patent application. See MPEP § 2137.01. Conception is defined as “the complete performance of the mental part of the inventive act,” and is “the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice.” *Townsend v. Smith*, 36 F.2d 292, 295, 4 USPQ 269, 271 (CCPA 1921); see also MPEP § 2138.04. Reduction to practice is generally irrelevant in determining inventorship, except in the instance of simultaneous conception and reduction to practice. See MPEP § 2137.01; see also MPEP § 2138.05 (“Reduction to practice may be an actual reduction or a constructive reduction to practice which occurs when a patent application on the claimed invention is filed.”).

In Germany, it is generally understood that “[a]n invention is thought to have been created as soon as an ‘inventor’ has conceived a complete and, hence, *executable technical teaching*.” Sarah Matheson, *et al.*, AIPPI Group Report Q244 – Inventorship of multinational inventor (2015). This definition substantially corresponds to the definition of inventorship in the United States.

Therefore, if an invention is conceived in the United States, but solely reduced to practice in Germany (i.e., no conception of any of the claimed subject matter occurred in Germany), according to the laws of both countries, the invention is considered to have occurred only in the United States. However, if some of the claimed subject matter in a patent application is conceived in the United States, and other claimed subject matter is conceived in Germany (e.g., further development of the initial invention), the invention is considered to have occurred in both the United States and Germany. The relative “percentage” of the invention conceived in either country is not relevant, only that some portion of the claimed subject

matter is conceived there. It is also irrelevant whether an inventor is a company employee or employed by a third party.

2. First Filing Requirements

The United States and Germany consider different criteria in determining whether a patent application must be filed domestically first. The United States considers where the invention occurred, while Germany considers the nature of the subject matter.

For example, patent applications for inventions conceived in the United States must be filed in the United States first, unless a foreign filing license is obtained to file in a foreign jurisdiction. *See* 35 U.S.C. § 184(a). However, in Germany, patent applications for inventions conceived in Germany may be filed in foreign jurisdictions without a foreign filing license *unless* the application contains a state secret. *See* German Patent Act § 52. In fact, if the application contains a state secret, it does not matter where the invention occurred—it must be filed in Germany first. *Id.*

Other jurisdictions, for example, Denmark, Finland, India, Italy, Portugal, the United Kingdom, France, Israel, and Sweden, consider the *citizenship or residence of the inventors* in determining if an application must be filed domestically first. *International applications and national security considerations*, World Intellectual Property Organization (Dec. 18, 2019), https://www.wipo.int/pct/en/texts/nat_sec.html. Therefore, it is important to understand the requirements of all jurisdictions where invention occurred and where inventors reside or have citizenship before filing a patent application.

B. Export Licenses

As discussed above, foreign filing licenses allow the limited disclosure of information to foreign jurisdictions solely for the purpose of filing patent applications. However, *separate* from a foreign filing license, information regarding certain technologies (typically those which can have military applications) may not be communicated to persons in foreign countries, or to foreign nationals living in the United States, without first obtaining an export license.

The website for the United States Department of Commerce outlines the Export Administration Regulations (EAR)², which impose controls on the export of certain technologies that are not regulated by the International Traffic in Arms Regulations (ITAR). The EAR should be consulted when determining whether information related to a product or technology may be subject to export controls.

Other helpful export control resources are provided below:

- [Scope of the EAR](#)³
- [Steps for Using the EAR from the Bureau of Industry and Security](#)⁴
- [The Commerce Control List Index](#)⁵

C. Practical Application

In view of the above, companies should consider implementing procedures such as the ones below to ensure compliance with foreign filing and export control requirements.

1. File patent applications in the United States first, or obtain a foreign filing license from the USPTO before filing in any foreign jurisdictions when an invention is at least partially conceived in the United States.

As discussed above, Germany does not impose a first filing requirement except where a patent application includes a German state secret. However, if an invention is at least partially conceived in the United States, a corresponding patent application must be filed first in the United States, or a foreign filing license must be obtained prior to filing in foreign jurisdictions. Accordingly, for inventions that are partially conceived in the United States and partially conceived in Germany, companies should default to filing corresponding patent applications in the United States first. Typically, a foreign filing license is granted on the Official Filing Receipt, which is usually issued by the USPTO within a few weeks after filing a new patent application.

Alternatively, if it is necessary or desired to file a PCT application with a foreign receiving office, or other foreign application first, companies should apply for and obtain a foreign filing license from the USPTO prior to filing abroad.

