

Technology Center 1600

Nonstatutory Double Patenting: *Myth vs. Reality*

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PATENT AND TRADEMARK OFFICE ®

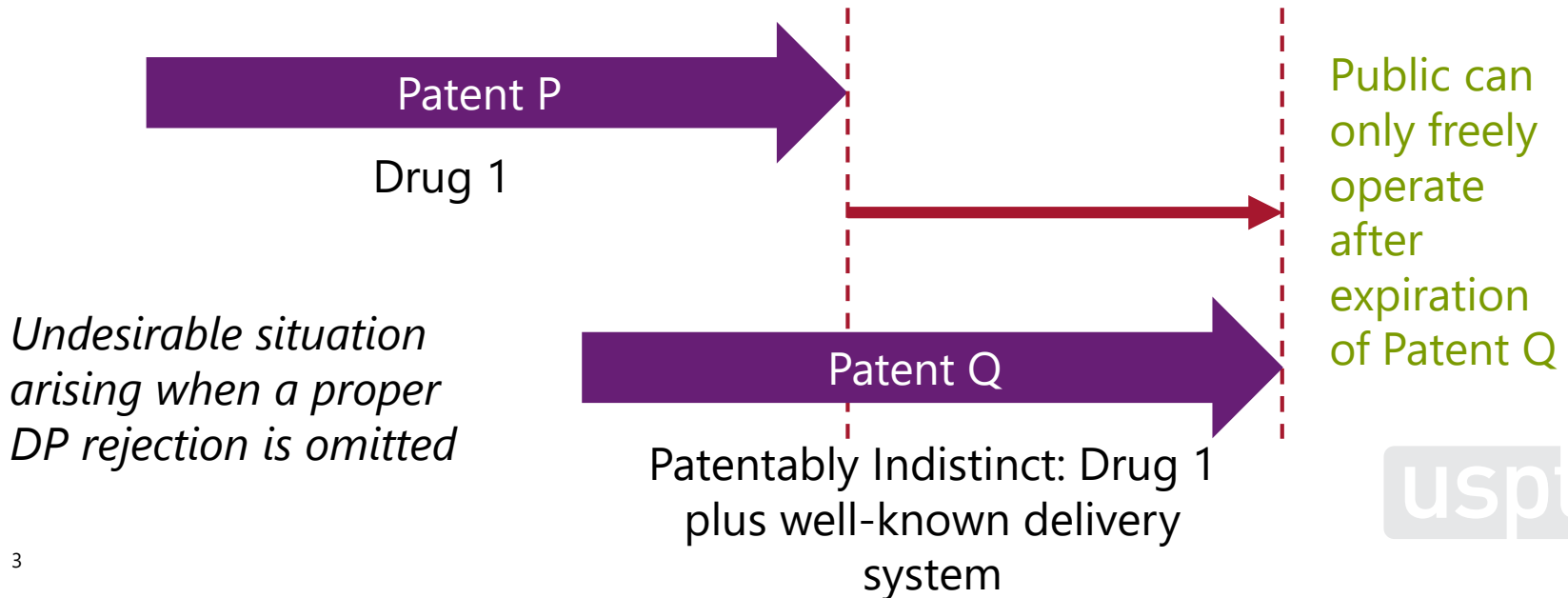
Why this training?

- Nonstatutory double patenting (NSDP) is expected to rise as the number of related applications in the same family or in a parallel family increases.
- NSDP guards against the improper timewise extension of patent rights on inventions that are patentably indistinct and prevents the possibility of multiple suits against an accused infringer by different assignees.
- Understanding the impact of correct NSDP practice on the public is critical to examination.
- Training reflects current practice; a Request for Comments on this topic closed February 1, 2023



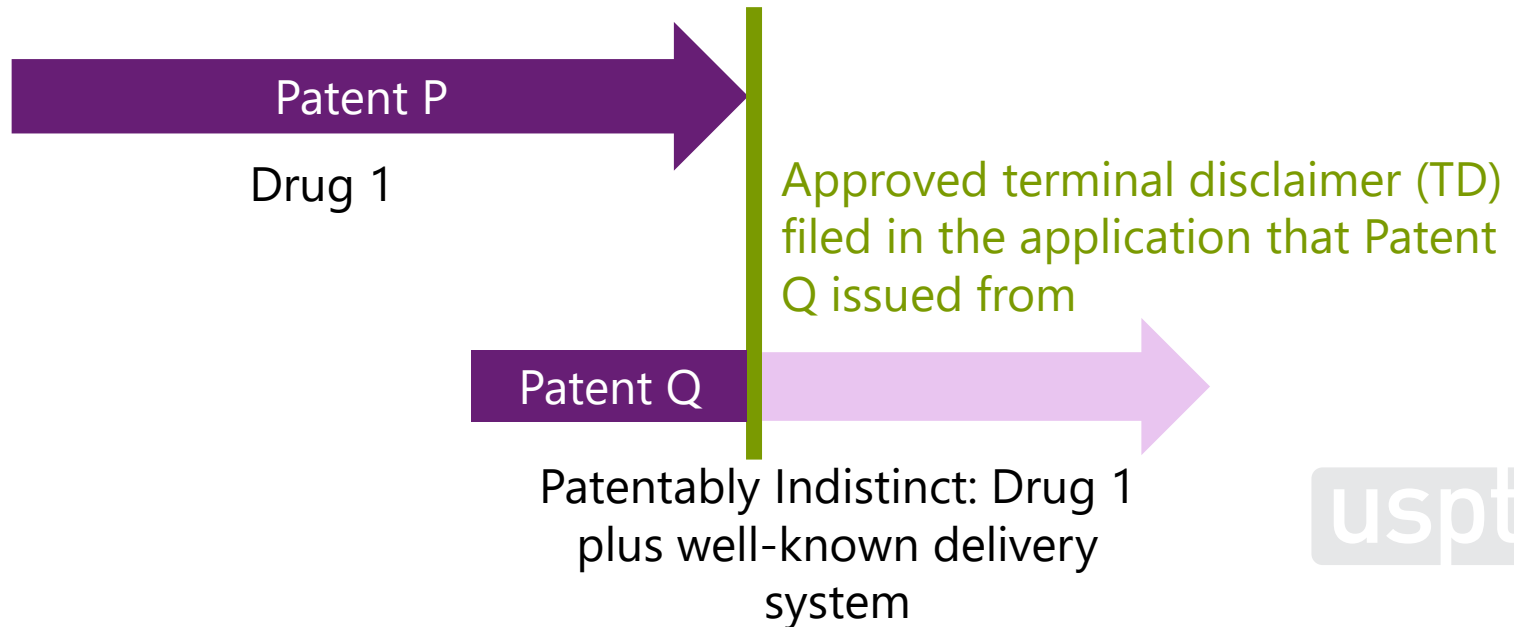
Why is double patenting important?

