THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



THE SAFE HARBOR OF 35 U.S.C. § 121: JUDICIAL DEVIATION FROM CONGRESSIONAL INTENT IS NOT NECESSARY TO UPHOLD 35 U.S.C. § 101

JEANETTE M. BRAUN

Abstract

35 U.S.C. § 101 allows one patent per invention. Congress recognized that patent applications may disclose more than one invention and in 1952, enacted 35 U.S.C. § 120 and 121 to allow parent patent applications to birth child applications. The rights of patent blood lines have been understood and relied on for decades. In 2015, the Federal Circuit changed the rights of patent blood lines and ruled that the order in which patent applications were birthed destroyed 35 U.S.C. § 121 protection of divisional applications.

This article analyzes the congressional intent of 35 U.S.C. § 121, the rights of patent blood lines, and whether consonance passes from a parent application through a continuation application to a divisional application. The analyses found that granting a divisional application stemming from a continuation application instead of the parent application entrance into the § 121 safe harbor does not violate the one patent per invention requirement of 35 U.S.C. § 101. "We cannot destroy kindred: our chains stretch a little sometimes, but they never break." ~Marquise de Sévigné

Copyright © 2018 The John Marshall Law School



Cite as Jeanette M. Braun, The Safe Harbor of 35 U.S.C. § 121: Judicial Deviation from Congressional Intent Is Not Necessary to Uphold 35 U.S.C. § 101, 18 J. MARSHALL REV. INTELL. PROP. L. 205 (2018).

The Safe Harbor of 35 U.S.C. § 121: Judicial Deviation from Congressional Intent Is Not Necessary to Uphold 35 U.S.C. § 101

JEANETTE M. BRAUN

I. Introduction	206
II. BACKGROUND	210
A. Patent Families and Fleets in 1836	
B. Once a Twin, Now a Step-Child	212
C. Misunderstanding Consonance Caused the Familial Change	213
III. Analysis	214
A. Plain Language of 35 U.S.C. § 121	214
B. Mathematical Proofs Show Congress' Intent is Logical and the Recent	
Judicial Decisions are Not	215
IV. Proposal	
V. Conclusion	219

THE SAFE HARBOR OF 35 U.S.C. § 121: JUDICIAL DEVIATION FROM CONGRESSIONAL INTENT IS NOT NECESSARY TO UPHOLD 35 U.S.C. § 101

JEANETTE M. BRAUN*

I. Introduction

Whether a patent applicant receives a patent for related but distinct inventions depends on the order in which the identical patent applications are filed. This oddity is the result of the Federal Circuit deviating from the safe harbor for related inventions that Congress intended to give under 35 U.S.C. § 121.¹ The Federal Circuit has deviated from the congressional intent of § 121 to uphold the one patent per invention requirement under 35 U.S.C. § 101,² which is not necessary. The order in which patent applications in a family are filed should not impact whether a patent application is granted.

A patent gives its owner a right to exclude others from making, using, selling, offering for sale, or importing a claimed invention for a limited term in exchange for the applicant advancing science by teaching the public how to make and use the claimed invention.³ To prevent persons from extending the limited term by obtaining patents covering essentially the same invention, Congress allows only one patent per invention.⁴ 35 U.S.C. § 101⁵ sets forth the doctrine of statutory double patenting,

^{* ©} Jeanette M. Braun 2018. J.D. candidate, May 2019, The John Marshall Law School. Registered Patent Agent. Jeanette is a second-generation patent practitioner. She started working in her mother's patent firm (McManus & Associates) when she was thirteen years old, and has spent her career helping inventors capture and harvest intangible assets through IP right acquisition and enforcement. She holds a B.S. in Chemistry and Minor in Mathematics from the University of Illinois at Chicago, and practices in a vast array of technology areas (mechanical, chemical, pharmaceutical, biotechnological, and computer science). Jeanette gives sincere and special thanks to John Kilyk, Jr., Member of Leydig, Voit & Mayer, LTD, for suggesting the topic for this comment, and providing counsel about the current issues surrounding divisional practice, Donna Megregian, Vice President and Actuary at RGA for assisting with creating and proofing the mathematical proofs, Gunnersmate Second Class Roger Trutsch for providing the naval terminology, Peter K. Trzyna, Founder of Peter K. Trzyna Law Office P.C. for editing this comment, and the RIPL Board for their time, energy, and effort readying this issue for publication. "Teamwork makes the dream work." ~John C. Maxwell.

¹ 35 U.S.C. § 121 (2012).

² 35 U.S.C. § 101 (2012) (An inventor "may obtain a patent.").

³ U.S. Const. art. I, § 8; 35 U.S.C. § 271 (2012); Chicago & N.W. Ry. Co. v. Sayles, 97 U.S. 554, 555 (1878) ("A party who invents a new machine never used before, and procures letters-patent therefor, acquires a monopoly as against all merely formal variations thereof; but if the advance towards the thing desired is gradual, and proceeds step by step, so that no one can claim the complete thing, each inventor is entitled only to his own specific form of device.").

^{4 35} U.S.C. § 101.

⁵ In re Basell Poliolefine Italia S.P.A., 547 F.3d 1371, 1375 (Fed. Cir. 2008) (citing to the holding in Eli Lilly & Co. v. Barr Labs, Inc., 251 F.3d 955, 967 (Fed.Cir.2001) that ODP "prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent."); Chenghua Luo et al., 5 Ways to Avoid Obviousness-Type Double Patenting, LAW360 (May 13, 2016), http://www.skgf.com/uploads/

^{1426/}doc/5_Ways_To_Avoid_Obviousness-Type_Double_Patenting.pdf ("Obviousness-type double patenting (ODP) is a judicially created doctrine intended to prevent an improper timewise

which states in the singular that a patent applicant may obtain only one patent per invention. Where an applicant's patent application claims the same invention as another pending application or granted patent, the United States Patent and Trademark Office ("USPTO") will issue a statutory double patenting rejection.⁶ This type of rejection can be overcome by amending or cancelling claims identified in the rejection as already pending or granted.⁷

Congress recognized that patent applications may disclose more than one invention. In some cases, the application may disclose unrelated inventions, such as a bicycle and a chemical composition, or related inventions, such as a chemical that has several uses and a particular process that may or may not use the chemical. To accommodate these possibilities, Congress enacted 35 U.S.C. § 120 and 121 which allow claiming the benefit of the filing date of an original or parent (i.e., first-filed) patent application in subsequent patent applications that is a continuation or divisional application.

