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Life Sciences IP Tool Kit 2025

Introduction

Intellectual property (IP) strategy in the life sciences evolves as rapidly as the scientific breakthroughs driving the industry. Since the America Invents Act reshaped the U.S. patent system more than a decade ago, courts and policymakers have continued to refine how its provisions apply, particularly in areas critical to life sciences, such as patent subject matter eligibility, biosimilar development, and regulatory exclusivities. Protecting innovation in this environment requires more than strong patents. Life sciences companies must also safeguard trade secrets, secure trademarks that reinforce brand identity, and anticipate how competitors may challenge or design around their IP.

At Sterne Kessler, we have spent almost five decades helping life sciences companies of all sizes—from emerging biotechnology companies to global pharmaceutical leaders—protect and advance their innovations. Our team combines deep technical knowledge with a sophisticated understanding of how the United States Patent and Trademark Office, courts, and the Patent Trial and Appeal Board approach IP rights. We work closely with clients to develop strategic IP portfolios and ensure their innovations are well positioned for commercialization and enforcement.

This Life Sciences IP Tool Kit was created as a practical reference to highlight some of the strategies and best practices our professionals apply every day. As the landscape continues to shift in 2025 and beyond, we stand ready to help life sciences companies protect their discoveries, maximize the value of their IP, and stay ahead in a competitive market.

Marsha Rose Gillentine, Ph.D., Carla Ji-Eun Kim, Eric K. Steffe

Editor & Authors

Marsha Rose Gillentine, Ph.D., Director, Editor
mrose@sternekessler.com

Paul A. Ainsworth, Director
painsworth@sternekessler.com

John M. Covert, Director
jcovert@sternekessler.com

Jorge A. Goldstein, Ph.D., Director
jgold@sternekessler.com

Carla Ji-Eun Kim, Director, Co-Chair, Patent Prosecution Practice
ckim@sternekessler.com

Gaby L. Longsworth, Ph.D., Director
glongs@sternekessler.com

Robert C. Millonig, Ph.D., Director
bobm@sternekessler.com

Bonnie Nannenga-Combs, Ph.D., Director, Co-Chair, Patent Prosecution Practice
bncombs@sternekessler.com

Eric K. Steffe, Director
esteffe@sternekessler.com

Monica Riva Talley, Director, Head of Trademark & Brand Protection Practice
mtalley@sternekessler.com

Lori M. Brandes, Ph.D., Counsel
lbrandes@sternekessler.com

Mark T. Roundtree, Associate
mroundtree@sternekessler.com

Deepa Shiwcharan, Pharm.D., Associate
dshiwcharan@sternekessler.com

Bree A. Vculek, Associate
bvculek@sternekessler.com

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Patenting the Product Label

By: Marsha Rose Gillentine, Ph.D.

When the U.S. Food and Drug Administration (FDA) 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 (i.e., a generic or biosimilar pharmaceutical company) is required to package its product with a product label. The generic product label is required to be substantially similar to the brand product label.

Litigation involving pharmaceutical-related patents typically occurs prior to the launch of a generic or biosimilar product. So infringement by the generic or biosimilar pharmaceutical company is based upon the product or product label proposed to the FDA to be approved.

A generic or biosimilar pharmaceutical company rarely performs a step recited in a method of use patent, such as "treating a patient." Therefore, to establish patent infringement, a patentee must demonstrate the generic pharmaceutical company induces a third party (e.g., the doctor or patient) to perform a claimed method, such as "treating a patient."

Overview of Inducement as Applied in the Pharmaceutical Context

- A party "causes, urges, encourages, or aids" a direct infringement by another party.
- It must establish that the alleged infringer (e.g., a generic or biosimilar pharmaceutical company) knowingly induces infringement and has a specific intent to encourage the third party to infringe the patent.
- A generic or biosimilar 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.
- Draft claims directed to new indications and patient subpopulations, especially if there is a difference in efficacy in a particular patient subpopulation.
- Draft claims directed to combination therapies, especially if the combination impacts the safety and efficacy of the original patient population.
- Draft claims with claims directed to the pharmacokinetic parameters (e.g., Cmax, Tmax, and AUC) included on the product label.
- If you 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.

Obviousness-Type Double Patenting

By: Gaby L. Longsworth, Ph.D., & Bree A. Vculek

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 that are not "patentably distinct" from the claims of a first patent. *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997).

1. 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 noncommonly 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).

2. Understanding the Impact of Terminal Disclaimers on Patent Term and 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 TD 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).

3. The 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. Sept. 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 ODP on other grounds).
- "ODP for a patent that has received PTA, whether or not a terminal disclaimer is required or has been filed, must be based on the expiration date of the patent *after* PTA has been added." *In re Cellect, LLC*, No. 2022-1293, 2023 WL 5519716, at *9 (Fed. Cir. Aug. 28, 2023) (emphasis added).
- A first-filed, first-issued, later-expiring patent claim cannot be invalidated for ODP by a later-filed, later-issued, earlier-expiring reference patent claim having a common priority date. *Allergan USA, Inc. v. MSN Laboratories Priv. Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024).
  - This decision clarifies the scope of *In re Cellect* and confirms the value of obtaining PTA in a first-issued patent in a patent family and the inapplicability of ODP to the first-issued patent over a later-issued, earlier-expiring continuation patent. *Allergan USA, Inc. v. MSN Laboratories Priv. Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024).
- 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. *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 to 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(l)(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).