- Complete and correct double patenting analysis protects the public.
 - Ensures that patentably indistinct inventions **do not receive an unjustified extension of patent exclusivity beyond the term of a patent**



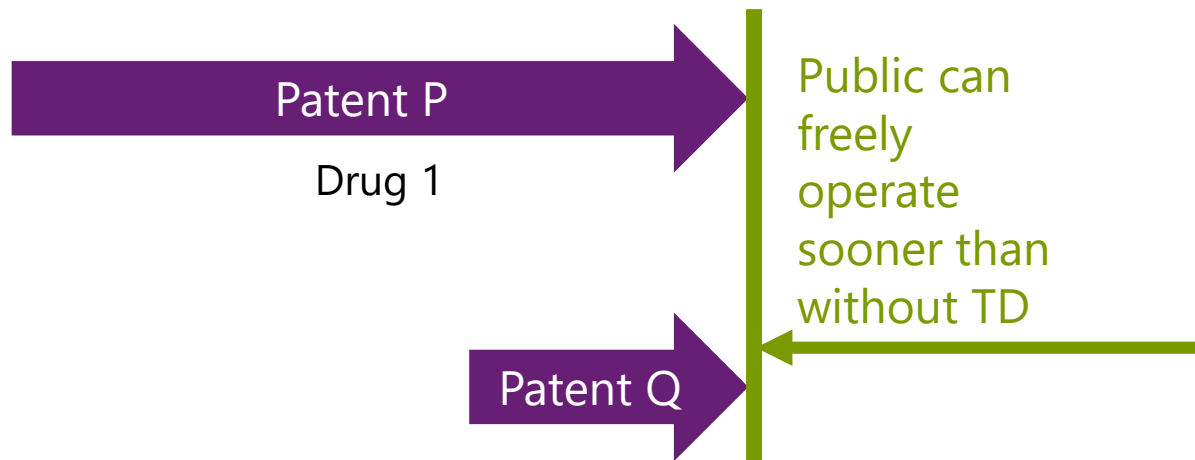
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Why is double patenting important?

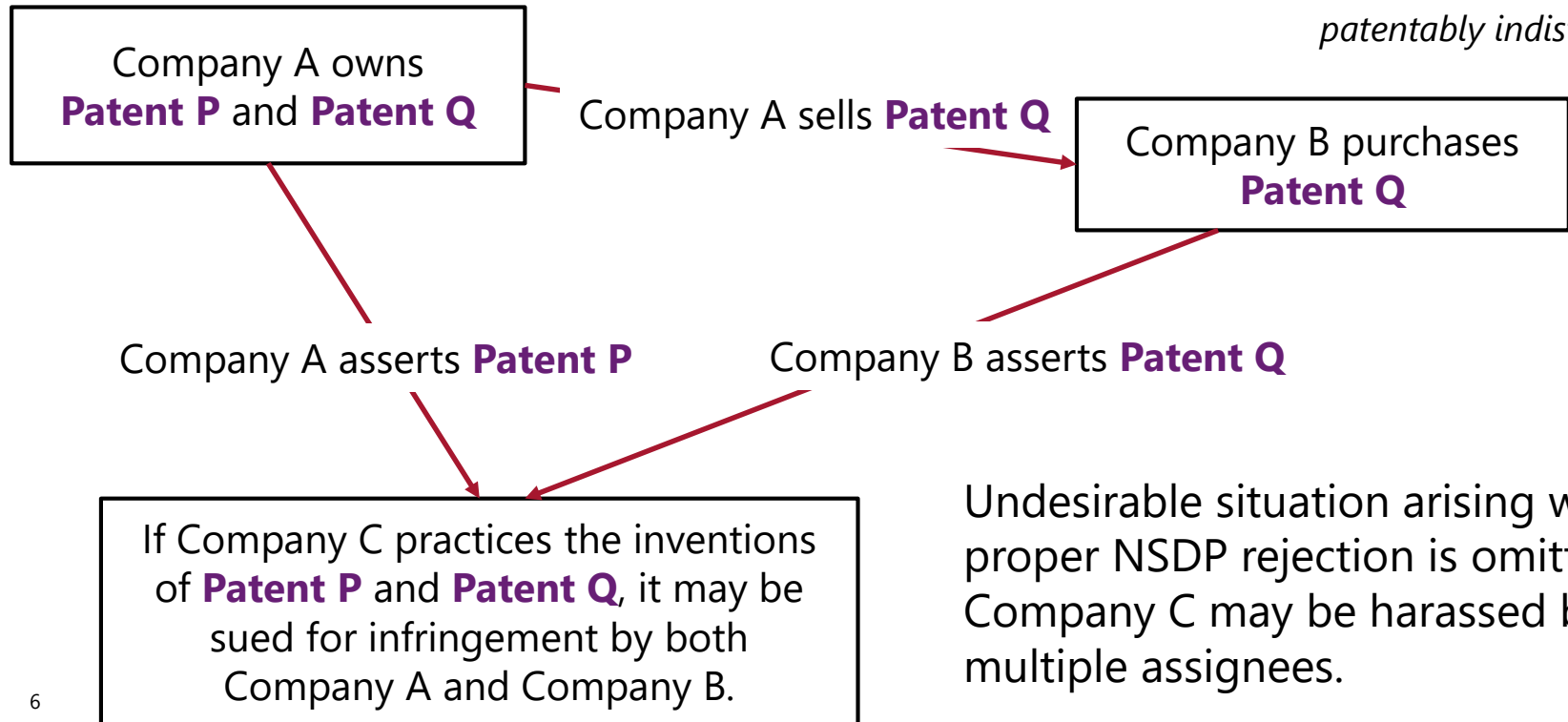
- Complete and correct double patenting analysis protects the public.
 - Ensures that patentably indistinct inventions **do not receive an unjustified extension of patent exclusivity beyond the term of a patent**



Why is double patenting important?

Scenario 1: Proper NSDP rejection omitted
No approved TDs

Claims in Patent P and Patent Q share a joint inventor and are patentably indistinct



Undesirable situation arising when a proper NSDP rejection is omitted. Company C may be harassed by multiple assignees.

Why is double patenting important?

Scenario 2: NSDP rejections resulted in approved TDs in **Patent P** and **Patent Q**

Claims in Patent P and Patent Q share a joint inventor and are patentably indistinct

Company A owns **Patent P** and **Patent Q**

Company A sells **Patent Q**

Company B purchases **Patent Q**

In view of the language of the TD filed in **Patent P** and sale of **Patent Q**, **Patent P** is unenforceable

In view of the language of the TD filed in **Patent Q**, **Patent Q** is unenforceable

If Company C practices the inventions of **Patent P** and **Patent Q**, it may not be successfully sued for infringement by either Company A or Company B because **Patent P** and **Patent Q** are **not commonly owned**.

