



Reviewing Common Themes in Double Patenting



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What is Double Patenting (DP)?

- **Statutory DP**
 - Based on 35 USC 101
 - An applicant (or assignee) is prohibited from obtaining two patents for same invention
- **Nonstatutory DP (e.g., obviousness-type)**
 - Based on a judicially created doctrine
 - An applicant (or assignee) is prohibited from obtaining a patent for an invention that is an obvious variation of an invention for which the applicant (or assignee) already has a patent (unless certain conditions are met, i.e., Terminal Disclaimer filed)

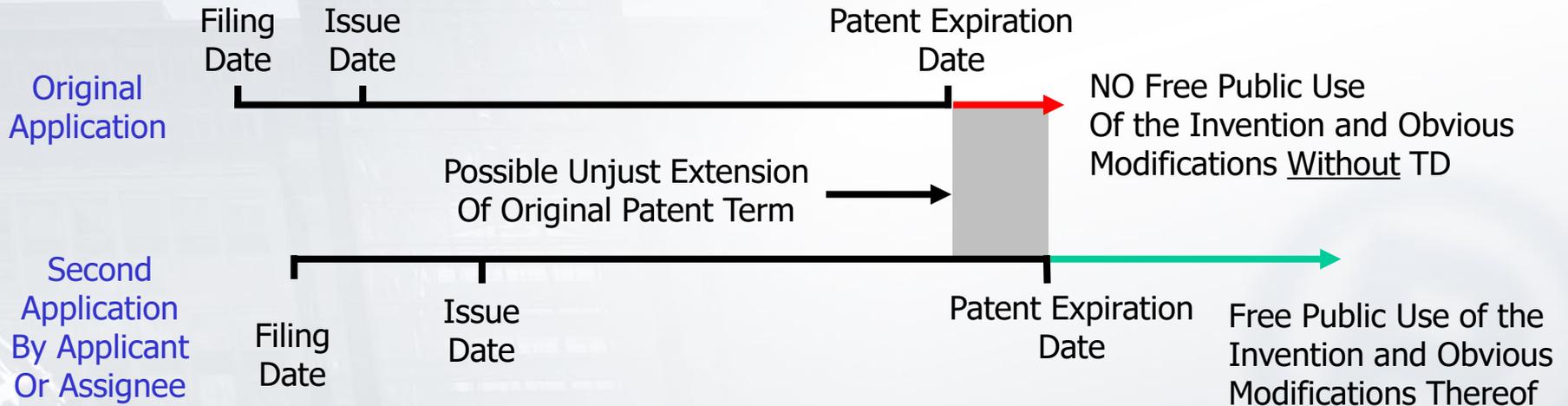


The Purpose Behind the Policy

- Double Patenting
 - Prevents unjustified extension of rights
 - Prevents harassment from multiple owners. *In re Van Ornum*, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982).
 - After expiration, public should be able to:
 - Freely use the claimed invention
 - Freely use obvious modifications of the claimed invention



Graphical Representation of an Example of Unjustified Extension





Common Flags: What are they?



Represents a Good Practice or Legal Requirement for Proper Double Patenting Prosecution



Represents a Potential Issue that Might Need to be Corrected by the PTO or Require Greater Attention by Examiner



Represents an Issue that Needs to be Corrected by the PTO



Disclose Information Material to Patentability

- Disclose any relevant USPTO unpublished applications, published applications and patents to inform the examiner of potential double-patenting references under 37 C.F.R. § 1.56 (“Duty of Candor”)
- Possible DP situations include:
 - Filed by the same inventive entity
 - Filed by different inventive entities having a common joint inventor
 - Filed by at least one Applicant in common who is not a common joint inventor (for AIA cases)
 - Filed by a common assignee
 - Filed by different assignees, but subject to a joint research agreement with each other (pursuant to the CREATE Act for pre-AIA first-to-invent cases, or to 35 U.S.C. 102(b)(2)(C) and 102(c) for AIA first inventor-to-file cases)
- Applicant must provide a copy of each cited pending unpublished U.S. application - 37 CFR §1.98(a)(2)(iii)