If a company does not have time to obtain a foreign filing license from the USPTO, but needs or desires to have an application filing date in a foreign country by a certain date, a PCT application may be filed with the USPTO—the United States does not require a foreign filing license for PCT applications so long as the USPTO is the receiving office. Similar to the first filing requirement in the United States for regular patent applications, if any of the inventors in the PCT application are United States nationals or residents, the application *must* be filed with the USPTO, but residents or nationals of any of the PCT Member Countries may file PCT applications with the USPTO as well. *See* 35 U.S.C. § 361; MPEP § 1805. Accordingly, if a company plans on filing a PCT application before a United States non-provisional application is filed, the PCT should be filed with the USPTO as the receiving office.

However, if any of the inventors in a PCT application are from a country (other than the United States or Germany) that has its own first filing requirement, that country may require that the application be filed with a receiving office other than the USPTO. In this scenario, a foreign filing license may need to be obtained from either the USPTO or the foreign country in question prior to filing.

2. Consult the EAR and/or export control counsel prior to collaborating with company employees in other countries.

Export control is a complicated area of the law, so it is advisable to seek the expertise of an attorney who specializes in this area if a company is concerned that its technology may be subject to the EAR. If a particular technology is subject to export controls, an export license may need to be obtained prior to disclosing any information to company employees in another country or non-U.S. citizen employees in the United States. Even if the information is communicated to a foreign national inside a company facility within the United States, that disclosure is still considered to be an “export.” *See e.g.*, J. Triplett Mackintosh & Monique A. Tuttle, *Export Control Laws and the Employment of Foreign Nationals*, 10 No. 11 Colo. Emp. L. L1 (2001).

The links provided in Section II.B of this memo may aid in determining whether it is advisable to seek the guidance of counsel specializing in export control law.

¹ Since we are not German patent attorneys, our analysis is based on our basic understanding of German patent law.

² <https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear>

³ <https://www.bis.doc.gov/index.php/documents/regulations-docs/2382-part-734-3-14-19/file>

⁴ <https://www.bis.doc.gov/index.php/documents/regulation-docs/411-part-732-steps-for-using-the-ear/file>

⁵ <https://www.bis.doc.gov/index.php/documents/regulations-docs/2329-commerce-control-list-index-3/file>

Tab 16: Global Design Patent Guide



Global Design Patent Guide

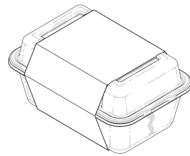
By: Tracy-Gene G. Durkin, Ivy Clarice Estoesta, and Bethany M. Kokanovich

Product design holds tremendous monetary value globally. This often leads to successful designs falling victim to knock-offs that can damage brand loyalty and reduce revenue. Design patents, which protect the ornamental appearance of an article, are a proven effective tool in combating copycats. While consumer products, like footwear and wearable technology, are obvious candidates for design patent protection, it is easy to overlook design patent protection for other types of goods such as industrial products, graphical user interface, and type fonts. Below is a sampling of various products that are protected by design patent.

Design Patent Examples



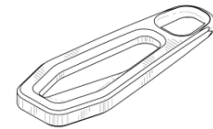
Electric Lighter
D780,515
TYL, Inc.



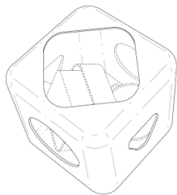
Container
D850,902
Blue Apron, LLC



Shoe
D819,323
Reebok International Limited



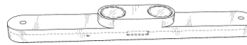
Zipper Puller
D829,600
Thule, Inc.



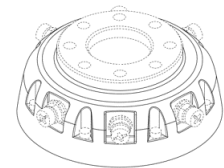
Toy
D807,967
Bioserie



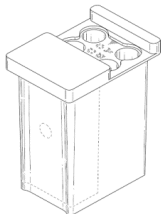
Electronic Device
D842,853
Apple Inc.



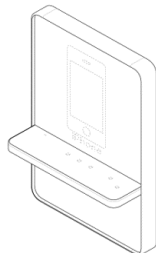
Sensor Module
D772,736
SZ DJI TECHNOLOGY CO., LTD.



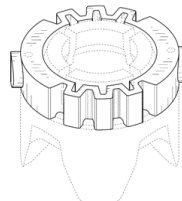
Connector
D827,686
KUKA Roboter GmbH



Receptacle Holder
D855,826
GEN-PROBE INCORPORATED



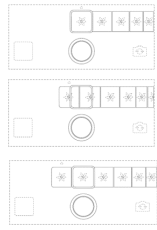
Retail Fixture
D867,035
Apple Inc.



Multipart Collar
D852,951
West Pharmaceutical Services, Inc.



**Display Screen or Portion Thereof
with Graphical User Interface**
D812,093
salesforce.com, inc.



abcdefghijklm
nopqrstuvwxyz

ABCDEFGHIJKLM
NOPQRSTUVWXYZ

0123456789

**Display Screen or Portion Thereof with
Animated Graphical User Interface**

D846,587

Apple Inc.