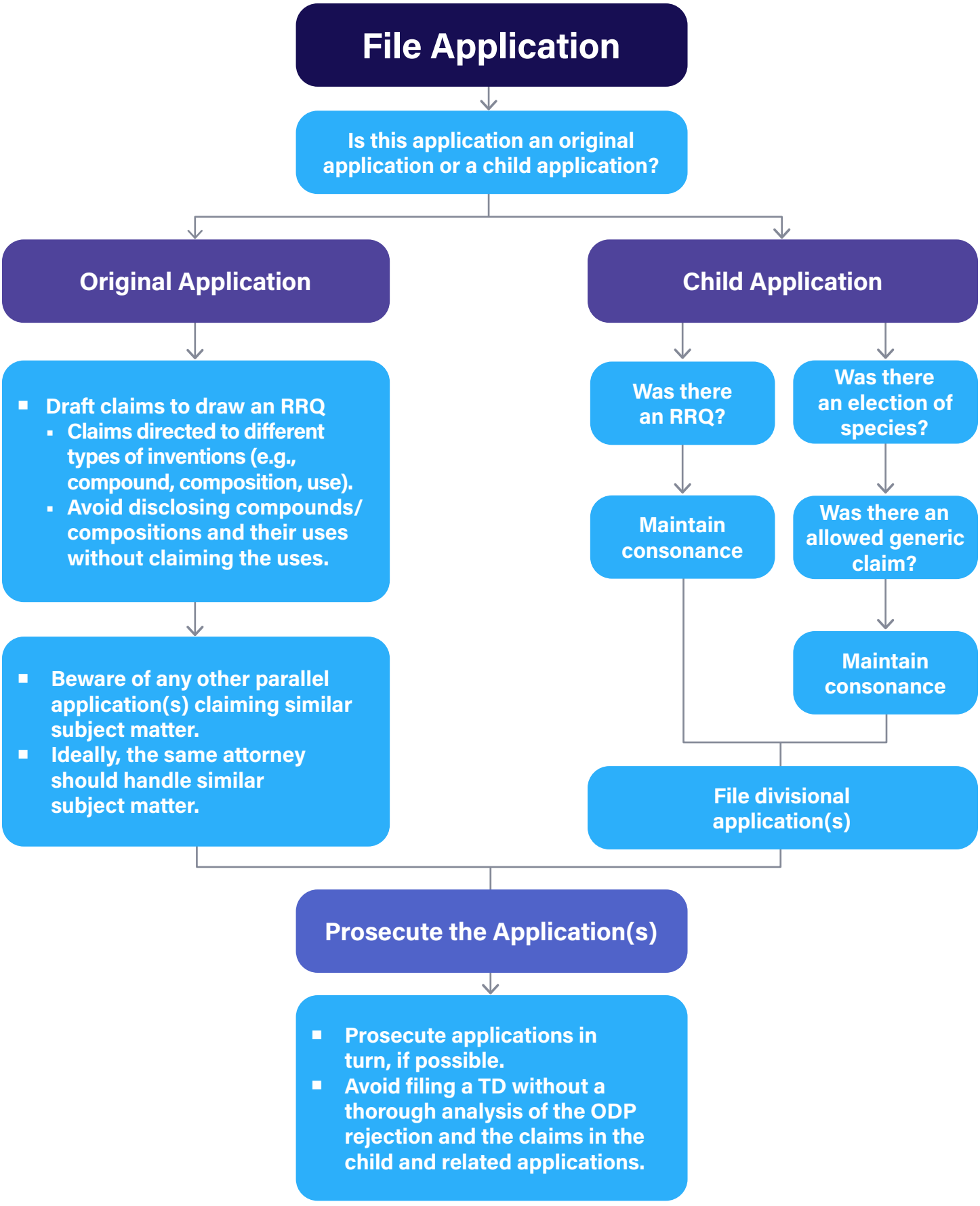
5. How to Overcome ODP Post-Issuance and/or in Litigation

- If patents can trace their lineage back to a common parent that 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 an 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).
    - However, amending a continuation to be a divisional is allowed to obtain safe harbor protection under § 121 as long as consonance is maintained. *Acadia Pharms., Inc. v. Aurobindo Pharma Ltd.*, No. 2024-1401 (Fed. Cir. June 9, 2025).
  - 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 Sauerber*g, 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.
  - If a statutory disclaimer over a claim or claims challenged under ODP is not filed, the claim will not be finally canceled and the merits of a patentability challenge will be addressed. *Best Med. Int'l, Inc. v. Elekta Inc.*, 46 F.4th 1346 (Fed. Cir. 2022).
- 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, ask yourself:
  - Is this an original application or a child application?
    - Original application: draft claims to draw an 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. *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).
- Prosecuting the application:
  - Prosecute applications in turn, if possible.
  - Beware of later-filed, earlier-issued patents in related families.
    - For example, 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).


File Application
Is this application an original application or a child application?
Original Application
Child Application
Draft claims to draw an RRQ
Claims directed to different types of inventions (e.g., compound, composition, use).
Avoid disclosing compounds/ compositions and their uses without claiming the uses.
Was there an RRQ?
Was there an election of species?
Maintain consonance
Was there an allowed generic claim?
Maintain consonance
Beware of any other parallel application(s) claiming similar subject matter.
Ideally, the same attorney should handle similar subject matter.
File divisional application(s)
Prosecute the Application(s)
Prosecute applications in turn, if possible.
Avoid filing a TD without a thorough analysis of the ODP rejection and the claims in the child and related applications.

Polymorph Patents

By: Deepa Shiwcharan, Pharm.D., & Robert C. Millonig, Ph.D.

Companies interested in researching, developing, and commercializing pharmaceutical compounds should be aware of not only strategies for patenting the compound itself, but strategies for patenting polymorphs of the compound.

A polymorph is a 3D crystalline structure of a chemical compound. These variations in crystal structure are unpredictable and result in differing physiochemical properties, such as melting point, solubility, dissolution rates, bioavailability, and stability. Therefore, patenting polymorphs can potentially add value to an IP portfolio.

Original Compound Patent

An initial application directed to a pharmaceutical compound would likely constitute as prior art to any subsequently filed polymorph patent under 35 U.S.C. § 102(a)(1) and should be drafted with the prior art effect in mind. Therefore, although the specification should include a synthetic method for making the compound, it should not include working examples reciting specific recrystallization conditions, generic disclosures of suitable recrystallization solvents or conditions, or general discussions concerning physical forms of the compound (e.g., hydrates or solvates, crystalline or amorphous).

However, it should be noted that, in some rare situations, it is possible for a polymorph patent to be entitled to the priority date of a provisional application that is directed to a pharmaceutical compound even if the compound patent does not explicitly disclose the polymorph. In *Amgen Inc. v. Sandoz Inc.,* 66 F.4th 952 (Fed. Cir. 2023), the Federal Circuit, without reaching the issue of inherency, held that such a provisional application actually disclosed the crystalline form of the compound. The court's decision rested on the fact that the patentee provided the results of over a dozen experiments following the procedure in an example of the provisional application, all of which resulted in the specific crystalline form of the compound, whereas the defendant did not produce the results of any experiment showing that the crystalline form was not produced.

For the remainder of this article, it is assumed that the polymorph patent does not claim priority to the compound patent. However, the ability to claim a polymorph based on an inherent disclosure should not be discounted.

First Polymorph Patent(s)

Let's say a polymorph screen is conducted during formulation development. The compound is determined to be highly polymorphic, but only a single polymorph, anhydrous Form A, having the best formulation characteristics, (e.g., flowability and hygroscopicity) is fully characterized and selected for drug development. A patent application directed to this polymorph is then drafted.

CONTENT OF THE APPLICATION

The specification should include detailed information concerning several recrystallization conditions and solvent mixtures that yield Form A, provide an X-ray powder diffraction (XRPD) spectrum showing all of its peaks (including strong peaks, intermediate peaks, and minor peaks), as well as the differential scanning calorimetry (DSC) and infrared (IR) spectra. XRPD peak tables should also be provided, as well as express teachings that define Form A by its major peaks or, alternatively, by the major peaks together with the intermediate and minor peaks. The patent application can also disclose the administration of Form A to humans in an oral dosage form, but it may be silent as to the precise dosage conditions, such as frequency of administration or whether the drug is administered with or without food.