A continuation application⁸ is a subsequent patent application for the same invention claimed in a preceding patent application, whereas a divisional patent application⁹ is a subsequent patent application for a different invention claimed in a preceding patent application. Both continuation¹⁰ and divisional¹¹ patent applications have a disclosure (specification and drawings) that are identical to the disclosure in the original application: no new matter can be added to these applications.¹² The original patent application's claims as filed with the original application are considered part of the original disclosure and become a part of a continuation application's disclosure¹³ so long as the continuation meets the criteria set out in § 120 for a proper continuation application.¹⁴

Continuation and divisional patent applications must be filed while the original patent application is pending, and also must identify the original application as the

extension of patent rights by prohibiting the issuance to a single entity of claims in a second patent which are not "patentably distinct" from the claims of a first patent.").

 $^{^6}$ Manual Of Patent Examining Procedure $\$ 804.02 (9th ed. Rev. Aug. 2017) [hereinafter MPEP].

⁷ *Id*

⁸ MPEP § 201.01 Continuation Application [R-07.2015] ("A continuation application is an application for the invention(s) disclosed in a prior-filed copending nonprovisional application, international application designating the United States, or international design application designating the United States. The disclosure presented in the continuation must not include any subject matter which would constitute new matter if submitted as an amendment to the parent application.").

⁹ MPEP § 201.06 Divisional Application [R-07.2015] ("The Court of Appeals for the Federal Circuit has concluded that the protection of 35 U.S.C. 121 does not extend to continuation-in-part applications... the disclosure presented in a divisional application must not include any subject matter which would constitute new matter if submitted as an amendment to the parent application.").

 $^{^{10}}$ MPEP § 201.01.

¹¹ MPEP § 201.06.

¹² Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1362 (Fed. Cir. 2008) (explaining that "the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications.").

¹³ Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1341 (Fed. Cir. 2010) (en banc) (holding that claims originally filed in a patent application are part of the disclosure and can satisfy the written description requirement).

¹⁴ MPEP § 2161.01; 35 U.S.C. 112(a) (2015).

parent application, along with any intervening patent applications in the family lineage. ¹⁵ Continuation and divisional applications are given the same birth date (filing date) as the original application as long as the family lineage is identified in the application. ¹⁶ Thus, continuation applications and divisional applications are each twins of the original application.

The USPTO reviews patent applications to determine if they contain more than one invention.¹⁷ If the USPTO decides the application does contain more than one invention, it will require the applicant to restrict the application to one invention.¹⁸ Where the USPTO decides that the patent applications are obvious variants, the restriction will be an obvious-type double patenting rejection ("ODP").¹⁹ ODP is a "judicially created doctrine aimed at preventing patent owners from extending patent protection beyond the statutorily afforded term." ²⁰

Congress has provided a safe harbor under 35 U.S.C. § 121 for the inventions that were restricted out of the first application based on an ODP by allowing a divisional patent application to capture the variant(s), provided that the patent term is not extended beyond that given to the original application and common ownership is maintained.²¹

Divisional applications are not subject to ODP rejections "as long as the subject application was formally labeled a divisional and the claims that were issued were consonant with those withdraw from an earlier case pursuant to a restriction requirement."²² Divisional applications have been, and continue to be, defined as offspring of the original application, as long as they "show blood stream connection with [the original application]."²³ Historically, a patent owner has had the right to

¹⁵ Patent Act of 1952, Ch. 950, 66 Stat. 792, § 120 (July 19, 1952) ("An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application...").

¹⁶ *Id*.

^{17 35} U.S.C. § 121.

¹⁸ *Id*.

¹⁹ *Id*.

 $^{^{20}}$ Aaron Reinhardt, $Obviousness\mbox{-}Type\mbox{-}Double\mbox{-}Patenting\mbox{-}Considerations}, IPWATCHDOG\mbox{(July 19, 2017)}, http://www.ipwatchdog.com/2017/07/19/obviousness-type-double-patenting-$

considerations/id=85791/; *In re Byck*, 48 F.2d 665, 666 (C.C.P.A. 1931) (holding that only new and useful inventions are entitled to patents, beneficial uses of a product are not new and useful inventions, and "[i]t would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.").

²¹ Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1361 (Fed. Cir. 2008) (explaining that if a patent owner complies with an improper restriction requirement, the original application should not be used as a reference against the later filed divisional).

²² Jeffrey M. Jacobstein, *The Safe Harbor Provision of 35 U.S.C. § 121 Against Double Patenting Rejections Just Got A Little Less Safe*, FINNEGAN (June 2, 2017), https://www.finnegan.com/en/insights/blogs/prosecution-first/the-safe-harbor-provision-of-35-u-s-c-%C2%A7-121-against-double-patenting-rejections-just-got-a-little-less-safe.html.