Type Font

D802,049

Apple Inc.

Almost five years ago, the U.S. joined the Hague Agreement, providing U.S.-based entities the possibility of filing up to 100 designs in one International Design Application (IDA) designating multiple countries that are a party to the Hague Agreement. With 73 countries (including 4 of the largest intellectual property offices in the world) now participating in the Hague system, and others, like China, exploring eventual membership, applicants may be wondering what is the better way to secure worldwide protection for a design. In other words, is it better to file a single IDA through the Hague system or file multiple separate national design applications directly with each intellectual property office of interest?

For applicants domiciled or that have a real and effective place of business in a country that is party to the Hague Agreement, filing a single IDA might sound more appealing. Indeed, unlike filing multiple national design applications (which requires an applicant to engage local counsel to make the filing on the applicant's behalf), filing through the Hague system provides the upfront cost benefit of avoiding the expense of local counsel. It also provides the long term benefit of administrative efficiency because, for example, renewals may be made for all or some of the industrial designs included in the international registration and for all or some of the designated countries.

But, before deciding to filing an IDA, it is important to note that an IDA is examined according to each designated country's particular rules (which vary from country to country), including whether the IDA will be examined only for formalities or substantively for patentability. And, if an IDA is objected to or rejected during examination, local counsel would need to be engaged to address the objection/rejection, cancelling out the upfront cost benefit of filing an IDA.

Regardless of which filing system an applicant decides to use, there is, in general, limited ability to change the representations of a design and maintain Paris Convention priority after their home country patent application is filed. Therefore, all applicants should be mindful of the particular rules of the countries they plan to direct file in or designate in their IDA to ensure that their initial application contains representations that are ready to file abroad. To that end, the following quick-reference guide provides a sampling of design preparation and prosecution requirements in a variety of countries around the world.

Country	Preparation							Prosecution			
	Hague member state	Shading allowed	Broken lines allowed	GUI designs protectable	Multiple embodiments allowed in a single registration	Detailed written description of the design features required	Multiple Locarno sub-classes permitted	Substantive examination conducted (automatic or on request)	Average length of prosecution (from filing to issuance)	Process for expediting registration available	Approximate total costs from filing to grant
Argentina	N	Y	Y	Y	Y	N	N	N	1-2M	N	\$3,050
Australia	N	Y	Y	N	N	N	Y	Y	1-2M	N	\$2,950
Brazil	N	Y	N	Y	Y	N	N	Y	1-2Y	N	\$3,150
Canada	Y	Y	Y	Y	Y	N	N/A	Y	1-2Y	Y	\$2,500
Chile	N	Y	Y	Y	Y	Y	Y	Y	2Y	N	\$5,200
China	N	N	N	Y	Y	N	N	N	1Y	N	\$1,850
Colombia	N	Y	Y	Y	Y	N	N	N	1Y	N	\$2,700
Croatia	Y	Y	N	Y	Y	N	Y	N	1Y	N	\$2,200
Europe	Y	Y	Y	Y	N	N	Y	N	1-2M	N	\$2,400
Hong Kong	N	Y	Y	Y	N	N	Y	N	6M	N	\$1,900
India	N	N	N	N	N	N	N	Y	1Y	N	\$1,800
Indonesia	N	Y	Y	N	N	N	N	Y	1-2Y	N	\$1,800
Israel	Y	Y	Y	Y	Y	N	N	Y	8-12M	Y	\$2,200
Japan	Y	Y	Y	Y	N	N	N	Y	1Y	Y	\$2,900
Jordan	N	Y	Y	N	N	Y	N	Y	1Y	N	\$2,200
Korea	Y	Y	Y	Y	N	N	N	Y	7-8M	Y	\$2,150
Malaysia	N	Y	Y	N	N	N	N	Y	9M	N	\$2,200
Mexico	N	Y	Y	Y	Y	N	N	Y	1-2Y	N	\$3,450
New Zealand	N	Y	Y	Y	N	N	Y, PTO DISCRETION	Y	6M	N	\$2,600
Norway	Y	N	Y	Y	Y	N	Y	Y	6M	N	\$2,300
Paraguay	N	Y	Y	N	Y	N	N	Y	2-3Y	N	\$2,050
Russia	Y	Y	Y	Y	Y	Y	Y	Y	1-2Y	Y	\$2,650
Singapore	Y	Y	Y	Y	Y	N	Y	N	4-6M	N	\$1,950
South Africa	N	Y	Y	Y	N	N	N	N	9M	Y	\$2,020
Switzerland	Y	Y	Y	Y	Y	N	Y	N	1-2M	Y	\$2,200
Taiwan	N	Y	Y	Y	N	Y	Y	Y	1-2Y	N	\$1,900
Thailand	N	N	N	Y	N	N	Y	Y	3-4Y	Y	\$2,040
Turkey	Y	Y	Y	Y	Y	Y	Y	N	1-2Y	N	\$2,030
Ukraine	Y	Y	N	Y	Y	Y	N	N	8-10M	N	\$1,825
United Kingdom	Y	Y	Y	Y	Y	N	Y	Y	3-6M	N	\$2,065
United States	Y	Y	Y	Y	Y	N	N/A	Y	1.5Y	Y	\$3,500
Vietnam	Y	Y	N	N	N	Y	Y	Y	1-2Y	Y	\$1,580