Applicants should be cautious if claiming polymorphs by large numbers of XRPD peaks. In *Glaxo v. Novopharm II,* 110 F.3d 1562 (Fed. Cir 1997), the patentee attempted to enforce a polymorph claim reciting a 29-peak IR spectrum. The Federal Circuit held that the patentee must establish that the XRPD of the alleged infringing material contains each

of these 29 peaks to establish infringement. As some of these peaks are low intensity that may not be identifiable in the XRPD of a given batch, claiming polymorphs by large numbers of XRPD peaks can create difficulties when trying to establish infringement. *See Merck Sharp & Dohme Corp. v. Amneal Pharmaceuticals LLC,* 881 F.3d 1376 (2018) (to establish infringement, a one-to-one correspondence is not required).

Applicants should also be cautious of claiming a polymorph by a few major XRPD peaks. As the claims could inadvertently read on multiple polymorphs that share the same low resolution XRPD pattern but differ in other physical properties, it could leave such a claim open to a 35 U.S.C. § 112 attack for lack of written description or enablement. *See AbbVie Deutschland v. Janssen Biotech,* 759 F.3d 1285 (Fed. Cir. 2014).

Therefore, applicants should pursue claims of varying scope to (1) a polymorph characterized by the XRPD pattern, (2) a polymorph characterized by the major peaks, (3) a polymorph characterized by the major and moderate peaks, and (4) a polymorph defined by melting point, DSC, and/or IR spectra, either independently or together with the XRPD information. Errors in the d-spacing values should be expressly recited in the claims so the courts do not impute an error value broader or narrower than intended.

TIMING OF FILING THE APPLICATION

The timing of filing a polymorph application is an important consideration. If the polymorph application is filed before the prior art date of the compound patent, it would not provide significant additional patent term beyond the term of the compound patent. If, on the other hand, the polymorph application is filed too long after the prior art date of the compound patent, third parties may begin to research and file patent applications covering any polymorphs they identify.

If the compound exhibits a high degree of polymorphism and the compound patent is silent as to physical forms and recrystallization conditions, the filing of the polymorph application can be delayed past the prior art date of the compound patent to maximize effective patent term.

On the other hand, if the prior art includes a process to produce a crystalline form, then characterizing the crystalline form resulting from that process would likely be held obvious. *See Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals, Inc.,* 98 F.4th 1056 (Fed. Cir. 2024) (the court held that the polymorph claim was obvious because the methods for characterizing the crystalline form were well known and readily available to a person of ordinary skill in the art and were nothing more than routine optimization).

Balancing the risks, if a compound exhibits a high degree of polymorphism or if the compound was not previously known to exist in a highly polymorphic state, a first polymorph application can be filed before the clinical results of the compound are widely reported in scientific literature.

POLYMORPH STRATEGY FOR EUROPE

In EPO Board of Appeals decision T 777/08, the claims were directed to a particular polymorph of crystalline atorvastatin hydrate and the closest prior art was the amorphous form of atorvastatin. The Board held that, in the absence of any technical prejudice or unexpected property, a new crystalline form of a known compound does not involve an inventive step. This case has been distinguished in two subsequent cases. *See* T 0643/12 (a polymorph of the mesylate salt of lenvatinib exhibited inventive step when the mesylate salt was not in the prior art); T 1422/12 (crystalline form of tigecycline exhibited inventive step in light of unexpected improvement in stability with respect to an epimerization reaction); T 1418/22 (crystalline form of acalabrutinib exhibited inventive step in light of the "technical difficulty" of crystallizing this polymorph, and the crystalline form exhibited unexpected non-hygroscopicity). However, the general rule in Europe is, contrary to the law in the United States, that a prejudice in the field or unexpectedly superior properties are necessary to obtain a patent on a polymorph in the EPO.

In light of the divergent legal standards for polymorph patents between the United States and Europe, filing polymorph patents in Europe should proceed only in situations where there are potential unexpected or superior properties or some teaching away in the art.

Best Practices

1. In a patent application directed to a new chemical compound, specific disclosure concerning precise recrystallization conditions or physical forms of the compound (salts, hydrates, polymorphs) should be avoided.

2. A polymorph screen should be conducted early in the product development process, and patent applications should be filed directed to the polymorph to be used in the drug product as well as any potentially bioequivalent alternatives.

3. Applicants should bear in mind potential hurdles to filing a polymorph application, including prior public use and prior art disclosures of a process to produce the crystalline form.

4. If the compound of interest exhibits a high degree of polymorphism or if the compound of interest was not previously known to exist in a polymorphic state, filing patent applications after the prior art date of the compound patent can be considered on a case-by-case basis.

5. The pharmaceutical drug product should be evaluated on a regular basis for new polymorphic forms of the API.

6. Polymorphic forms should be claimed in multiple ways—by XRPD peaks listings of various lengths, XRPD spectra as well as other physical properties such as melting point or IR spectra.

7. When claiming polymorphic forms in terms of XRPD peak listings, the language "characterized by" should be used in defining the recited peaks.

8. Interconversions of various polymorphic forms should be considered. Efforts should be made to identify and claim the lowest energy form without purity limitations in the absence of prior art constraints. However, make sure to include a description of purity levels in the specification to have broader levels of written description support if necessary.

Patent Term Adjustment

By: Lori M. Brandes, Ph.D. & 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 (USPTO) in issuing a patent.

Why Review PTA?

The USPTO continues to work on reducing application pendency and inventory of unexamined applications. However, the USPTO's statistics from 2024 show that only 32% of applications received a first action within 14 months of filing, and 24% of applications had not issued within 36 months of filing. USPTO delays are still prevalent.

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"):
  - USPTO issues an office action or notice of allowance more than 14 months after the application is filed.
  - USPTO acts more than four months after applicants file a reply to office action.
  - USPTO acts more than four months after a decision on appeal or decision by a federal court finding at least one claim allowable.
  - USPTO 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 USPTO 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 USPTO 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 USPTO notice or office action.
    - Submitting an amendment or other paper after a notice of allowance.
    - Submitting a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the USPTO, after a reply has been filed.
    - 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.
    - Failing to file a petition to withdraw abandonment or revive an application within two months from issuance of a notice of abandonment.