Focus on the Claims

- Claims of the potentially conflicting patent or application versus the examined claims is basis for consideration
- Use of the specification of potentially conflicting patent or application is generally prohibited
 - Limited exceptions apply – to be discussed more fully later



Withdrawn Claims Need to be Considered in Copending Case

- Withdrawn claims in a reference (copending) application must be considered in a provisional NSDP analysis of elected claims in an application under examination.
- Withdrawn claims in the case under examination should never be considered in a NSDP rejection



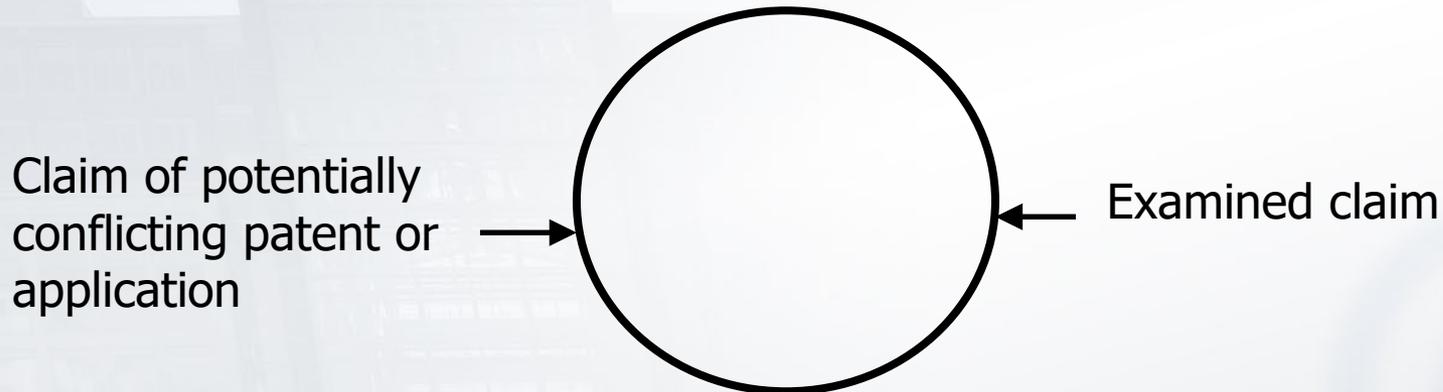
35 U.S.C. § 101 (Same Invention)

- Is the same invention being claimed twice?
- A reliable test:
 - Is there an embodiment that falls within the scope of one claim, but not the other?
 - Could one claim be literally infringed without literally infringing the other claim?
 - If the answer is “yes” to either question, then there is no basis for a statutory double patenting rejection. See: MPEP §804(II)(A).