 $^{^{23}}$ Coltman v. Colgate-Palmolive-Peet Co., 104 F.2d 508, 515 (7th Cir. 1939) (holding that the same amendment rules apply to divisional applications as they apply to original applications and no new matter can be added to the specification).

capture the restricted inventions, whether restricted properly or improper, when a continuation application is filed between the parent application and divisional application because a continuation application is one continuous application with the parent. 24

However, in 2004, the United States Court of Appeals, Federal Circuit, declined to extend the twin status to a continuation application, and relabeled it a step-child. The Federal Circuit held that a divisional application must be filed directly from the application in which the restriction requirement was issued for it to fall inside the safe harbor under § 121.26 This means that if a continuation application is filed between the divisional and parent, and the divisional claims priority from the continuation and not the parent, the divisional does not enter the safe harbor. 27

The consequences of this decision are profound. In the biotechnology and pharmaceutical industries, continuation and divisional practices are heavily used.²⁸ These practices are standard in the industry for building patent portfolios.²⁹ Patent prosecution strategies set up the success or failure of enforcement and are created many years before a patent can be enforced.³⁰ The safe harbor under § 121 is relied on when prosecution strategies need to be amended after receiving a restriction request from the USPTO.³¹ Patents are now being invalidated due to ODP when there is an intervening continuation application between the parent and divisional.³²

²⁴ Godfrey v. Eames, 68 U.S. 317, 326 (1863) (holding that a continuation application is to be viewed as one continuous application of the parent it stems from).

²⁵ Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1348 (Fed. Cir. 2004) (holding that a continuation application did not provide consonance with the parent application).

²⁶ Janssen Biotech, Inc. v. Celltrion Healthcare Co., 210 F. Supp. 3d 278, 281-282 (2016) (holding claims of a divisional application were invalid under ODP because they were indistinct from the continuing application which was filed between the parent and divisional and no restriction was issued in the continuation).

²⁷ G.D. Searle LLC v. Lupin Pharms., Inc., 790 F.3d 1349, 1357-1358 (2015) (holding that restriction issued in a parent application did not flow down to the continuation application and the divisional filed off the continuation did not enter the safe harbor under § 121).

²⁸ John R. Allison & Mark A. Lemley, Who's Patenting What? An Empirical Exploration of Patent Prosecution, 53 VAND. L. REV. 2099, 2125, 2154 (2000) (reporting the average pharmaceutical patent issued from 2.27 applications and the average biotechnology patent from 2.38 applications).

²⁹ Gene Quinn, Patent Strategy: Building a Patent Portfolio with Meaningful Rights, IPWATCHDOG (May 9, 2015), http://www.ipwatchdog.com/2015/05/09/patent-strategy-building-a-patent-portfolio-with-meaningful-rights/id=57553/.

 $^{^{30}}$ Gene Quinn, An Overview of the U.S. Patent Process, IPWATCHDOG (Mar. 15, 2014), http://www.ipwatchdog.com/2014/03/15/an-overview-of-the-u-s-patent-process-2/id=48506/ ("The patent process starts well before you file a patent application..."); U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, 2016 REPORT ON PERFORMANCE AND ACCOUNTABILITY (2016), https://www.uspto.gov/sites/default/files/documents/USPTOFY16PAR.pdf (reporting the average pendency of a patent application was 25.3 months averaged across all technology groups).

³¹ KENNETH D. SIBLEY, THE LAW AND STRATEGY OF BIOTECHNOLOGY PATENTS: BIOTECHNOLOGY SERIES, 124-125 (Kenneth D. Sibley, ed., 1994) ("The constraints imposed by the enablement requirement often present a dilemma to a potential patent applicant....").

³² Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1348 (Fed. Cir. 2004); Anthony M. Insogna et al., *Obviousness-Type Double Patenting: Who Would Have Thought It Would Have Such a Profound Effect on the Pharmaceutical Industry?*, A.B.A. LANDSLIDE (Oct. 2012), https://www.americanbar.org/publications/landslide/2012_13/september_october_2012/obviousnessty pe_double_patenting_who_would_have_thought_it_would_have_such_profound_effect_the_pharmaceutical_industry.html ("For litigators, the obviousness-type double patenting defense has taken on

Recent decisions were made using inaccurate GPS data and now the water surrounding the § 121 safe harbor is full of mines.³³ The unsafe waters have left the patent fleets adrift and sounding their general quarters alarms.³⁴ This article argues that the recent decisions deviate from the congressional intent for establishing the safe harbor under 35 U.S.C. 121 and well-established case law.³⁵ This article concludes with providing a simple solution for the U.S. Supreme Court or Congress to fix the error.

II. BACKGROUND

The first Patent Act was passed in 1790 and its purpose was to "promote the progress of useful arts." The 1790 act set out what information must be disclosed in a patent application, but it did not set out the different types of applications or the familial relationships that are available today. The Patent Act was amended in 1793, 1800, 1832, and again in 1836, which birthed the concept of continuation applications. The first continuation applications were published in 1838 and named the A.I. series for patents that covered improvements to a previous invention. The U.S. Supreme Court confirmed Congress' intent of continuation applications in 1863 with its decision in *Godfrey v. Eames*, 68 U.S. 317 (1863) and declared continuations

an entirely new life, and can lead to a finding of invalidity or the necessity to terminally disclaim and cut short a patent with valuable term remaining.").