Challenging the USPTO's Calculation of PTA

- File a request for reconsideration of PTA at the USPTO
  - 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 USPTO 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 USPTO's decision on a request for reconsideration have an "exclusive remedy" by civil action within 180 days after the date of the USPTO's decision. 78 Fed. Reg. 19416; *Daiichi v. Lee* (Fed. Cir. 2015).
  - Ordinary tolling of the 180-day deadline is allowed while awaiting the USPTO'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 (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

- It has been reported that approximately 50% of patents granted in 2024 had applicant-caused delays. Avoiding these delays can preserve a PTA to which a patentee may otherwise be entitled.
- Independently carry out a PTA calculation according to the current rules and case law, and if there is an error, file a petition with the USPTO to challenge the PTA calculation.
- 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 in other countries 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, for example, 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 an A delay sooner than it would end 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 preexamination notice or restriction requirement at the three-month deadline.
- To maximize a delay, pay the issue fee on the deadline rather than before the deadline.
- Carefully consider the consequences of filing a terminal disclaimer.
  - It may or may not negatively affect PTA.
  - Preserve the largest-possible PTA in parent applications in the event a terminal disclaimer is filed in later child applications.
  - A "first-filed, first-issued, later-expiring claim" cannot be invalidated for obviousness-type double patenting (ODP) by a "later-filed, later-issued, earlier-expiring reference claim" having the same priority date. *Allergan v. MSN* (Fed. Cir. 2024). This decision limited the scope of a prior decision holding that a patent having PTA can be invalidated for ODP over earlier-expiring patents in the same family. *In re Cellect* (Fed. Cir. 2023).
- Avoid filing a request for continued examination (RCE).
  - Time in "continued examination" is excluded from a B delay, but only for the time before allowance. *Novartis v. Lee* (Fed. Cir. 2014).
  - May still be entitled to PTA for an A or a C delay.
  - Consider filing an appeal instead of an RCE to preserve a 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 USPTO notice or request.
- 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 v. 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).

PTA Around the World

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

Country	Requirements
Canada	▪ A new system went into effect on January 1, 2025, providing additional patent term to compensate patent owners for "unreasonable delays" by the Canadian Intellectual Property Office in issuing patents. ▪ A patent owner must apply for PTA within 3 months of patent issuance. ▪ The patent must have a filing date of on or after December 1, 2020, and must have issued after the later of (1) the fifth anniversary of the "applicable day" and (2) the third anniversary of the day that examination was requested.
Chile	▪ 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.
China	▪ PTA was introduced in 2020 to compensate for "unreasonable delays" in the patent prosecution process not caused by the applicant. ▪ Available for invention patents granted more than 4 years after filing and more than 3 years after a request for substantive examination.
Colombia	▪ 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.

Country	Requirements
Costa Rica	▪ 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	▪ 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.
El Salvador	▪ 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	▪ 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	▪ 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.
Japan	▪ Available for applications filed on or after March 10, 2020, when (1) the application grants more than 5 years from the filing date or (2) patent examination continues beyond 3 years from the date of filing a request for examination.
Mexico	▪ PTA was introduced in 2020 to address unjustified delays in prosecuting and granting patents. ▪ Request for PTA should not exceed 5 years and is submitted when replying to a notice of allowance.
Nicaragua	▪ 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.

Country	Requirements
Singapore	▪ 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 (e.g., 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.
South Korea	▪ 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 (e.g., extensions of time). ▪ Request must be filed within 3 months of grant.

Patent Term Extension

By: John M. Covert & 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 (USPTO), 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 that 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 five 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:** 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 six 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 USPTO 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 period, the right to exclude with the patent only reaches, for example, the approved drug and approved indication
      - The Federal Circuit held that ODP did not invalidate an otherwise validly obtained PTE under 35 U.S.C. § 156. *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018)
      - The Federal Circuit held 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."
  - USPTO 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 the 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 for the different products
  - The USPTO will provide a period of time (usually one month) for the patent owner to elect the product for which extension is desired
- The USPTO has permitted an applicant under 37 C.F.R. § 1.103 to suspend action on a PTE application for up to six months upon showing good and sufficient cause
  - **Useful when:**
    - An applicant wants the PTE to apply to a reissue patent that has not yet been granted rather than to the original patent
    - There is 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 USPTO'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 those of 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 USPTO'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

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Patenting Antibodies — the Latest Case Law and What Biotech Companies Need to Know

By: Jorge A. Goldstein, Ph.D.

Introduction

Antibody-based therapies have revolutionized modern medicine. They have led to unprecedented success in treating various cancers, autoimmune diseases, and other conditions, many of which previously had no known treatment.

The need for broad patent protection for new antibodies is therefore a major concern of the antibody-related research community. Several recent court decisions dealing with enablement and written description of a broad genus of antibodies have cast a veil on the ability of inventors and their assignees to receive claims of worthwhile scope. It has become difficult to obtain and enforce a genus claim that goes beyond one or two specific antibodies.

The critical hurdle is that if a genus claim of therapeutic antibodies contains any semblance of biological function, the need for an understanding of structure-function correlation rears its head. Such understanding is a common requirement for the two portions of the statute, 35 U.S.C. § 112 (a): enablement and written description.[1]

The Legal Landscape

While the underpinning factual analyses used for both portions of the statute have become increasingly similar, the legal requirements are not identical. Enablement of a genus claim requires evidence that, at the desired priority date, a person of skill in the art could achieve the full scope of the claim "without undue experimentation." In contrast, written description requires evidence that, at the desired priority date, the inventor had "possession" of the full scope of the claim. A genus claim must comply with both. Let us now look at each one in turn.

ENABLEMENT

Two cases on the enablement of a genus of antibodies control today's legal landscape: *In re Wands* (1988) and *Amgen v. Sanofi* (2023).

In re Wands established the eponymous eight "*Wands* factors" by which to measure claim enablement (or lack thereof) in view of a specification, in the context of the state of the art at the time of filing. The *Wands* factors are (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. All eight need to be considered and balanced in order to reach a conclusion.

The important thing to understand about the *Wands* factors is that the claims in the case contain no biological function. The claims are to plain antibodies defined by antigen binding; what we will call its "binding definition." The court upheld the claims in *Wands* as enabled by screening alone.

That was not the situation, however, in *Amgen v. Sanofi*, where the Court of Appeals did not uphold the enablement of the claims. The major distinction between the two cases is that, in addition to antigen binding (as in *Wands*), the claims in *Amgen* have a biological function: the binding of antigen also has to block the antigen's interaction with its cellular receptor. The lack of predictability of how to obtain antibodies that bound to the antigen *and* that blocked the receptor compounded the enablement problem. In 2023, in affirming the decision of the court in *Amgen*, the U.S. Supreme Court added the need to set forth the existence of a "general quality common" to all members of the genus that would perform the required biological function. We will call this the "common quality" test.

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1) For a more detailed and annotated version of this chapter, see Jorge Goldstein, "Solutions to the Problem of Antibody Genus Claims," 52 *AIPLA Quarterly Journal,* No. 3, 513-64 (Summer 2024)

WRITTEN DESCRIPTION

The main cases controlling the landscape for written description of a genus of antibodies are *Regents of U. California v. Eli Lilly* (1997), *Capon v. Eshhar* (2005), *AbbVie Deutschland v. Janssen Biotech* (Fed. Cir. 2014), and *Juno v. Kite* (2021).

In *Regents*, the court held that to meet the written description for a genus of biomolecules, the specification, in the context of the state of the art at the filing date, had to set forth either of two alternatives. The first alternative echoes the "common quality" analysis later used in *Amgen* for enablement: it is to establish a common structure-function correlation between the claimed molecular structure and its biological function. The second alternative is to describe a representative number of species encompassed by the genus. Either one will do.