A 35 U.S.C. § 101 DP Rejection Requires the Exact Same Scope

Venn Diagram

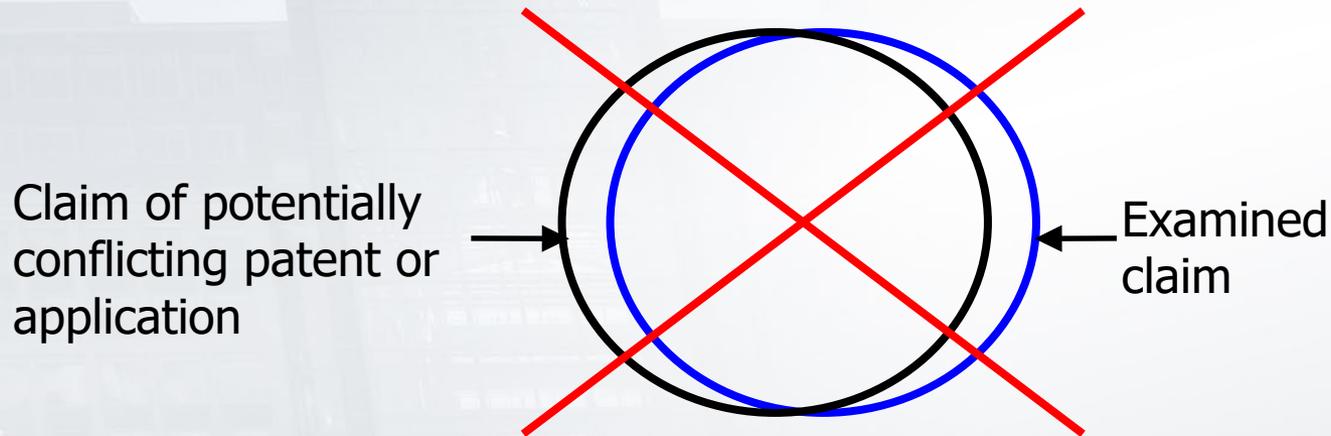


Examined claim and claim of potentially conflicting patent or application exactly match in scope – statutory (35 U.S.C. 101) double patenting appropriate.



35 U.S.C. § 101 DP Rejection (continued)

Venn Diagram



Examined claim and claim of potentially conflicting patent or application **DO NOT** exactly match in scope – **DO NOT** make a statutory (35 U.S.C. 101) double patenting rejection. Perform further analysis to determine whether a rejection on non-statutory double patenting grounds is appropriate.



A TD will NOT Overcome a 35 U.S.C. 101 Rejection

- A Terminal Disclaimer (TD) will NOT overcome a 35 U.S.C. 101 Rejection
- The 35 U.S.C. 101 Statute:
 - Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
(Emphasis added)



Nonstatutory Double Patenting: Obviousness Type (ODP)

- Analogous to 35 U.S.C. 103 analysis
- Determine the scope and content of the “Prior Art”
- Ascertain the differences between the “Prior Art” and the claim at issue
- Resolve the level of ordinary skill in the art
- Evaluate evidence of secondary considerations



Non-statutory DP & Prior Art

- Non-statutory double patenting is NOT a prior art rejection
 - Patent or co-pending application does NOT need to qualify as prior art
 - Any secondary references used in obviousness analysis should qualify as prior art within the meaning of 35 U.S.C. § 102



Example: Method Can Render Product Obvious

- Claim Under Examination:
- Claim 1. A compound represented by Formula I.



Method/Product Example (continued)

- Issued Patent:
- Same inventors, not prior art to the application being examined.
- Claim 1. A method for preparing an edible product, comprising adding a compound of Formula I to a natural or commercial edible product.



Method/Product Example (continued)

- There is no restriction on the record in either application.
- The compound of formula 1 is required to practice the method of the issued patent.
- The method of the issued patent should be used to reject the compound of formula 1 under non-statutory double patenting.



Typical Ways to Overcome Nonstatutory DP Rejections

- Amend Claims to encompass non-obvious subject matter
- Provide persuasive arguments as to why the current claims are not obvious variants over the co-pending application/patent claims
- Pursuant to 35 U.S.C. § 253, an applicant can disclaim the terminal portion of a patent term by filing an appropriate “terminal” disclaimer (TD) in the U.S. Patent and Trademark Office.
- Abandon one of the cases



DP Depends on Filing Date NOT Issue Date

- Typically a TD is required in the later filed case. See MPEP 1490(VI)(D)
 - If two (or more) pending applications are filed, in each of which a rejection of one claimed invention over the other on the ground of provisional nonstatutory double patenting (ODP) is proper, the provisional ODP rejection will be made in each application. If the provisional ODP rejection is the only rejection remaining in the earlier-filed of the two pending applications, (but the later-filed application is rejectable on other grounds), the examiner should then withdraw the provisional ODP rejection and **permit the earlier-filed application to issue as a patent without a terminal disclaimer**. If the provisional ODP rejection is the only rejection remaining in the later-filed application, (while the earlier-filed application is rejectable on other grounds), **a terminal disclaimer must be required in the later-filed application, before the provisional ODP rejection can be withdrawn**.
- A later issued patent may invalidate an earlier issued patent
 - See *Gilead Sciences, Inc. v. Natco Pharma Ltd.* (Fed. Cir. 2014) where an earlier filed but later issued patent invalidated a later filed but earlier issued patent using nonstatutory double patenting