Company C is protected from harassment by multiple assignees.

NSDP topics in this presentation

- This presentation will address:
 - When to consider making NSDP rejections
 - Provisional NSDP rejections
 - Statutory prohibition on NSDP rejections under some circumstances (35 U.S.C. 121)
 - Drafting a proper NSDP rejection
 - Overcoming an NSDP rejection

Standard for NSDP

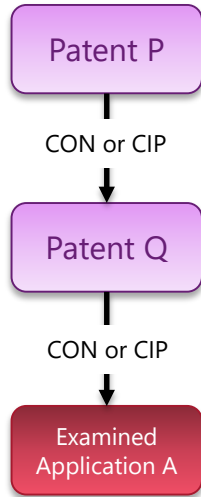
- “A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either **anticipated by**, or **would have been obvious over**, the reference claim(s).” (emphasis added)
 - The reference patent/application that contains the conflicting claims does not need to qualify as prior art under 35 U.S.C. 102.
 - “The analysis employed with regard to [obviousness-type] nonstatutory double patenting is ‘similar to, but not necessarily the same as that undertaken under 35 U.S.C. § 103.’”

MPEP 804, part (II)(B)(2)

What are potential NSDP references?

- MYTH: All reference claims on subject matter related to the examined claims can be considered as potential NSDP references.
- REALITY: Before considering an NSDP rejection,* confirm that your examined application and the reference patent/copending application:
 - Have at least one common joint inventor OR
 - Have at least one common applicant OR
 - Are commonly assigned/owned OR
 - Are non-commonly assigned/owned but deemed commonly owned based on a joint research agreement as set forth in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2)

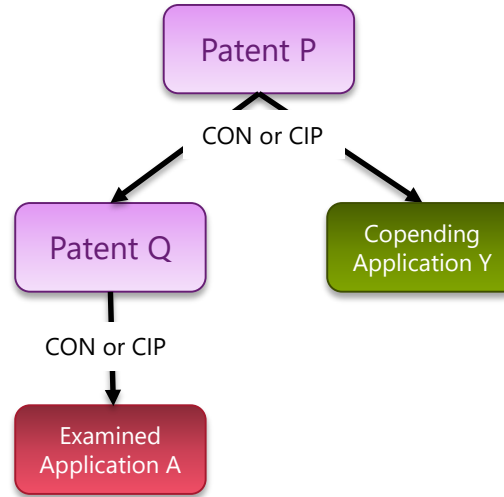
Common scenarios



Benefit chain

Direct relationship to a single parent

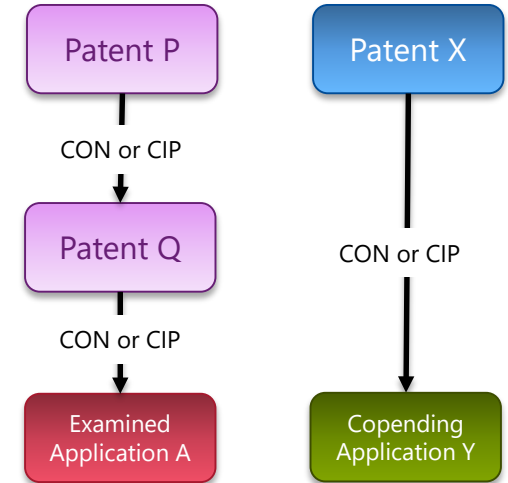
Applications/patents that the application under examination is directly related to by filing under 35 U.S.C. 120, 121, or 365(c)



Continuity map

Indirect relationship but shared parent

Applications/patents with which the application under examination shares at least one common parent application, even if they are not in the same benefit chain



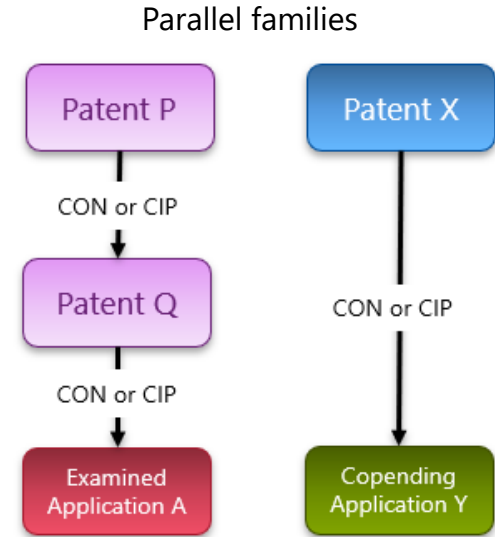
Parallel families

No shared parent

Applications/patents that may serve as a basis in an NSDP rejection and claim similar subject matter but are not in the same benefit chain or continuity map

Making all proper NSDP rejections

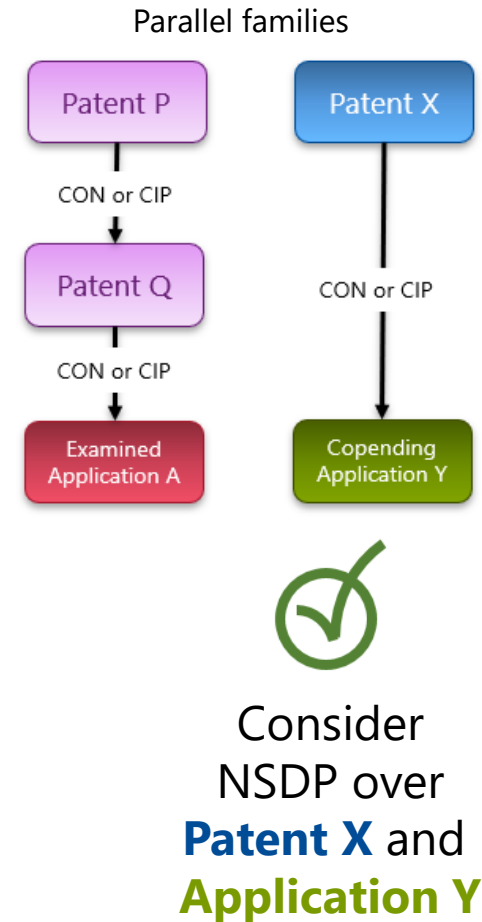
- Examiners must consider not only consider the patents and copending applications in the examined application's benefit chain or continuity map when assessing NSDP.