A few years later, the court in *Capon* used an analysis reminiscent of the eight factors in *Wands*, and enunciated several elements to determine if a specification shows sufficient written description to support genus claims. These "*Capon* factors" are defined as (1) the nature of the invention at issue; (2) the extent and content of the prior art; (3) the maturity of the science or technology; (4) the predictability of the aspect at issue; (5) the scope of the claimed invention; and (6) other considerations appropriate to the subject matter. As in *Wands* for enablement, all *Capon* factors need to be considered and balanced when analyzing the written description of the full scope of a genus claim.

AbbVie Deutschland applied the *Regents* "representative number of examples" alternative to a genus of antibodies. It held that the examples in the specification were in a single class that was not representative of the genus in that they failed to encompass another class to which the accused antibody belonged.

And in *Juno*, the court applied *Regents*, this time to a genus of single-chain antibodies fusions. The fusions are multicomponent nucleic acid sequences, where only one of the sequence components is that of a single-chain antibody, while the other component is not. The court analyzed each component under the *Regents* two-alternative test. The claim failed the written description requirement.

CONFLUENCE OF ENABLEMENT AND WRITTEN DESCRIPTION

Under the present state of the law, the conclusion reached by the courts as to compliance with full-scope enablement for genus claims with biological functions starts with a balancing of the *Wands* factors. Applying *Amgen*, the courts then focus on the presence or absence of a common quality among all members of the genus.

In turn, the conclusion regarding full-scope written description starts with a common structure-function correlation or representative number of examples under *Regents*. It further depends on a balancing of the *Capon* factors and on the full-scope representativeness of examples under *AbbVie*. Under *Juno*, the court then applies this analysis to every structural element of the claim.

The confluence of both aspects of the statute leads to what we may call the *"Wands/Capon"* factors, supplemented by either alternative in *Regents* and by the search for a "common quality" under *Amgen*.

How to Draft and Defend Antibody-Related Genus Claims

In most instances when the court has examined a genus claim to an antibody *per* se that includes a biological function, or to a method of using an antibody, it has held that the claim lacked either full-scope enablement or full-scope written description. It should be obvious that one solution to the problem of complying with the overall statute for a genus claim lies in avoiding the inclusion of any biological function. Let us explore possible ways of achieving this.

PROMISING ANTIBODY GENUS CLAIMS: CLAIM AS A PRODUCT PER SE

The first approach is not to rely solely on method-of-treatment claims, such as administering to a patient an antibody that treats a disease. *A priori,* the inclusion of a treatment step introduces a biological function into the claim. The claim is then susceptible to questions about structure-function correlations or common qualities and to a balancing of the *Wands/Capon* factors. If we use method-of-treatment claims — as we invariably will — we must be aware that such claims are highly vulnerable to challenge.

A claim format based on antibody products per se without function has a better chance of surviving challenges. Several formats come to mind, depending on whether the target to which the antibody binds is novel.

WHEN THE TARGET IS NOT NOVEL: CLAIM BY USING A COMPETITIVE ASSAY FORMAT

A very common scenario occurs when the target X is *not* novel. Assume that the inventor has discovered that blocking the known target leads to a heretofore-unknown beneficial therapeutic effect. In such a situation, claiming the antibody per se by its binding to the target may not be possible, as such antibody may be considered obvious. Assume that our inventor has made one specific antibody (a), which performs a newly discovered therapeutic effect when it binds to target X. The specific antibody (a) is novel; that is, there is no identical antibody in the prior art. Because it exhibits the therapeutic effect, the antibody can be demonstrated to be nonobvious.

Now assume that our inventor has sequenced antibody (a) or placed its production cells on deposit at the American Type Culture Collection. Claiming only antibody (a) (known as the "reference antibody") will produce a narrow claim that can easily be avoided by competitors. Yet with the sequence (or deposit), our inventor can put forth a claim with some scope beyond antibody (a). The claim should include a part (b) drawn to a genus of antibodies that compete with antibody (a) in its binding to target X:

> **Model claim.** An antibody that binds to target X, selected from the group consisting of:
> (a) a reference antibody, wherein the light chain of said reference antibody comprises the amino acid sequence of SEQ ID NO: 1 and the heavy chain of said reference antibody comprises the amino acid sequence of SEQ ID NO: 2 [alternatively, antibody (a) can be claimed by its ATCC deposit number]; and
> (b) an antibody that competitively inhibits the binding of reference antibody (a) to target X.

Part (b) is a genus that could prevent others from making highly similar antibodies to (a) while literally avoiding the reference antibody.

A challenge for lack of full-scope enablement of a claim with a similar competitive binding requirement was made and fended off in *Johns Hopkins University v. CellPro, Inc.* (1998), an encouraging precedent. Another, more recent case dealing with a genus of antibodies claimed by competitive binding to a reference is *Immunex Corporation v. Sanofi-Aventis U.S. LLC, et al.* (2020). The reference antibody in *Immunex,* just like that in our model claim, is defined by its light- and heavy-chain sequences.

Neither the proposed model claim nor those in *Hopkins or Immunex* contain any biological function. They are to a genus of antibodies defined by nothing but a competitive immunoassay. Such immunoassays are more like the immunoassay claims that survived in *Wands* than the claims that were invalidated in *Amgen*.

AUTOMATED SCREENING FOR CLAIMS FORMATTED AS COMPETITIVE ASSAYS

The immediate enablement question raised by our model claim is: Can a person of skill in the art (POSA) generate new antibodies that fall within limitation (b) without undue experimentation? A POSA would do so by running an immunoassay test to detect competition for target X between a new antibody and reference antibody (a). While some of the tests may be positive and others not, the law post-*Amgen* is that some amount of routine screening is still permissible to comply with the enablement requirement.

There is another argument in favor of routine screening for enablement analysis of a genus of antibodies claimed in competitive assay format: the advent of automated artificial intelligence (AI)-assisted, high-throughput methods. Screening for antibodies that bind a target and finding among those the ones that compete with a reference antibody for it are no longer as slow and labor intensive as they were in the past. In 2025, these tasks are done by computerized AI-assisted robots.

If the equipment to do AI-assisted high-throughput screening is not readily available, the specification should at least describe how modern day screening is done by such techniques. The inventor will then be able to rely on two strengthened *Wands* factors: the advanced state of the art (factor 5) and the high level of skill (factor 6).

WRITTEN DESCRIPTION OF CLAIMS FORMATTED AS COMPETITIVE ASSAYS

Screening, no matter how high-tech, is not a proper method to comply with full-scope written description. Therefore, our arguments about the enablement of a claim that includes a binding definition plus competitive binding requirement do not apply to written description.