The information contained in this quick-reference guide should not be construed as a legal opinion or as legal advice. The quick-reference guide is intended to convey general information only, and may not address fact-specific nuances.

Tab 17: Medical Device Considerations



Medical Device Considerations

By: Trevor M. O'Neill and Mark W. Rygiel



Preparing and prosecuting medical device patents can be unique and challenging. Patent owners and practitioners often must consider a wide range of converging technologies from the mechanical, electrical, chemical, and biotechnological arts. Here are a few best practices to keep in mind as part of your medical device prosecution toolkit:

Provide meaningful disclosure of the device as it relates to the underlying drug. Many products approved as drugs by the U.S. Food and Drug Administration (FDA) are delivered via a medical device. When drafting a patent application directed to the device, practitioners may include disclosure of structural details and functional parameters of the medical device that improve delivery of the specific drug involved. For example, a particular plunger force may be critical to the proper delivery of the drug. Also, practitioners should consider including claims of varying scope that recite the structural details and functional parameters of the device together with the drug to be administered. This can help support patentability, for example with pre-filled syringes and other devices, where at least some structural details of the device itself may be in the prior art but the use of such structure in the context of the underlying drug are not. Incorporation of the underlying drug into the patent claims may also improve the Orange Book eligibility of your medical device patent.

Generally include a robust disclosure of the structural elements of the device. Even outside the context of an underlying drug to be delivered, medical device applications should include as much detail as possible regarding the structure of the device. Practitioners may consider, for example, including dimensions of different structural elements, their relative positions, and how the elements are interconnected. Include detailed figures as necessary, including cross-sectional figures showing the internal design of the device. Consider these additional best practices for effectively disclosing and claiming a medical device:

- **Link functional language to structural elements in the disclosure.** For example, in a device configured to inject a drug, carefully describe what structural elements actually accomplish the injection (*e.g.*, needle, plunger, actuator, etc.). If possible, provide alternative structure to perform the desired function.
- **Discuss material selection.** Consider including multiple material options for important device elements, and discuss any advantages of choosing certain materials for a given element.
- **Consider linkages between the medical device and external networks and Internet of Things.** For some devices, a robust disclosure discussing any possible connection between the device and a digital network may be critical. Consider including the advantages gained in some embodiments by connecting the device to a network or the internet (*e.g.*, remote monitoring, improved maintenance, consumable reordering, etc.)
- **Include a method of using and/or method of manufacturing the device.** Include disclosure and claims discussing the method of using/manufacturing the device. The method of manufacturing the device may often be more relevant for infringement purposes, but the end user (*i.e.*, the method of using claims) may also be relevant. In general, these method sections are usually presented immediately following the structural description of the device.
- **Consider divided infringement when drafting the disclosure.** Where possible, ensure that the disclosure and claims provide opportunity to target infringement by a single desired entity, as well as by multiple entities. Depending on the nature of the device, it may be necessary to draft the disclosure and claims to address contributory infringement.

Keep other jurisdictions in mind. FDA approval in the United States and CE marking in Europe are often critical to medical device manufacturers. The patent rules in these jurisdictions are quite different and must be followed in the first filed priority application for your medical device invention. For example, for cases first filed in the United States, European patent practice must be considered when claiming and describing your medical device invention. For example, because the European Patent Office is very restrictive when it comes to amendments based on a combination of features from the general specification and the examples, the disclosure should specifically describe each relevant combination of features together. Also, because the EPO may not consider subject matter “incorporated by reference” to be part of your specification, the specification should include the most essential parts of the reference if you consider these to be important to the invention. Perhaps the most important strategy to implement is one that establishes effective

communication among your global prosecution team.

Consider design patent protection. In the United States, design patents protect the “look and feel” of a device or product. For medical device manufacturers, the non-functional appearance of the device may impart value that is not protected by a related utility application, and, thus, design protection can strengthen the medical device patent portfolio. In addition to mechanical features, design protection can protect the look of graphical user interface aspects of the medical device, and design of replacement components, for example. In the United States, design patents are often less expensive and quicker to obtain than utility patents.