2 TDs Needed for Same Day Filing



- To overcome provisional NSDP rejections absent an effective amendment, where both applications are filed on the same day, the provisional NSDP rejection made in each of the applications should be maintained until showing made that the claims are patentably distinct or filling of a terminal disclaimer in both applications.
- See MPEP 1490, 1490(VI)(D) for a definition of “earlier filed” - in summary, the “earlier filed” application is the one having the earlier effective U.S. filing date, when taking into account each of the benefit claims under 35 U.S.C. 120 , 121 , and 365(c); 35 U.S.C. 119(e) and 35 U.S.C. 119(a) (provisional benefit or foreign priority) are NOT taken into account in determining which is the “earlier filed“ application.



Helpful Reminders for Terminal Disclaimers

- Common reasons for terminal disclaimer disapproval:
 - Identifies a party who is not the applicant (applies to applications filed on or after 9/16/2012)
 - Signer must be identified as the applicant in the applicant information section of the Application Data Sheet (ADS)
 - Does not include the “enforceable only during the period of common ownership” clause required by 37 CFR 1.321(c).
 - Does not state the extent of ownership/interest of the person who signed or the extent of the business/organization entity’s ownership interest on whose behalf the person signed (37 CFR 1.321(b)(3)).
- Resubmission should include a corrected/replacement TD



Example: How many TDs should I file?



TD needed?

Patent B (is CIP of A)

Application

TD filed in Patent B
against A

TD filed in application
against A

Patent A

*Let us assume that Patents A and B claim obvious variations of the current claims.
Let us also assume that there is no 121 shield.*

Is a TD needed for application over B given fact pattern above?

Answer = No,- follow the “n-1” rule UNLESS all applications were filed on same day



Proper Uses of Specification

- Specification can be used in certain circumstances – See MPEP 804 II (b)(1)
 - Dictionary for claim terminology
 - Portions of the disclosure which provide support for the claims in the potentially conflicting patent or application to determine whether claims sets represent an obvious variation



In re Basell Poliolefine Italia S.P.A. 89 USPQ2d 1030 (Fed. Cir. 2008)

'687 Claims (exam)

'987 Claims (art)

'987 Specification

Copolymerizing

Copolymerizing

(1) α -olefin ($>C_4$)

(1) α -olefin (C_{3-6})

(2) ethylene

(2) any olefin

(2) ethylene, propylene, butene

“[The specification] may be used to learn the meaning of terms and in interpreting the coverage of a claim.” *In re Basell Poliolefine Italia S.P.A.*, 89 USPQ2d 1030, 1036 (Fed. Cir. 2008).

“[T]he specification of the '987 patent itself refers to ethylene, propylene, butene, and other olefins which indicates that those olefins were intended to fall within the meaning of the claims.” *Id.*

Thus, a Non-statutory DP rejection of the '687 claims using the '987 claims was proper



In re Basell (cont.)

- MPEP § 804 II (B)(1): Specifications of both the earlier and later commonly owned patents can be used to:
 - Learn the meaning of terms
 - Interpret the coverage of a claim
 - Determine whether claims are obvious variants
- Thus, even though the '687 claims (claims being examined) were more specific than the '987 claims (prior art) and therefore not necessarily anticipated or obvious in view of those claims, the species of the '687 claims were disclosed in the '987 specification, and thus the '687 claims were not patently distinct from the '987 claims.