To comply with full-scope written description under *Regents* for part (b) of the model claim, the inventor is well-advised to provide multiple examples of additional antibodies and show that they successfully compete with antibody (a) to target X. The inclusion of multiple, and hopefully representative, examples of other antibodies will avoid the pitfall of *AbbVie Deutschland*. And *Capon* factor (3), the maturity of the technology, should also help.

TARGET NOVEL OR NOT: CLAIM BY USING MEANS-PLUS-FUNCTION FORMAT

The next possibility for claiming a genus of antibodies without including biological function arises out of the "means-plus-function" statute, 35 U.S.C. § 112(f). This statute allows *combination* claims to be drafted solely by function, "without the recital of structure."

Following the statute, we might draft an antibody *per se* claim as follows:

> **Model claim.** In combination, (1) means for binding a molecular epitope in target X such that the binding of target X to its receptor Y is blocked, together with (2) a pharmaceutically acceptable carrier.

Since the case law suggests that means-plus-function claims not include any "means" structure whatsoever, there is no mention of an antibody or any other such "means." Principally, the claim contains the function: "that the binding of target X to its receptor Y is blocked."

In *Ex Parte Aaron Keith Chamberlain, et al*. (2024), the Patent Trial and Appeal Board approved means-plus-function claims for antibodies. Following *Chamberlain*, the specification supporting the "means" part of the model claim need not describe more than one example of an antibody that binds to target X.

However, as shown by the later *In re Xencor* (2025), the full scope of means-plus-function claims is not free from the rigorous written description requirement of *Regents* or *Capon*. It is therefore good practice to include as lengthy a description as possible of the many distinct "means" to carry out the claimed binding function. These may include antibodies of different types (e.g., IgG, IgE, IgD, IgM, single chain variables (ScFv), minibodies, nanobodies, chimeric, humanized, fully human, bivalent, fusions of antibodies, receptors, fusions of receptors, antibodies from different germ lines, and the like).

WHEN TARGET IS NOVEL: CLAIM BY ANTIGEN BINDING ONLY

We will finally discuss the increasingly rare situation where an inventor discovers a heretofore-unknown target X. Assume that this is a novel receptor, the blocking of which leads to a biological result.[2] In such situation, and following *Chiron v. Genentech* (2004), the inventor may be able to present a genus claim to the antibody *per se* with a binding definition only:

> **Model claim.** A monoclonal antibody that binds to target X.

Assume that no matter how much our inventor tries, she cannot, at the first filing date, deduce a common quality or common structure-function correlation for all members of the genus. She is then—at least initially—unable to meet the *Wands/Capon* requirements, the common quality of *Amgen,* or either of the two alternatives of *Regents*. Our inventor should therefore not immediately file for claims, even dependent ones, which include a biological function. Yet our inventor should not wait to file an application until she has elucidated a common quality or common structure-function correlation. She can still obtain a broad antibody genus claim with nothing but a binding definition.

For this to work, the specification should include detailed descriptions of at least *two uses* for the novel antibody: *The first* is a diagnostic immunoassay for the target and *the second* is therapy based on blocking the target.

For the first use, the specification should describe nonlabeled, labeled, and solid-phase-bound forms of the antibody. The labeled and solid-phase-bound antibodies can be used in various types of *in vitro* immunoassays or *in vivo* tissue imaging. Following *In re Magerlein* (1979), the nonlabeled antibody should be described as a useful intermediate that leads to the labeled and solid-phase-bound ones utilized in assays. These nonlabeled antibodies should immediately be claimed. With appropriate written description, our inventor may be able to obtain a genus claim to the new and nonobvious unlabeled antibody claimed as a per se product. Such a broad antibody claim should still dominate the use of the same antibody for therapeutic, as well as future, uses.

For the second use, the first specification should describe the therapeutic function that comes from blocking a pathway involving the novel target X. However, while not initially presented, a claim to a novel and nonobvious method of therapy focused on blocking (or activating) the novel target X should eventually be presented. This can happen when there is a better understanding of a common quality or a common structure-function correlation. Because such a claim will *a priori* include a biological function, it will bring along a full analysis under *Amgen, Regents,* and the *Wands/Capon* factors. However, because including a later-elucidated common quality will likely generate a new filing date, the inventor should not wait too long to file the therapy claim. If she does, her own published first patent application disclosing the therapy becomes prior art.

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2) For more detail on the treatment of the situation in this section, please see Goldstein, footnote 1.

Federally Funded Inventions and Compliance with the Bayh-Dole Act

By: Bonnie Nannenga-Combs, Ph.D., & 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 ongoing 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 business 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 six 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 60 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.
- No 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 ongoing 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 60-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 60 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 60 days, the defect was cured. However, under the 2018 revised regulations, there is not an objection period. 37 C.F.R. § 404.14(d)(1). Instead, the government can object at any time and presumably obtain title, 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.

A subsequent revision to the regulations in 2023 provides the potential to cure a breach of one or more of the contractor's obligations. The breach can be brought to the attention of the funding agency and a waiver can be requested. New and renewed funding agreements on or after April 24, 2023, allow the recipient to cure a defect in its obligations and seek a waiver from the agency.

- If the funding agreement is dated after May 14, 2018, but prior to April 24, 2023 (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 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. iEdison provides for automatic extensions of certain deadlines if requested in advance.

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**.

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Avoiding Sequence Listing Pitfalls Under ST.26

By: Carla Ji-Eun Kim

Sequence listings are a critical component of many biotechnology and life sciences patent applications. Under 37 C.F.R. §§ 1.821–1.825, U.S. patent applications must comply with specific sequence listing rules.

On July 1, 2022, the World Intellectual Property Organization (WIPO) implemented the Standard ST.26, replacing the long-standing Standard ST.25. Because there was no transition period, both formats remain relevant depending on the application's filing date. Navigating this transition is essential to avoid costly errors or loss of priority.

Below are key considerations for preparing and filing sequence listings:

1. **ST.25 Required**
   Applications with a filing date on or before June 30, 2022, must continue using the ST.25 format throughout prosecution. Even if a sequence listing is filed after July 1, 2022, it cannot be converted to ST.26. For U.S. national phase applications, the international filing date serves as the relevant filing date for determining which standard applies.

2. **ST.26 Required**
   Applications with a filing date on or after July 1, 2022, must use the ST.26 format, even if they claim priority to an earlier application that used ST.25.

3. **Continuations and Divisionals (CON/DIV)**
   If a CON or DIV application is filed on or after July 1, 2022, its sequence listing must be in ST.26 format, even when the parent application was filed under ST.25 rules.

4. **Best Practice**
   First submit the ST.25 listing, wait for the USPTO to issue a Notice of Defective Sequence Listing, and then submit the ST.26 version. This process ensures that all parental sequence information remains on record, reducing the risk of accidental omissions during conversion.

5. **Short Sequences**
   ST.26 excludes sequences of fewer than 10 specifically defined nucleotides or four specifically defined amino acids. If these short sequences are included only in the original ST.25 listing, they must be added to the specification to prevent loss of subject matter, which could affect priority.