- ³³ G.D. Searle LLC, 790 F.3d at 1357-1358; Mat Gordon, Bad GPS Data: What/Why/How, STRAVA (Oct. 30, 2013), https://support.strava.com/hc/en-us/articles/216917707-Bad-GPS-Data-What-Why-How ("We use the term 'Bad GPS data' to describe any circumstance where your GPS device records location (or other) data that does not accurately represent your activity.").
- ³⁴ Telephone Interview with Gunnersmate Second Class Roger Trutsch, U.S. Navy Active Duty 1990-1999, Reserves 2001, Reactivated in Support of Operations Noble Eagle and Enduring Freedom 2001-2002 (Oct. 24, 2017) (Gunnersmate Second Class Trutsch defined "sounding the general alarm" as the term the U.S. Navy uses to define the order given to sailors when a ship is under attack and all sailors are to ready it for battle); Anish, Different Types of Alarms on Ships, MARINE INSIGHT (Sept. 28, 2017), https://www.marineinsight.com/marine-safety/different-types-of-alarms-on-ship/ ("General Alarm: The general alarm on the ship is recognized by 7 short ringing of bell followed by a long ring or 7 short blasts on the ship's horn followed by one long blast. The general alarm is sounded to make aware the crew on board that an emergency has occurred." The crew is to go to their stations when the alarm sounds.).
 - ³⁵ Godfrey v. Eames, 68 U.S. 317, 326 (1863).
 - ³⁶ Patent Act of 1790, Ch. 7, 1 Stat. 109-112 (Apr. 10, 1790).
- ³⁷ A Brief History of the Patent Law of the United States, LADAS & PARRY EDUC. CTR. (May 7, 2014), https://ladas.com/education-center/a-brief-history-of-the-patent-law-of-the-united-states-2/.
- ³⁸ Patent Act of 1836, Ch. 357, 5 Stat. 117, § 7 (July 4, 1836) ("In every such case, if the applicant shall elect to withdraw his application . . .[and] applicant in such case shall persist in his claim for a patent, with or without any alteration of his specification... if the specification and claim shall not have been so modified as, in the opinion of the Commissioner, shall entitle the applicant to a patent....").
- ³⁹ MPEP § 901.04 ("A.I. Series. From 1838 to 1861, patents covering an inventor's improvement on his or her own patented device were given a separate series of numbers preceded by "A.I." to indicate Additional Improvement. In citing, the letters and the number must be given, e.g., A.I. 113. About 300 such patents were issued."); Traitel Marble Co. v. U.T. Hungerford Brass & Copper Co., 22 F.2d 259, 261 (2d Cir. 1927) ("The issuance of the first patent does not abandon the unclaimed matter in its disclosure, the pendency of the second application rebutting any such inference.").

to be viewed as one continuous application of the parent, i.e., a twin, even though it is later born. 40

The Patent Act of 1952 recognized continuation applications as they are known today by introducing § 120 to 35 U.S.C.⁴¹ Continuation applications are given the benefit of the filing date of the parent, so long as it is filed while the parent is pending and it identifies the parent application as the parent application.⁴²

The Patent Act of 1952 also established the safe harbor for divisional applications by creating \S 121 of 35 U.S.C.⁴³ Divisional applications can be voluntarily filed or nonvoluntarily filed.⁴⁴ Congress defined a nonvoluntary divisional application as one filed to comply with a restriction requirement issued by the USPTO.⁴⁵

A. Patent Families and Fleets in 1836

In 1836, the first patent fleets were envisioned, when Congress allowed patents to have families, and the fleets set sail in 1838.⁴⁶ Congress said the fleets could include replicas (twins) of the first ship built, and the U.S. Supreme Court followed the Congress' fleet building plans 1863 with its decision in *Godfrey v. Eames*, 68 U.S. 317 (1863).⁴⁷ In that case, the Court declared a continuation application is one continuous application of its parent, i.e., its twin.⁴⁸

The Patent Act 1836 shored the concept of continuation applications.⁴⁹ The first continuation applications were published in 1838 under the A.I. series which denotes improvement applications for a previous invention.⁵⁰ In 1863, the U.S. Supreme

⁴⁰ Godfrey, 68 U.S. at 318 (finding that the language in The Patent Act of 1863 allows continuation applications).

⁴¹ Patent Act of 1952, § 120.

 $^{^{42}}$ *Id*.

⁴³ Id. § 121 ("A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.") (emphasis added).

⁴⁴ Gary D. Fedorochko & Paul M. Rivard, *New USPTO Definition: A Potential Mine Field*, LAW360 (Oct. 25, 2007), https://bannerwitcoff.com/_docs/library/articles/FedRivIP360.pdf.

⁴⁵ Patent Act of 1952, § 121 ("If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application.").

⁴⁶ Patent Act of 1836, § 7; MPEP § 901.04; Traitel Marble Co. v. U.T. Hungerford Brass & Copper Co., 22 F.2d 259, 261 (2d Cir. 1927) ("The issuance of the first patent does not abandon the unclaimed matter in its disclosure, the pendency of the second application rebutting any such inference.").

⁴⁷ Godfrey, 68 U.S. at 318.

¹⁸ *T.J*

⁴⁹ Patent Act of 1836, § 7.

⁵⁰ *Id*.

Court followed Congress' intent of continuation applications and declared them to be one continuous application of the parent, i.e., a twin of the parent.⁵¹

The waters surrounding the fleets were uncharted until 1952, when Congress, using a sextant and celestial chart,⁵² mapped them and provided a safe harbor for divisional applications under 35 U.S.C. § 121. Congress intended the safe harbor⁵³ to be wide enough to allow the ship's crewmen to man the rails⁵⁴ with ease when navigating the mouth of the harbor.⁵⁵The 1952 Patent Act codified Congress' intent of allowing familial relationships in patent fleets by introducing § 120 to 35 U.S.C.⁵⁶

Continuation applications were given the status of twin to the original application and not a step-child. The step-children in the family are continuation-in-part applications because matter can be added or removed from the application when comparing it to the original application.

Patent fleets have navigated the § 121 waters, unchanged since 1952, until 2015, when the Federal Circuit Court held in *G.D. Searle LLC v. Lupin Pharms., Inc.*, 790 F.3d 1349, 1357-1358(2015) that restriction issued in a parent application did not flow down to the continuation application, and that the divisional filed off the continuation did not enter the safe harbor under 121 because there was no consonance in the claims.⁵⁷ This decision narrowed the entrance into the 121 safe harbor,⁵⁸ leaving the ships nearing its entrance adrift.⁵⁹ The fleets had set sail before the court changed the familial powers of the fleet.

B. Once a Twin, Now a Step-Child

The twin status of continuation applications (viewed as a continuous application with the parent application) and divisional applications held judicially until the

⁵¹ Godfrey, 68 U.S. at 318.

⁵² Patent Act of 1952, § 120.

 $^{^{53}}$ *Id*.