Making all proper NSDP rejections

- NSDP must be considered in **Application A** not only over the claims of **Patent P** and **Patent Q**, but over the claims of every patent and copending application that share a joint inventor, applicant, or assignee or are made by a party to a joint research agreement.
- Whether the invention in **Application A** is patentably indistinct from the claimed invention in the reference patent or application is a separate inquiry.

MPEP 804



NSDP across statutory categories

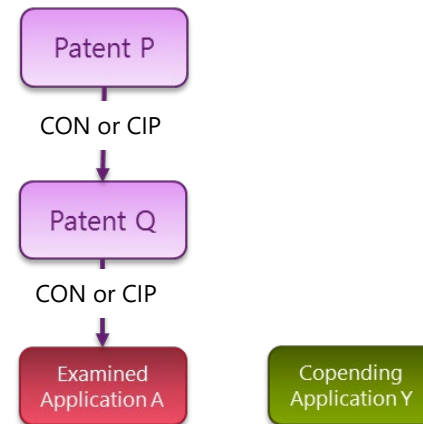
- If **Application Y** claims only an agent, and **Application A** from a parallel family claims only a method of using the agent, NSDP should be considered.
- There is no per se prohibition on NSDP across statutory categories.

MPEP 804



Consider
NSDP

Parallel families



Claim: A
method of
treating
cancer with
Compound
X.

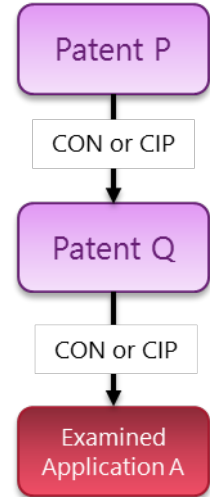
Claim:
Compound
X.



Make all available proper NSDP rejections

- MYTH: If I write a proper NSDP rejection over **Patent P**, I don't need to consider NSDP over **Patent Q** because once applicants file a TD over **Patent P**, there will be no improper timewise extension since **Application A** will expire with **Patent P**.
- REALITY: All available proper NSDP rejections must be made in every application - thereby protecting the public.
 - In addition to protecting the public from multiple infringement suits, it may be that Patent P and Patent Q will not actually expire the same day due to the possibility of patent term adjustment.

Benefit chain



Consider
NSDP over
**Patent P and
Patent Q**

Continuing . . .

Make all available proper NSDP rejections

- MYTH: If I write a proper NSDP rejection over **Patent P**, I don't need to consider NSDP over **Patent Q** because once applicants file a TD over **Patent P**, there will be no improper timewise extension since **Application A** will expire with **Patent P**.
- Due to patent term adjustment, **Patent P** and **Patent Q** will not necessarily expire on the same day even though the patent term of each patent is measured from the same domestic benefit date.
- Conduct a full inventor, applicant and assignee search each time the application comes up for action to see whether children and/or additional families have been filed.

Benefit chain



CON or CIP



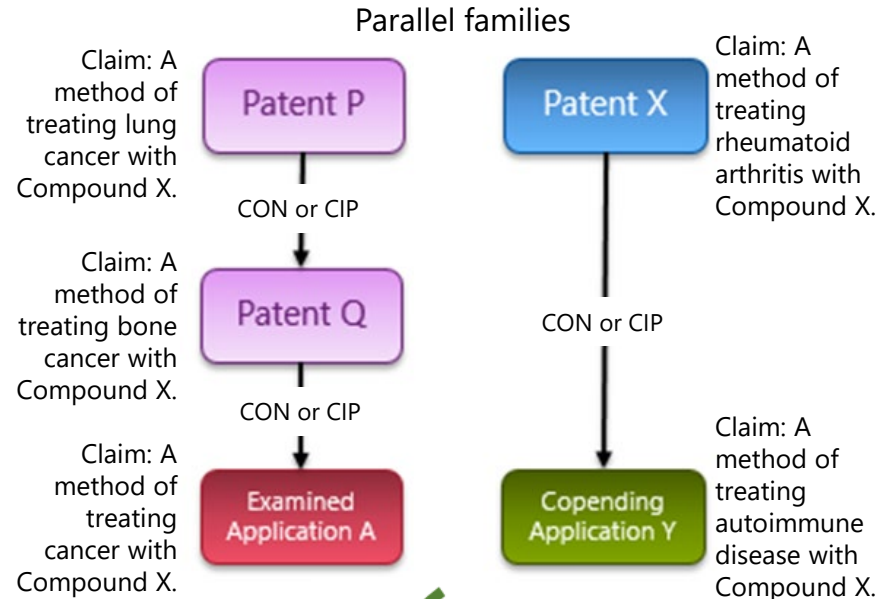
CON or CIP



Consider
NSDP over
Patent P and
Patent Q

Make all available proper NSDP rejections

- MYTH: If I write proper NSDP rejections over all of the applications in the benefit chain/continuity map, I have addressed all of the possible NSDP issues.
- REALITY: Applications and patents on related subject matter that do not share a parent with the examined application must be considered for possible NSDP rejections.
- A NSDP rejection here must account for the different diseases and provide an obviousness rationale.



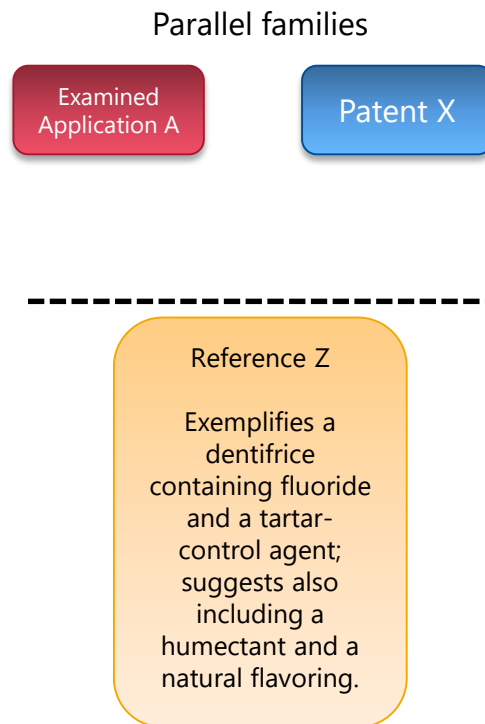
Consider
NSDP over
Patent X and
Application Y



NSDP in view of a secondary reference

- If the examined claim would have been obvious over **Reference Z** alone, it may have also been patentably indistinct over claim of **Patent X** in view of **Reference Z**, following an NSDP analysis based on obviousness.
- It would have been obvious to combine **Reference Z**'s tartar-control agent, humectant, and natural flavoring with **Patent X**'s claimed fluoride-containing dentifrice for similar reasons given in the § 103 rejection.
- **Patent X**'s claim to a composition **comprises** fluoride and a peroxide donor, so it is open to the inclusion of **Reference Z**'s tartar-control agent, humectant, and natural flavoring.