6. **Wildcards**
   Under ST.25, "Xaa" represents any amino acid without restriction. Under ST.26, "X" is limited to the 22 naturally occurring amino acids, a narrower interpretation that may require careful review during conversion.

7. **Amino Acid Representation**
   ST.25: Amino acids are shown in a three-letter uppercase format (e.g., Ala, Gly, Ser). ST.26: Amino acids are shown in a single-letter uppercase format (e.g., A, G, S).

8. **RNA Sequences**
   RNA sequences are not directly represented under ST.26. Instead, they must be written as DNA sequences and identified as RNA using the "mol_type" qualifier.

9. **Double-Stranded DNA**
   For double-stranded DNA, only the sense strand needs to be included, unless the antisense strand is essential to the invention. If the antisense strand is relevant, it should be provided as a separate sequence, clearly identified as antisense.

While sequence listings may seem like a formality, errors can lead to loss of subject matter or priority, impacting patent enforceability. Careful attention to the filing date, format requirements, and nuances of the ST.25 to ST.26 transition will help ensure compliance and protect valuable intellectual property rights.

Protecting Your Life Sciences Trade Secrets

By: Paul A. Ainsworth

Trade secrets are indispensable to an intellectual property protection program. For the life sciences industry, trade secrets work hand-in-hand with patent protection to ensure that others cannot freeload on a company's investments in innovation.

Trade secret information is often found in a variety of technology areas. Importantly, trade secrets do not need to meet statutory requirements for patentability (novel, nonobvious) so long as they provide economic value to the company by being held secret. For the life sciences industry, some important categories of trade secret information may include:

- Therapeutic targets and related modalities
- Assays and testing methods (e.g., protocols for detecting important biomarkers)
- Manufacturing procedures and equipment configuration (unique fermentation or purification techniques)
- Proprietary cell lines, unique strains of bacteria or years
- Formulation and/or formulation strategies
- Software and algorithms
- Research data and experimental results
- Development plans and strategies
- Supplier/vendor information
- Unpublished inventions

Under both federal and state law, a trade secret owner must demonstrate that they have taken *reasonable* measures to protect their secrets from disclosure. While there is no one-size-fits-all answer to what constitutes reasonable measures, there are a number of factors that are commonly taken into account:

- Existence of a trade secret policy
- Use of non-disclosure agreements for employees, consultants, and anyone else with access to company confidential information
- Limiting trade secret access to only those individuals with a need to know
- Restrictions on physical access to facilities
- Restrictions on access, printing, and sharing of electronic resources
- On-boarding and off-boarding procedures
- Employee education on protocols for protecting company confidential information

In adopting protocols for protecting trade secret information, it is important to take into consideration the practicalities of keeping the information secret. While in some cases it may be that the number of people who need access to the information can be strictly limited to a handful of employees, in other cases there may be a number of employees exposed to the information in order to perform their work responsibilities.

In any agreements permitting access to trade secret information, those agreements should address the following:

- Restrictions on use, dissemination, or disclosure of trade secret information
- Ownership of all trade secret information, including trade secrets generated under the agreement
- Prohibitions on use of third-party confidential information
- For employee or consultant agreements, notice of whistleblower rights must be provided
- Return/destruction of any company confidential information upon termination

It is also important to have a clear understanding of what constitutes the trade secret(s) that are important to the company. Key considerations include:

- Protocols for identifying potential important trade secret subject matter
- Protocols for ensuring trade secret information is not inadvertently published or otherwise disclosed
- Strategic consideration of what innovative subject matter should be patented and what should be kept as a trade secret
- Practicality of keeping information confidential

Trademark Strategies for Life Sciences Companies

By: Monica Riva Talley

Why Do Brands Matter?

In the life sciences fields, including biotech, pharmaceuticals, and medical devices, trademark and trade dress are useful forms of intellectual property that protect the branding, look, and unique features of products and even research services or platforms unique to your company.

Strong brand protection helps companies stand out and achieve market success. The appearance and name of a product helps healthcare professionals, patients, and consumers instantly distinguish between options, and in an industry where patient safety is crucial, trademarks create trust and loyalty by ensuring patients receive a product of consistent quality and efficacy. A trusted and unique trademark adds value to a company, enhancing its market position and influencing how consumers perceive the brand.

Trademark Longevity

Trademarks and brands play an important role in communicating goodwill long after other forms of intellectual property have expired or generics have been allowed to enter the market. Consumer goodwill associated with a brand is priceless and is a shorthand way of identifying and reaffirming all that consumers and partners value and trust about a company and a product. Strong trademark protection also keeps competitors from profiting off the reputation of the brand, by protecting against adoption of confusingly similar marks.

Trademarks also drive price and purchasing decisions. A trademark confers credibility and communicates the source of the goods. A **recent article** in *Fortune* magazine noted that branded pharmaceuticals cost an average of 79% more than generic drugs. And many categories of consumers are willing to pay the premium for the trust and goodwill associated with the brand name.

Trademark strategy is particularly key in the life sciences and pharmaceutical spaces. Trademark protections can extend long past patent terms so long as the trademark identifies the product or collaboration using the technology. Brands can help maintain consumer loyalty even as competitors enter the field. Strong trademark protection, including registration and a thoughtful international portfolio, can also help enforce and deter infringers.

Forms of Trademarks in the Pharma and Life Sciences Space

Trademarks that identify drug brands are typically given a wider scope of protection than marks in other industries, in an effort to prevent confusion between prescriptions and in dosing. This is one of the reasons life sciences and pharmaceutical companies often select made-up words as brand names — even if they are difficult to pronounce. Trademarks take many forms and are defined as an indicia that identifies the source of a product or service. These can include:

- **Words (including made-up words)**
- **Phrases (slogans)**
- **Symbols**
- **Designs**
- **Configurations**
- **Colors**
- **Sounds**
- **Smells**
- **Tastes**
- **Textures**
- **(Or a combination of the above)**

The trade dress of a product, including the appearance of a drug (e.g., packaging, labeling, specialized applicator, pill shape and color, and inner and outer packaging) can also be protectable as a trademark to the extent such elements are not functional. A classic example is Pfizer's registration of the blue color and diamond shape of its Viagra erectile dysfunction tablet.

Trademarks Are Evaluated Differently in the Pharma Business

Life sciences companies face unique challenges when it comes to brand selection and protection. Pharmaceutical trademark owners must surmount two hurdles before they can use and register their trademarks in the U.S. For U.S. Food and Drug Administration (FDA)-approved products, clearing a drug name is a two-step process:

- **Trademark Registration:** Brand owners must obtain approval of the USPTO to obtain federal trademark registration.
- **FDA Approval to Use:** Brand owners must obtain approval from the FDA to use the pharmaceutical name. Both the USPTO and the FDA purport to accept only names that will not cause confusion between drug names, both agencies compare different universes of data in making these determinations, and apply somewhat different standards.