In re Basell Poliolefine Italia S.P.A. 89 USPQ2d 1030 (Fed. Cir. 2008)



The Specification Can Also be Used to Determine the Utility of a Claimed Compound

(1) See *Sun Pharmaceutical Industries v. Eli Lilly and Co.*, 611 F.3d 1381, 1389 (2010)

U.S. 4,808,614 ('614) patent claimed gemcitabine and methods of using gemcitabine for treating viral infections. The patent also disclosed (but did not claim) using these compounds to fight cancer

U.S. 5,464,826 ('826) patent claimed methods of using gemcitabine for treating cancer

Brief holding: “The asserted claims of the later '826 patent simply claim the anticancer use disclosed in the specification of the '614 patent as a method of use claim. See *Pfizer*, 518 F.3d at 1363; *Geneva*, 349 F.3d at 1385. Therefore, we affirm the district court's judgment that the asserted claims, claims 2, 6, and 7, of the '826 patent are invalid for obviousness-type double patenting over the '614 patent.”



Double Patenting and 35 U.S.C. 121

- The Third Sentence of 35 U.S.C. 121 Provides:
 - 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 and Trademark 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



Double Patenting and 35 U.S.C. 121 (continued)

- MPEP § 804.01
 - This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.



When Prohibition Under 35 U.S.C. 121 Does Not Apply

- Two or more applications filed – no restriction requirement made (i.e., voluntary divisional)
- Claims amended such that they are not commensurate with the restriction requirement (i.e., consonance not maintained)
- Restriction withdrawn (e.g., rejoinder)
- Restriction (lack of unity) only made in PCT application
- Claims are directed to identical subject matter



Safe Harbor Requires Maintaining Consonance



- 35 U.S.C. 121 provides Applicants a safe harbor from ODP rejections
- However, consonance must be maintained with the original restriction requirement
- Further, this consonance applied to “species elections” as well
 - St Jude Medical, Inc. v. Access Closure, Inc., 592 F.3d (Fed Cir. 2013)



Nonstatutory Double Patenting: Anticipation

Examined claim

A ruler comprising:
an elongated member;
a groove positioned along
the member every inch.

Patent Claim

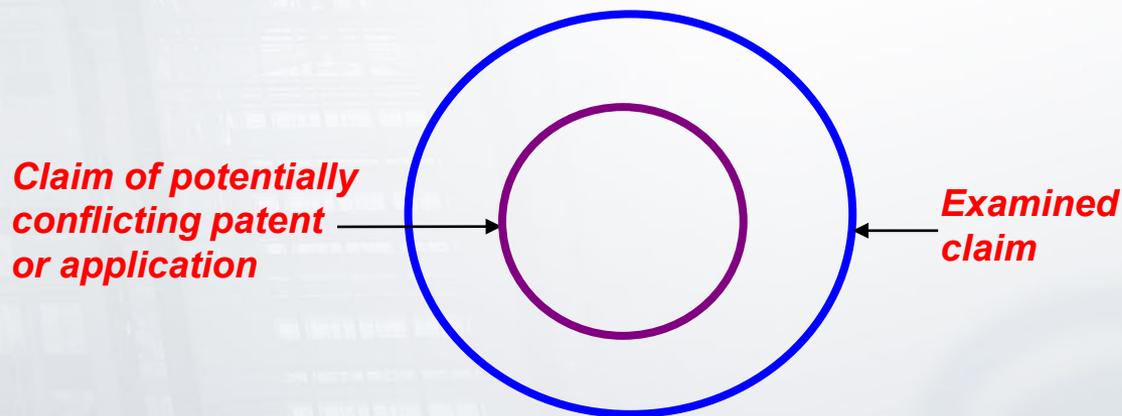
A ruler comprising:
an elongated member *with
sliding clamp member*;
a groove positioned along
the member every inch.

Examined claim anticipated by patent claim



Nonstatutory Double Patenting: Anticipation

- Examined Claims are generic to (fully encompassed by) a claim in the potentially conflicting patent or application
- No *Graham v. Deere* analysis needed



**ODP-Anticipation Rejection
Appropriate.**



THANK YOU

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