⁵⁴ Telephone Interview with Gunnersmate Second Class Roger Trutsch, U.S. Navy Active Duty 1990-1999, Reserves 2001, Reactivated in Support of Operations Noble Eagle and Enduring Freedom 2001-2002 (Oct. 24, 2017) (Gunnersmate Second Class Trutsch defined "man the rails" as the order given to Navy men when the ship is about to enter a harbor. All men on this ship stand on the decks while those that have the duty to ready it for docking prepare it to be docked.); Annalisa Underwood, *Manning the Rails: A Navy Tradition*, THE SEXTANT (Oct. 3, 2016), http://usnhistory.navylive.dodlive.mil/2016/10/03/manning-the-rails-a-navy-tradition/ ("Manning the rail, like the ceremonial military gun salute, is a centuries old practice for rendering honors aboard naval vessels.").

⁵⁵ Telephone Interview with Gunnersmate Second Class Roger Trutsch, U.S. Navy Active Duty 1990-1999, Reserves 2001, Reactivated in Support of Operations Noble Eagle and Enduring Freedom 2001-2002 (Oct. 24, 2017) (Gunnersmate Second Class Trutsch defined "mouth of the harbor" as the term the U.S. Navy uses to define an entrance into a harbor.).

⁵⁶ Patent Act of 1952, § 120.

⁵⁷ G.D. Searle LLC, 790 F.3d at 1357-1358.

⁵⁸ Godfrey, 68 U.S. at 317.

⁵⁹ Patent Timeline, BROWNS & MICHAEL (Feb. 1, 2002), http://www.bpmlegal.com/pattime.html ("Any of these applications can be filed at any time if as there is a pending (unissued) application."). This web post shows in 2002 it was believed that a continuation application could be filed between an original application and divisional application, with the divisional still entering the 121-safe harbor.

Federal Circuit Court issued its decision in *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343 (Fed. Cir. 2004).⁶⁰

In that case, the court held that a divisional application did not enter the safe harbor under § 121 because it was filed based on a continuation application, and not directly from the original application which received the restriction requirement. Even though the continuation application properly claimed priority to the original application, the court did not find the divisional had consonance with the parent application because the continuation application did not have the same claims as the parent application. 62

C. Misunderstanding Consonance Caused the Familial Change

Consonance is a judicially derived term and was coined in *Gerber Garment Tech.*, *Inc. v. Lectra Sys.*, *Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990).⁶³ In that case,⁶⁴ the court defined consonance as requiring "...the line of demarcation between the independent and distinct inventions that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement."⁶⁵ Consonance applies to the claims in divisional applications, not continuation applications, and requires the claims filed in the divisional application to be essentially the same as the claims that were not elected in the original application.⁶⁶ The Federal Circuit decided that when § 121 is construed in view of the § 101⁶⁷ single patent requirement, the different claims in continuation applications destroy consonance with the original application (the one that received the restriction requirement).⁶⁸

The once wide-mouthed safe harbor has been narrowed by the judicial decisions and made the "safe harbor…is a little less safe." The narrowing of the safe harbor is not what congress intended, as can be seen by analyzing the plain language of the statute and by using mathematical proofs.

⁶⁰ Bristol-Myers Squibb Co., 361 F.3d at 1343.

⁶¹ *Id*.

⁶² *Id*.

⁶³ Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed. Cir. 1990) (Holding that "consonance requires that the line of demarcation between the independent and distinct inventions that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement.") (Internal quotations omitted).

⁶⁴ *Id*.

 $^{^{65}}$ St. Jude Med., Inc. v. Access Closure, Inc., 729 F.3d 1369, 1377 (Fed. Cir. 2013) ("The judicially-created consonance....").

⁶⁶ Gerber Garment Tech., Inc., 916 F.2d at 688.

^{67 35} U.S.C. § 101.

⁶⁸ Bristol-Myers Squibb Co., 361 F.3d at 1343.

⁶⁹ Jacobstein, supra note 22.

III. ANALYSIS

A. Plain Language of 35 U.S.C. § 121

The plain language of § 121 unambiguously charts Congress' intended width of the safe harbor's mouth. $^{70}\,$

"A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent Office or in the courts against a divisional application or <u>against the original application or any patent issued on either of them</u>, if the divisional application is filed before the issuance of the patent on the other application." (emphasis added).⁷¹

Starting with the first underlined portion of the statute, Congress intentionally used the word "any" to identify the patent issuing from either the divisional or original application, which illustrates Congress' intent to keep it in the family.⁷² Congress would have used the word "the" in its stead if it meant to identify the patent as issuing from the parent only.

Congress also used the word "other" instead of "original" to name the application in which the divisional must be filed while it is pending.⁷³ Further, Congress defined a continuation application as "a continuous application of the original."⁷⁴ Using semantics to analyze the meaning of the words used in the statute, along with past judicial decisions and industry standard practices, Congress' intent of providing a § 121 safe harbor to a divisional stemming from a continuation is unambiguously clear.⁷⁵

When interpreting a statute, a court should "give effect, if possible, to every clause and word of a statute, avoiding, if it may be, any construction which implies that the legislature was ignorant of the meaning of the language it employed."⁷⁶ A court needs to assume each word used is a statute was used intentionally and has particular meaning within the statute.⁷⁷ This is not what the court did when it decided that continuation applications destroy consonance, thereby eliminating the divisional application's passage into the § 121 safe harbor.

In *G.D. Searle LLC*, the court ruled that a restriction requirement does flow from the original application to a divisional application that stems from a divisional, but not from an original to a divisional through a continuation because the examiner

^{70 35} U.S.C. § 121.

⁷¹ Patent Act of 1952, § 121.

 $^{^{72}}$ *Id*.

⁷³ *Id*.

⁷⁴ Godfrey, 68 U.S. at 317; Patent Act of 1836, § 7.

 $^{^{75}}$ Browns & Michael, supra note 59.

⁷⁶ Larry M. Eig, Statutory Interpretation: General Principles and Recent Trends, CONG. RESEARCH SERV. (Dec. 19, 2011), https://fas.org/sgp/crs/misc/97-589.pdf.