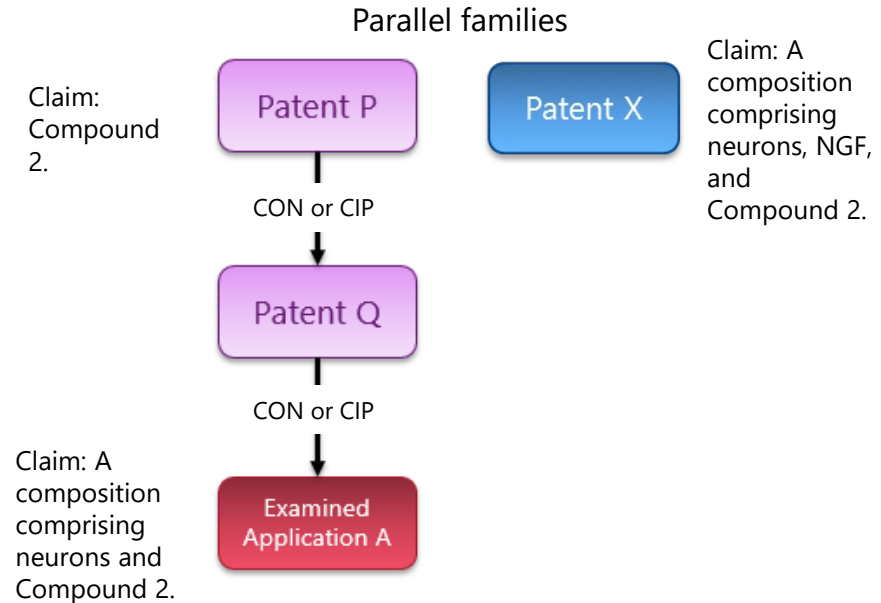
Claim: A dentifrice comprising fluoride, a tartar-control agent, a humectant, and a natural flavoring.



Claim: A dentifrice comprising fluoride and a peroxide donor.

NSDP based on an anticipation analysis over narrower reference claims

- **Patent X** claims a composition comprising neurons, nerve growth factor (NGF), and Compound 2.
- **Application A** claims a composition comprising only neurons and Compound 2, but no NGF.
- NSDP should be considered here even though **Patent X**'s composition contains NGF, which is not required in **Application A**'s composition.

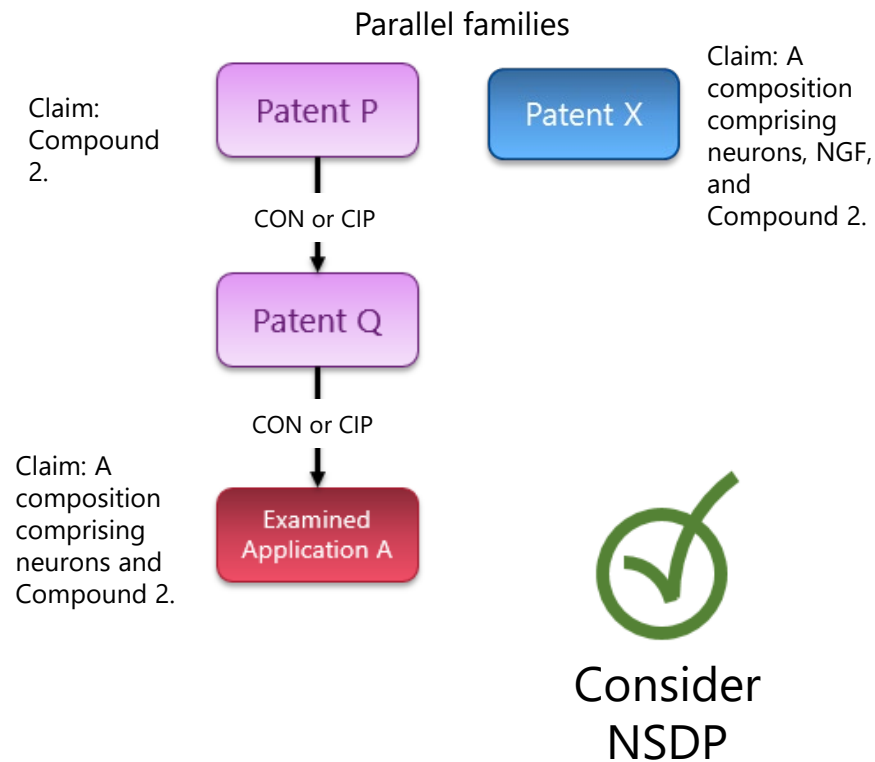


NSDP based on an anticipation analysis over narrower reference claims

- If the reference claims, when properly construed, are seen to provide coverage for an embodiment within the scope of the examined claims, the examined claims are anticipated by the reference claims and thus are patentably indistinct from the reference claims.
- The depicted situation is a one-way test only.
 - There is no need to establish that it would have been obvious to include NGF in **Application A**'s composition.

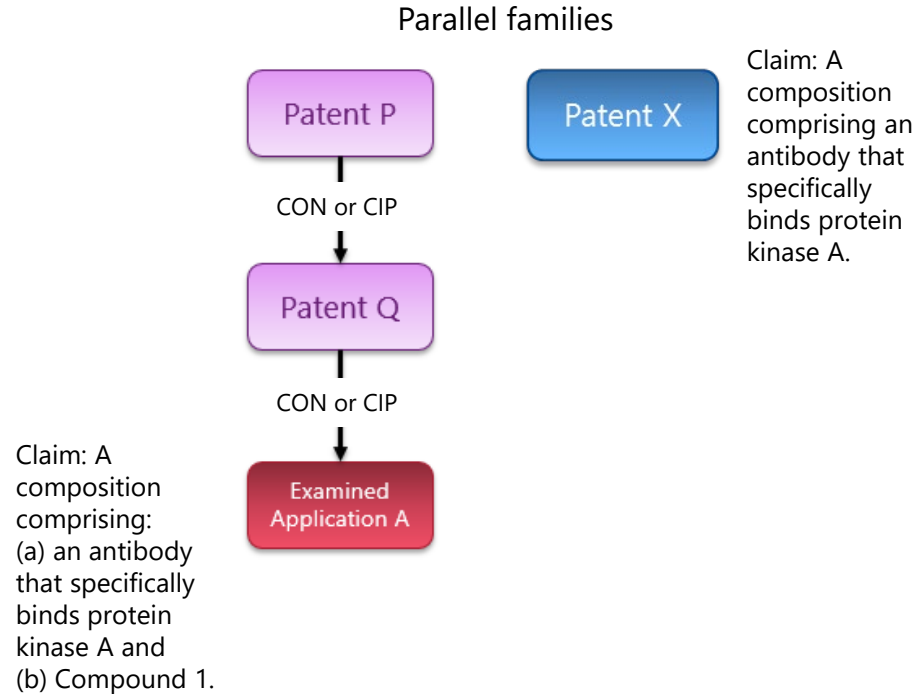
MPEP 804, part (II)(B)(1)