The USPTO will consider whether the proposed brand name is confusingly similar to marks that are already applied for and registered as trademarks. Often pharmaceutical companies apply for several alternative brands for a single product launch, and the USPTO's search may therefore result in a refusal to register a mark based on a trademark that will never appear in the FDA database.

In contrast, the FDA looks at nonproprietary pharmaceutical names, established USP-NF monographs, generic names, and trademarks approved for use by the FDA but not yet applied for or registered. Approval from both agencies is ultimately necessary before a brand can be considered available for use as a new pharmaceutical trademark.

Anti-Counterfeiting/Enforcement

Counterfeiting is a global concern, reaching virtually all industries in all countries. Pharmaceuticals are one of the most-counterfeited products, with studies attempting to quantify the counterfeit drug market estimating the total global sales between $200 billion and $431 billion annually. The World Health Organization (WHO) estimates that 10.5% of medicines worldwide are substandard or falsified.

Trademarks give companies the tools needed to protect their exclusive rights, preventing competitors from using branding that could cause confusion. But it is important to be proactive and put the necessary tools in place to enforce against bad actors. In particular, brand owners should consider:

- Recording trademarks with Customs to help stop importation of counterfeit goods
- Registering internationally in the countries in which the product will be sold or manufactured or where you maintain business relationships
- Defensively register in countries with large or growing economies, or those known to be bad actors.
- Consider copyright protection for design marks
- Monitoring services — trademarks, domain names, online/websites

Final Recommendations

- Think about branding early: allow adequate time to search and clear a mark before using it in clinical trials, promoting it within the industry, or submitting it to the FDA.
- Conduct a proper clearance: invest up front in a trademark/FDA clearance search conducted by an attorney experienced with pharmaceutical marks.
- Consider international strategy, including cultural and linguistic factors, ensuring that trademarks resonate globally and avoid misinterpretation.
- Be original: avoid words that look or sound similar to existing brands, do not borrow from an existing brand or generic name, do not use pharmaceutical stems as a prominent part of your drug name, and choose unique trade dress.
- Proactively register in geographic areas of interest.
- File for alternatives: the USPTO recognizes the challenges of obtaining FDA drug name approval and, for that reason, considers the filing of alternative drug names to be a bona fide intent to use a mark in commerce, as required to support an application.
- Collaboration between marketing and legal: a successful branding program requires buy-in from the entire business.
- "Think outside the name" of the product when considering brand expansion and trademark registration. Slogans, logos, product, and packaging appearance are just a few ways that marketing can help with creating brand identity, which may be registrable with the USPTO.

Small Entity Status for Life Sciences Companies — Determining Number of Employees

By: Mark T. Roundtree & Marsha Rose Gillentine, Ph.D.

A patent applicant that is considered a small entity—as defined in 37 C.F.R. § 1.27—is entitled to a reduction to most United States Patent and Trademark Office (USPTO) fees. Therefore, small entity status can help lessen the financial burden of patent prosecution for qualifying businesses in the life sciences industry.

Small Entities: The Basics

- 37 C.F.R. § 1.27(a) – A small entity for the purposes of the USPTO may be a person, small business concern, or nonprofit organization.
- A small business concern qualifies for reduced patent fees when:
  1) The number of employees, including those of affiliates, does not exceed 500 and
  2) When the concern has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to a party that would not qualify for small entity status.
  See 27 C.F.R. § 1.27(a)(2); see also 13 C.F.R. § 121.802.

How Should Businesses Calculate the Number of Employees?

- Employee numbers should be calculated per the standards of the Small Business Administration (SBA). See 37 C.F.R. § 1.27(a)(2).
- Per SBA standards, employee number is calculated based on the 24 months prior to the date of entity status certification to the USPTO. See 13 C.F.R. § 121.106(b)(1).
  - Employee number should be calculated as:
    1) The average number of a business's employees per pay period, plus
    2) The average number of employees per pay period for each of the business's affiliates.
    See 13 C.F.R. § 121.106(b)(1-4).
- If the business added an affiliate during the measurement period, then the new affiliate's employees should be added throughout the entire 24-month period. See 13 C.F.R. § 121.106(b)(4)(i).
- If an affiliation ended during the measurement period, then the employees of the former affiliate should not be included in the calculation. See 13 C.F.R. § 121.106(b)(4)(ii).

What Constitutes an Employee?

- Employees include all individuals employed on a full-time, part-time, or "other basis." See 13 C.F.R. § 121.106(b)(4)(i).
- Businesses should consider the totality of the circumstances of the relationship between business and individual when determining an individual's employment status. See 13 C.F.R. § 121.106(a). This includes the criteria for assessing potential employer/employee relationships used by the IRS for federal income tax purposes. See 13 C.F.R. § 121.106(a).
- Per IRS guidelines, relevant facts indicating an employer/employee relationship include:
  - Behavioral control—facts showing that the business has a right to direct and control how a worker does tasks for which the worker is hired. Examples include:
    - Providing instructions on when and where to work
    - Providing instructions on what tools or equipment to use
    - Providing instructions regarding what workers to hire or to assist with work
    - Providing instructions on where to purchase supplies and services
    - Providing instructions regarding what work specific individuals must perform
    - Training workers to perform services in a particular manner

- Financial control—facts showing that a business has a right to control the business aspects of a worker's job. Examples include:
  - The extent of unreimbursed expenses—contractors are more likely than employees to have unreimbursed expenses.
  - The extent of a worker's investment in facilities or tools necessary to perform relevant services.
  - The extent to which a worker can make their service available to the relevant market independent of the business.
  - The business's method of paying the worker.
- Type of relationship—facts that show the type of relationship between the parties. Examples include:
  - Written contracts describing the relationship.
  - Provision of employee-type benefits to the worker.
  - The permanency of the relationship.
  - The extent to which services performed by the worker are a key aspect of regular business.

What Is an Affiliate?

- Entities are affiliates of each other when one entity controls or has the power to control the other. 13 C.F.R. § 121.103(a)(1).
- Entities are also affiliates when a third party controls or has the power to control both entities. 13 C.F.R. § 121.103(a)(1).
- Factors to consider when determining affiliation status (see 13 C.F.R. § 121.103(a)(2)) include:
  - Ownership of the entities.
  - Management of the entities.
  - Previous relationships between the entities.
  - Contractual relationships between the entities.
- Businesses should also consider whether an affiliation has arisen from the following (13 C.F.R. § 121.103(c)-(i)):
  - Stock ownership in another entity.
  - Stock options, convertible securities, and merger agreements with another entity.
  - Common management with another entity.
  - Identities of interest with another entity (e.g., when firms are economically dependent through a contractual relationship).
  - Longstanding joint ventures between the business and another entity.
  - License agreements when there is common ownership or common management.

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Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

1101 K St. NW, 10th Floor
Washington, DC 20005

sternekessler.com