⁷⁷ Bailey v. U.S., 516 U.S. 137, 146 (1995) (assuming "that Congress used two terms because it intended each term to have a particular, nonsuperfluous meaning").

did not make the restriction requirement from the original application of record in the continuation.⁷⁸ The court looked at the prosecution history of the patent and a few cases from the past, but none of them addressed the exact issue of an intervening continuation application.⁷⁹

The Federal Circuit narrowly construed the lineage allowed under § 121, starting with its decision in *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343 (Fed. Cir. 2004).80 The trend continued in *G.D. Searle LLC*.81 Continuation applications provide the consonance needed for § 121 protection because the claims from the original application are inherently part of the continuation's disclosure.82 The court did not analyze congressional intent of § 121 when it made its ruling in *GD Searle*, and instead, relied on bad GPS data to map the width of the entrance into the § 121 safe harbor.83 This decision has the patent fleets sounding the general alarms while they are sitting right outside the § 121 harbor, and rightly so. They have a right to enter the harbor without hitting a mine. Congress intended the mouth of the § 121 safe harbor to be much wider than the Federal Circuit has ruled it is.84

B. Mathematical Proofs Show Congress' Intent is Logical and the Recent Judicial Decisions are Not

The Federal Circuit received its first miscalculated GPS data in 2004 and narrowed the mouth of the § 121 harbor in *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343 (Fed. Cir. 2004).⁸⁵ The bad GPS data continues to be relied on and in 2015, the Federal Circuit decided that the consonance of claims was destroyed when an intervening continuation application was filed between an original application and a divisional application.⁸⁶ The court labeled the continuation application a step-child and not a twin of the original application.⁸⁷

Mathematical logic can be used to show that an intervening continuation application does not close the § 121 safe harbor to a divisional application. Both Congress and the courts have held that a continuation application and a divisional application are both twins of the original application, differing only in claims. It should not make a difference that there is an intervening continuation application between the original and divisional patent application. The logical flaw in the GD

 $^{^{78}}$ G.D. Searle LLC, 790 F.3d at 1357-1358.

 $^{^{79}}$ G.D. Searle LLC, 790 F.3d at 1351 (tracing the prosecution history to determine if the safe harbor under \S 121 applies).

⁸⁰ Bristol-Myers Squibb Co., 361 F.3d at 1345 (determining that the application's prosecution history is key to determining if the safe harbor under § 121 is a defense against double patenting issues).

⁸¹ G.D. Searle LLC, 790 F.3d at 1351 (tracing the prosecution history to determine if the safe harbor under § 121 applies).

⁸² Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1341 (Fed. Cir. 2010).

 $^{^{\}rm 83}$ G.D. Searle LLC, 790 F.3d at 1351.

⁸⁴ Godfrey, 68 U.S. at 317.

⁸⁵ Bristol-Myers Squibb Co., 361 F.3d at 1345.

⁸⁶ G.D. Searle LLC, 790 F.3d at 1351.

⁸⁷ *Id*.

Searle LLC v. Lupin Pharms decision is illustrated below using simple mathematical arguments.⁸⁸

Let's call the original application A, the continuation application B, and the divisional application C.

The continuation application B is required to have the same disclosure (specification and drawings) as the original application A, and no new matter can be added to it.⁸⁹ The original application's claims as filed with the original application are considered part of the original disclosure and become a part of a continuation application's disclosure.⁹⁰ This means they are twin applications with different filing dates, but are given the same birth date as the original application.⁹¹ Therefore, $A = B \iff A \subset B$ and $B \subset A$.⁹²

The divisional application C is required to have the same disclosure (specification and drawings) as the original application A, and no new matter can be added to it.⁹³ Its claims must come from the parent and have been restricted out of the parent by the USPTO. Therefore, $C \subset A \iff (Cx) \ x \in C \Rightarrow x \in A$.

Using associative properties for mathematics, the continuation application does not break consonance of the claims if it is filed between a divisional and an original application. We know $A \subset B$ and $B \subset A$ are true statements (from both congressional intent and judicial decisions for 35 U.S.C. 120). We know $C \subset A$ is a true statement (from both congressional intent and judicial decisions for 35 U.S.C. § 121). It follows, then that $C \subset B$ is also a true statement.

Turning the mathematical statement into a word statement reveals a divisional application is a subset of a continuation application because the continuation application is the same as the original application. Mathematical logic points to congress' intended mouth width for the § 121 safe harbor.

⁸⁸ Id. at 1357-1358.

⁸⁹ MPEP § 201.01.

⁹⁰ Ariad Pharmaceuticals, Inc., 598 F.3d at 1341.

⁹¹ Gene Quinn, *Preparing for Future Litigation Before Your Patent Issues*, IPWATCHDOG (Oct. 26, 2010), http://www.ipwatchdog.com/2010/10/26/preparing-for-litigation-before-patent-

issue/id=12999/ ("A continuation is a second application for the same invention that was claimed in a prior nonprovisional patent application and filed before the prior nonprovisional patent application becomes abandoned or the patent issues."); Arnold B. Silverman, *Understanding the Benefits Obtainable from "Related" United States Patent Applications*, THE MINERALS, METALS & MATERIALS SOCY. (Sept. 2005), http://www.tms.org/pubs/journals/JOM/matters/matters-0509.html ("A continuation application is a re-filing of the prior application with the identical disclosure or no addition of new matter. The claims may be different from the claims of the original parent application. Such applications are frequently filed to obtain additional time for prosecution or make changes in the claims.").

⁹² Michael Hutchins, *Introduction to Mathematical Arguments*, MATH BERKELY (2007), https://math.berkeley.edu/~hutching/teach/proofs.pdf ("Two sets are equal if and only if they have the same elements; in terms of subsets, $A = B \iff A \subset B$ and $B \subset A$. For example, $\{1, 2, 3\} = \{2, 3, 1\}$, but $\{1, \{2\}\}$ 6 does not equal $\{1, 2\}$.").

⁹³ MPEP § 201.06; Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1362 (Fed. Cir. 2008).

⁹⁴ Hutchins, *supra* note 92 ("If A and B are sets, and if every element of A is also an element of B, we say that A is a subset of B, and we write $A \subset B$. In symbols, $A \subset B \iff (\forall x) \ x \in A \Rightarrow x \in B$.").