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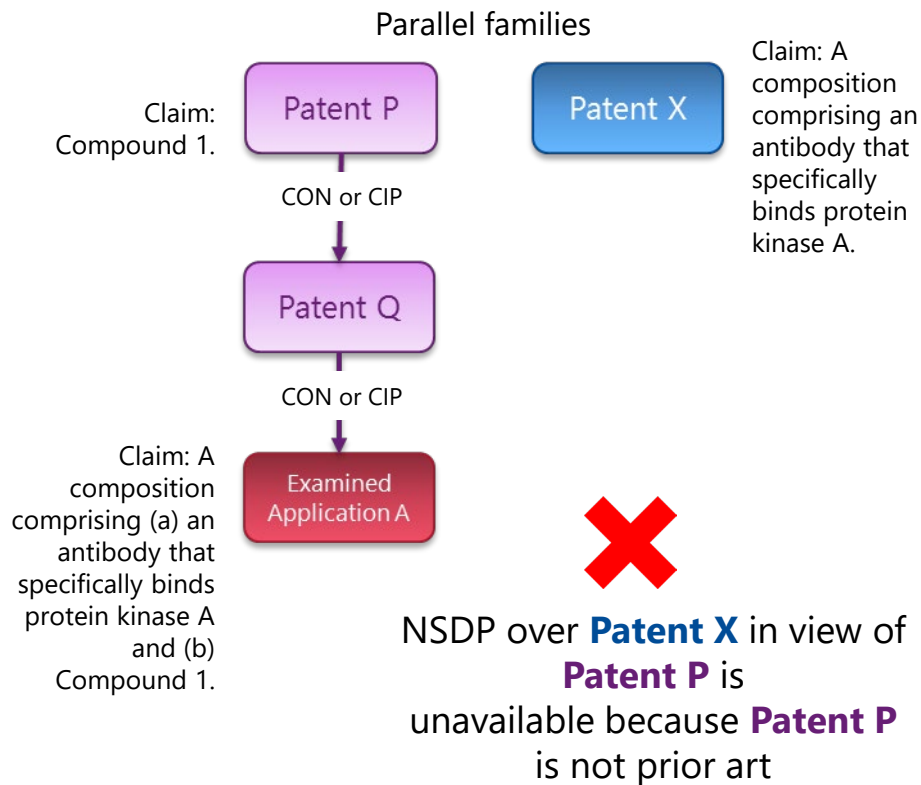
NSDP over broader reference claims

- If **Application A** claims a composition comprising the antibody of **Patent X** plus Compound 1, NSDP should not necessarily be **made** solely on the basis that **Application A**'s composition overlaps with **Patent X**'s antibody.



NSDP over broader reference claims

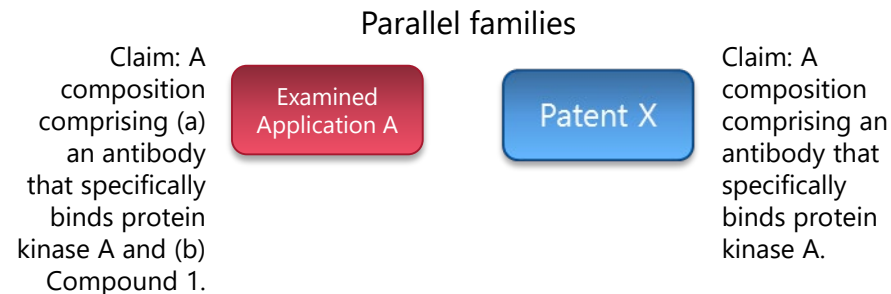
- Suppose **Patent P** claims **Compound 1**.
- The claim in **Patent X** is being considered as the conflicting claim.
- If the claim of **Application A** has the same effective filing date as the claim in **Patent P**, then **Patent P** is not available as a secondary reference for an NSDP rejection over the claim of **Patent X**.



MPEP 804, part (II)(B)(1); 2144.08

NSDP over broader reference claims

- Now: **suppose a prior-art reference discloses Compound 1.**
- Consider whether it would have been obvious to modify the claims of **Patent X** with the prior-art reference disclosing Compound 1 to render obvious the combination of Compound 1 with the antibody.



Not Enough Information

MPEP 804, part (II)(B)(1); 2144.08



Provisional NSDP rejections: the basics

- Provisional NSDP rejections may be made between two **copending** applications (i.e., not between an examined application and a reference patent).
- Provisional NSDP rejections are **not** always dropped when the examined application is otherwise allowable.
- Provisional NSDP rejections can be made over both published and unpublished applications.
- Provisional NSDP rejections can be made over claims that are withdrawn in the copending application.

Provisional NSDP rejections

- Two or more **copending applications** may raise an issue of double patenting if one of the applications becomes a patent.
- In order to be the basis for a NSDP rejection, a copending application must satisfy at least one of these criteria:
 - Be filed by the same inventive entity
 - Be filed by different inventive entities having at least one common joint inventor, a common applicant, and/or a common owner/assignee, **or**
 - Be filed by parties to a joint research agreement as defined by 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2)

NSDP over withdrawn reference claims

- **Application A** claims a composition comprising neurons and Compound 2.
- **Application Y** has a withdrawn claim to a composition comprising neurons, NGF, and Compound 2.
- A provisional NSDP rejection in **Application A** over **Application Y** **should** include **Application Y's** claim 2 as a reference claim because **Application Y's** claim 2 is withdrawn.

Parallel families

Examined
Application A

Claim 1.
(Original)
A composition comprising neurons and Compound 2.

Copending
Application Y

Claim 1.
(Original)
A method of treating Alzheimer's by administering a composition comprising neurons, NGF, and Compound 2.

Claim 2.
(Withdrawn)
A composition comprising neurons, NGF, and Compound 2.

NSDP over withdrawn reference claims

- Withdrawn claims in **Application Y** are available for provisional NSDP rejections in **Application A**.
- Withdrawn claims in **Application A** should not be rejected for NSDP.

Parallel families

Examined
Application A

Claim 1.
(Original)
A composition comprising neurons and Compound 2.

Copending
Application Y

Claim 1.
(Original)
A method of treating Alzheimer's by administering a composition comprising neurons, NGF, and Compound 2.

Claim 2.
(Withdrawn)
A composition comprising neurons, NGF, and Compound 2.