IV. PROPOSAL

The best way to remove the mines that the Federal Circuit has placed in the § 121 safe harbor is to have the U.S. Supreme Court grant certiorari to hear the issue. The Federal Circuit's ruling in G.D. Searle v. Lupin Pharms narrowed the width of the § 121 safe harbor. This decision left many patent fleets stranded after they left the dock but before they knew new mines were placed in the harbor. The patent fleets are sounding the general alarms and requesting help to retriangulate a safe entrance into the harbor.

The U.S. Supreme Court is not under any obligation to hear this issue; however, this problem has national significance, requires the harmonization of Congressional intent and Federal Circuit decisions, and has precedential value. T twould be best if the U.S. Supreme Court used the tools that Congress used when it crafted 35. U.S.C. § 121 in 1952, to determine what Congress intended with the statute. The Federal Circuit's GPS system has a mathematical glitch, and GPS system bugs are fairly common. To ensure pinpoint accuracy of mapping the § 121 entrance, a sextant and celestial chart are the best tools for the Court to use. These are the nautical mapping tools that were available in 1952, when Congress tabulated § 121.

In *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, the U.S. Supreme Court ruled "[i]f a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect." The ruling was made in 1984, thirty one years before the Federal Circuit ruled in *G.D. Searle v. Lupin Pharms*. The U.S.

⁹⁵ Supreme Court Procedures, U. S. COURTS, http://www.uscourts.gov/about-federal-courts/educational-resources/about-educational-outreach/activity-resources/supreme-1 (last visited Nov. 15, 2017) ("The Constitution states that the Supreme Court has both original and appellate jurisdiction.... Appellate jurisdiction means that the Court has the authority to review the decisions of lower courts.").

 $^{^{96}}$ G.D. Searle LLC, 790 F.3d at 1351 (finding a divisional did not have consonance with an original application).

⁹⁷ U. S. COURTS., *supra* note 95 ("The Court usually is not under any obligation to hear these cases, and it usually only does so if the case could have national significance, might harmonize conflicting decisions in the federal Circuit courts, and/or could have precedential value.").

⁹⁸ Patent Act of 1952, § 120.

⁹⁹ Francis Chao, *Workaround for Problems with Updating "Garmin" GPS Devices*, TUCSON COMPUT. SOC'Y. http://aztcs.org/meeting_notes/winhardsig/GPS/Garmin-problems.pdf (last visited Nov. 15, 2017) (GPS maps need to be updated in order to maintain accuracy, and update installations routinely fail. Workarounds have been developed so GPS can continue to be used accurately after an update fails.).

¹⁰⁰ Global Positioning System, WIKIPEDIA, https://en.wikipedia.org/wiki/Global_Positioning_Syst em#cite_note-1 (last visited Nov. 15, 2017) ("The GPS project was launched by the U.S. Department of Defense in 1973 for use by the United States military and became fully operational in 1995. It was allowed for civilian use in the 1980s.").

¹⁰¹ Eugene Griessel, *How the Sextant Works*, CLIPPERLIGHT.COM, http://www.clipperlight.com/howusesextant.html (last visited Nov. 5, 2017).

 $^{^{102}}$ Chevron, U.S.A., Inc., 467 U.S. 837, 843 (1984) (holding that courts must abide by congressional intent when deciding cases where the statute may be ambiguous).

¹⁰⁴ G.D. Searle LLC, 790 F.3d at 1349.

Supreme Court set the standard years ago: if congressional intent of a statute is clear, then no court can rule away from such congressional intent.¹⁰⁵

The Federal Circuit ruled away from the congressional intent of 35 U.S.C. § 121 in *G.D. Searle v. Lupin Pharms*, and has set an inaccurate precedent for triangulating the width of the § 121 safe harbor.

The timing is ripe for this issue to be addressed by the U.S. Supreme Court. Since at least 2014, the U.S. Supreme Court has added many intellectual property cases to its docket, having ten in 2014.¹⁰⁶ The Court has substantially increased the number of intellectual property cases on its docket since the 1990s, when it reviewed a total of six cases in that entire decade.¹⁰⁷ The Court had two intellectual property matters scheduled for its December 2017 sitting, and it has one matter scheduled for its December 2018 sitting.¹⁰⁸ The Court truly understands the economic importance of intellectual property and understands that "clarity is required to maintain that economic value."¹⁰⁹

The biotechnology and pharmaceutical industries are avid users of continuation and divisional practice. The U.S. pharmaceutical industry is the most important national market. The United States alone holds over 45 percent of the global pharmaceutical market, which equates to about \$446,000,000,000. Recent statistics show a pharmaceutical company has a mean intellectual property budget of approximately \$8,000,000.00 a year, a biotechnology company has a mean intellectual property budget of approximately \$5,000,000. a year, and there were about 2,673 US biotechnology firms in 2015. Even by using big crayon mathematics to estimate the total above, it is easy to determine the pharmaceutical and biotechnology industries invest enormous sums of money to protect their intellectual property rights.

¹⁰⁵ Chevron, U.S.A., Inc., 467 U.S. at 843.

¹⁰⁶ Ray K. Harris, *Intellectual Property Under Supreme Scrutiny*, FCLAW (Mar. 5, 2014), https://www.fclaw.com/insights/newsletters/2014/intellectual-property-under-supreme-scrutiny ("There are now ten intellectual property (IP) cases under review in the U.S. Supreme Court.").

 $^{^{107}}$ Id. ("This year alone the Supreme Court already has accepted for review 6 patent cases—the same volume it handled in the entire decade of the 1990s.").

 $^{^{108}\} Terms,$ SCOTUSBLOG, http://www.scotusblog.com/case-files/terms/ot2018/ (last visited Nov. 29, 2018).

¹⁰⁹ Harris, *supra* note 106 ("Why does the Supreme Court accept review in so many IP cases? Because IP rights have grown in economic importance and clarity is required to maintain that economic value.").

¹¹⁰ John R. Allison & Mark A. Lemley, Who's Patenting What? An Empirical Exploration of Patent Prosecution, 53 VAND. L. REV. 2099, 2117 (2000).

¹¹¹ U.S. Pharmaceutical Industry-Statistics & Facts, STATISTA, https://www.statista.com/topics/1719/pharmaceutical-industry/ (last visited Nov. 16, 2017).

¹¹³ 2017 Report of the Economic Survey, AIPLA (Aug. 2017) https://www.aipla.org/detail/journal-issue/economic-survey-2017; Key Biotechnology Indicators, ORG. FOR THE ECON. CO-OPERATION & DEV. (Oct. 2018), http://www.oecd.org/science/biotech/1_Number-of-firms-active-in-biotech.xls.

¹¹⁴ David M. Schwartz, *How Much is a Million*, READING RAINBOW (2005), https://davidschwartz.com/wp-content/uploads/2014/08/DSchwartzTeacherGuides-ReadingRainbow.pdf ("Estimation and measurement. Use a crayon as an alternative unit of measurement. Estimate first, then measure to address such questions as: 'How many crayons long is the table?' 'How many crayons tall are you?' 'How many crayons long is the door?' and others.").

The congressional intent behind 35 U.S.C. § 121 is clear and unambiguous. The U.S. Supreme Court could easily fix the errors made by the Federal Circuit's narrow construction of § 121 by ruling that an intervening continuation application does not destroy the § 121 safe harbor for a divisional application. If the U.S. Supreme Court does not follow its finding in *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, that congressional intention is the law and must be given effect when the intent is unambiguous, Congress can easily step in to fix the error. 115 "Congress acts... when it perceives that there is sufficient support in the Congress and in the affected communities for it to act on the perceived need and in the manner requested." 116

V. CONCLUSION

Congress' use of a sextant and celestial chart to map the § 121 safe harbor in 1952 created an accurate map of its mouth.¹¹⁷ Patent fleets have relied on the map without incident for over sixty years.¹¹⁸ In 1990, the accuracy of Congress' map first was called into question in *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.* ¹¹⁹ The Federal Circuit found Congress' map to be accurate, and decided consonance is required between the restricted claims of a parent application and the claims filed in a divisional application.¹²⁰

However, in 2015, the Federal Circuit missed an important update to its GPS system, and it decided that consonance does not flow through a continuation application to a divisional application. This decision left patent fleets adrift outside the § 121 harbor that they had set course for years before. The fleets are rightly sounding their general quarters alarms in panic of hitting a mine in the mouth of the § 121 safe harbor. 122

¹¹⁵ Chevron, U.S.A., Inc., 467 U.S. at 843.

¹¹⁶ Hayden W. Gregory, Patent Eligibility: Should Congress Overrule the Supreme Court's Recent Decisions? Would the Court Overrule the Overrule?, 7 LANDSLIDE 1, 2 (Aug. 2015) https://heinonline.org/HOL/Page?handle=hein.journals/Indslid7&div=77&g_sent=1&casa_token=&co llection=journals ("Any meaningful analysis of the possible outcome of such a legislative effort necessarily requires knowledge of the statutory changes proposed to reject recent the Supreme Court decisions and to prevent reassertion of the doctrine of those cases in future court decisions.... Congress acts...when it perceives that there is sufficient support in the Congress and in the affected communities for it to act on the perceived need and in the manner requested.").

¹¹⁷ Patent Act of 1952, § 120 (Both SAS Institute Inc. v. Matal, No. 16-969 [Arg: 11.27.2017]) and Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, No. 16-712 [Arg: 11.27.2017] raise intellectual property issues.).

 $^{^{118}}$ G.D. Searle LLC, 790 F.3d 1349 (The ruling in 2015 narrowed the entrance into the 121-safe harbor.).

¹¹⁹ Gerber Garment Tech., Inc., 916 F.2d at 688 (coining the term consonance which requires that the claims in a divisional application be substantially similar to those filed in a parent application).

 $^{^{120}}$ Id.

 $^{^{121}}$ G.D. Searle LLC, 790 F.3d 1349.

¹²² Id. at 1357-1358; Gordon, supra note 33 ("We use the term 'Bad GPS data' to describe any circumstance where your GPS device records location (or other) data that does not accurately represent your activity."); Telephone Interview with Gunnersmate Second Class Roger Trutsch, U.S. Navy Active Duty 1990-1999, Reserves 2001, Reactivated in Support of Operations Noble Eagle and Enduring Freedom 2001-2002 (Oct. 24, 2017) (Gunnersmate Second Class Trutsch defined

Congressional intent of the § 121 safe harbor was analyzed hereinabove by looking at the plain language of the statute and using mathematical proofs. Both analyses point to the same conclusion: consonance of claims flows from an original application to a divisional application through a continuation application, because a continuation application is a twin of the original application.

Congress intended the mouth of the § 121 harbor to be wide enough to allow these ships to enter, and recent judicial decisions have miscalculated its width. "If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect." ¹²³

The issue is whether consonance passes from an original application through a continuation application to a divisional application. The answer is: it does. Granting a divisional application stemming from a continuation application instead of the parent application entrance into the § 121 safe harbor does not violate the one patent per invention requirement of 35 U.S.C. § 101.¹²⁴

The best solution to the problem the Federal Circuit has created is to have the U.S. Supreme Court step in and correct the map the Federal Circuit has made. The Court should use the sextant and celestial map Congress used when it implemented the Patent Act of 1952. If the U.S. Supreme Court does not step in, Congress should enact new legislation that explicitly states the order in which patent applications are filed in a family does not prevent a divisional application from entering the § 121 safe harbor.

[&]quot;sounding the general alarm" as the term the U.S. Navy uses to define the order given to sailors when a ship is under attack and all sailors are to ready it for battle.); Anish, supra note 34.

¹²³ Chevron, U.S.A., Inc., 467 U.S. at 843.

¹²⁴ 35 U.S.C. § 101.