MPEP 804, part (II)(B)(1); 2144.08

Provisional NSDP over unpublished applications

- MYTH: A provisional NSDP rejection cannot be made in **Application A** over **Application Y** until **Application Y** is published.
- REALITY: Provisional NSDP rejections can be raised even when the reference application has not been published.

Provisional NSDP when examined application is otherwise allowable

- MYTH: A provisional NSDP rejection in **Application A** over **Application Y** should always be withdrawn when **Application A** is otherwise allowable.
- REALITY: Provisional NSDP rejections are only withdrawn when the application is otherwise allowable and is the earlier-filed application.
 - See MPEP 804(I)(B)(1) for determining which application has the earlier effective U.S. filing date.*

* MPEP 804 part (I)(B)(1)(b)(i); 1490 part (VI)(D)(1)

Examples: determining when to withdraw a provisional NSDP rejection when application is otherwise allowable

When **Application A** is otherwise allowable:

Examined
Application A

Co-pending
Application Y

Later filed	Earlier filed	Maintain provisional NSDP rejection in A
Filed same day	Filed same day	Maintain provisional NSDP rejection in A
Earlier filed	Later filed	Withdraw provisional NSDP rejection in A

*Effective U.S. Filing Date:
MPEP 804 part (I)(B)(1)(b)(i); 1490 part (VI)(D)(1)*

Provisional NSDP rejection over allowed claims

- MYTH: A provisional NSDP rejection in **Application A** over claim(s) in **Application Y** becomes nonprovisional as soon as **Application Y** is allowed.
- REALITY: A provisional NSDP rejection remains provisional until the NSDP reference application issues as a patent.
 - The examiner should note in the next Office action after **Application Y** issues that the NSDP rejection is no longer provisional.

MPEP 804, part (I)(B)(1)(b)(i)

35 U.S.C. 121: prohibition on double patenting in some circumstances

- “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.”

35 U.S.C. 121, third sentence



Evaluating the § 121 prohibition

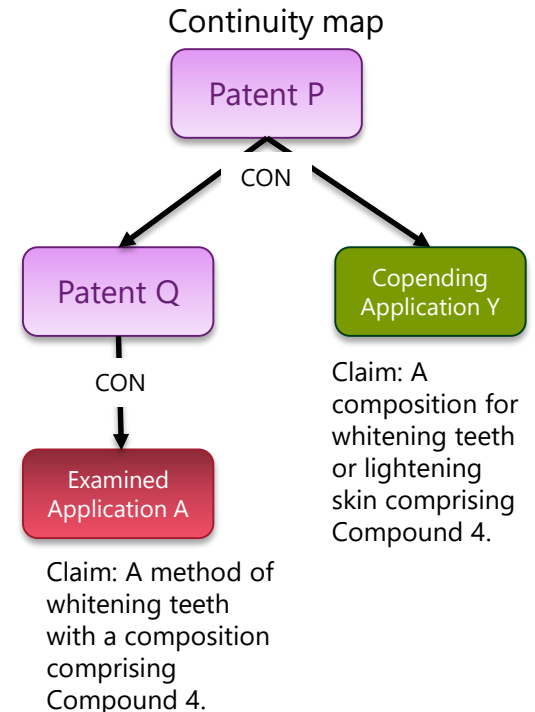
- First, determine whether a NSDP rejection (based on an anticipation analysis or obviousness analysis) is available between the examined claims and the reference claims.
- Then, assess whether the § 121 prohibition applies—coming up on next slide.
- Draft a rejection if the prohibition does not apply.

Assessing whether the § 121 prohibition is available

- Look at all related applications in the benefit chain and look for restrictions in each one.
 - **Check whether the restriction/election requirement was withdrawn in each application.**
- Determine whether your examined invention or species is a nonelected invention or species consonant with the restriction.
 - If it is, the § 121 prohibition may apply, in which case NSDP is not available.

NSDP in absence of a restriction

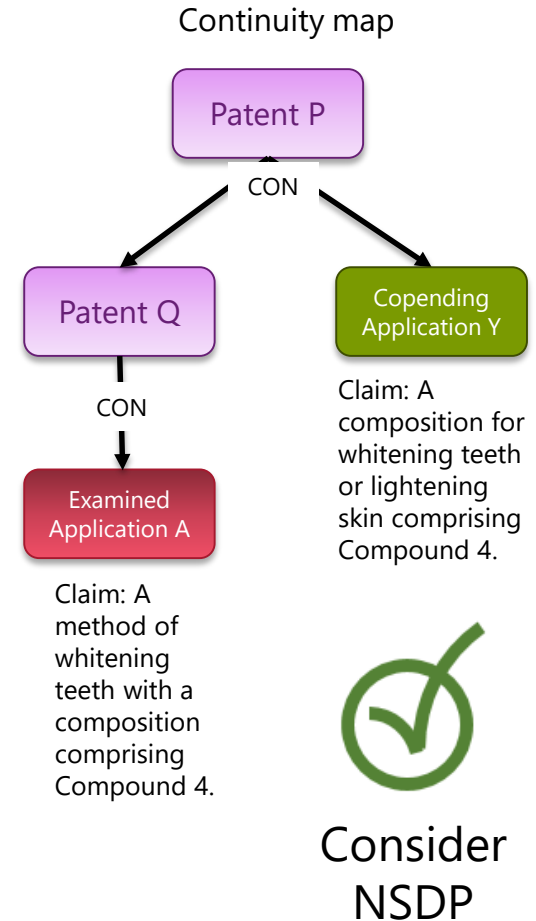
- **Application A** is a CON of **Patent Q**, which is itself a CON of **Patent P**.
- **Application Y** is a CON of **Patent P**.
- Neither **Patent P** nor **Patent Q** was subject to a restriction requirement.
- Compound 4 has multiple possible uses.
- 35 U.S.C. 121's prohibition on NSDP does not apply in **Application A** over **Application Y** because there was no restriction, **even though** these claims could properly be restricted from each other.



NSDP in absence of a restriction

- An NSDP rejection should be considered if there was no restriction in the parent(s), even if the invention in **Application A** could have been restricted from the invention in **Application Y**.
- 35 U.S.C. 121's prohibition on double patenting is only available when a divisional application is filed **as a result of a restriction requirement**.

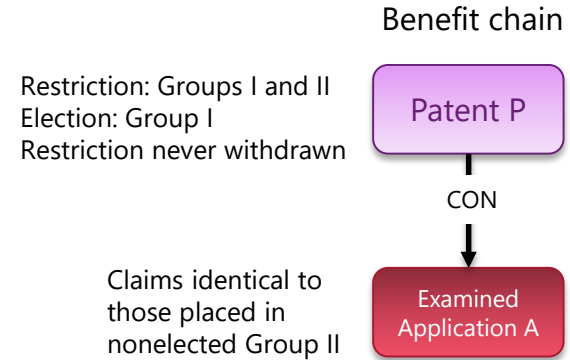
35 U.S.C. 121



NSDP in a CON of a restricted application

- MYTH: If there was a restriction made in the application issuing as **Patent P**, and **Application A** claims a nonelected invention and filed as a **continuation**, NSDP is not available.
- REALITY: 35 U.S.C. 121's prohibition on double patenting only applies when a **divisional application** is filed as a result of a restriction requirement.

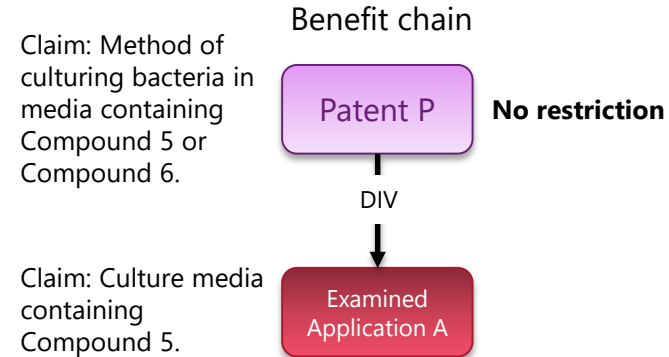
MPEP 804.01



Consider
NSDP

NSDP in a voluntary DIV

- MYTH: An NSDP rejection should not be made if **Application A** was filed as a **divisional** of **Patent P**, even if no restriction was actually made in the application that issued as **Patent P**.
- REALITY: 35 U.S.C. 121's prohibition on double patenting only applies when a divisional application is filed **as a result of a restriction requirement**.



Consider
NSDP

MPEP 804.01



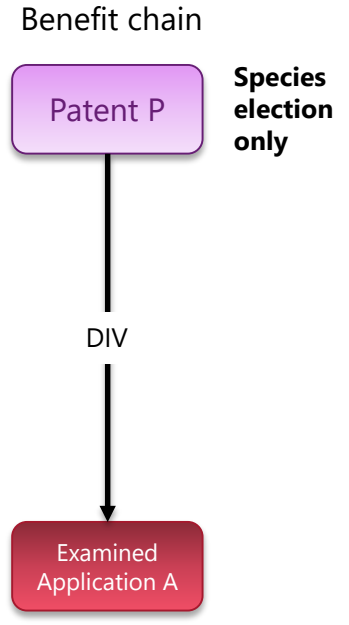
The 35 U.S.C. 121 prohibition and species

- **Patent P** claims a compound set forth as a Markush group with five different variables; Formula I includes 500,000 compounds.
- The examiner in **Patent P** required an election of a single compound from within the genus; applicants elected one compound and amended the claims to recite only that compound.
- **Application A** is a DIV that claims one of the nonelected species.
- Even though this was only a species election, **Patent P** cannot serve as basis for a NSDP rejection.

Claim: A compound of Formula I [chemical structure] wherein R1, R2, R3, R4, and R5 are each selected from a particular list of options.

Election requirement: Applicants elected one compound, then canceled the rest

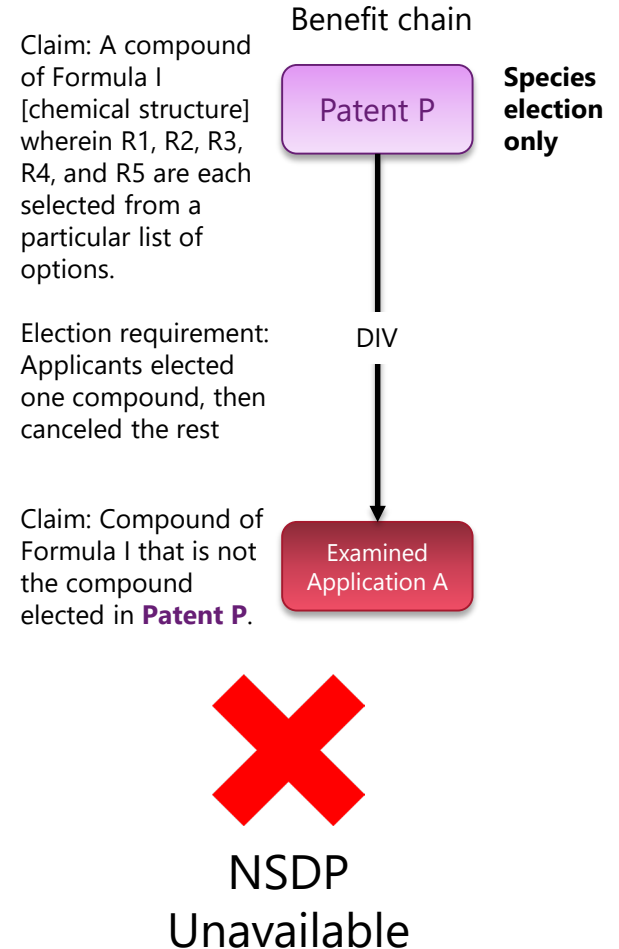
Claim: Compound of Formula I that is not the compound elected in **Patent P**.



The 35 U.S.C. 121 prohibition and species

- The 35 U.S.C. 121 prohibition on NSDP applies to restrictions based on grouped inventions **and** elections of species.
- In the depicted scenario, applicant may theoretically file 499,999 DIVs, each claiming one of the compounds not elected in **Patent P**, that may result in improper timewise extension of patent rights on inventions that are patentably indistinct.

MPEP 804.01



Establishing NSDP based on anticipation analysis

- A nonstatutory double patenting rejection is appropriate where a claim in an application under examination claims subject matter that is different, but not patentably distinct, from the subject matter claimed in a prior patent or a copending application. The claim under examination is not patentably distinct from the reference claim(s) if the claim under examination is anticipated by the reference claim(s).
 - When a claim being examined is, **for example**, generic to a species or sub-genus claimed in a conflicting patent or application, an NSDP rejection based on an anticipation analysis should **explain** the fact that the species or sub-genus claimed in the reference patent or application anticipates the claimed genus in the examined application being examined and, therefore, a patent to the genus would improperly extend the right to exclude granted by a patent to the species or sub-genus should the genus issue as a patent after the species or sub-genus.

Establishing NSDP based on obviousness analysis

- The obviousness analysis in an NSDP rejection is analogous to the obviousness analysis under 35 U.S.C. 103 except:
 - Only the claims of the reference patent/application are used as the basis for the NSDP rejection.
 - However, the disclosure of the primary reference can be used to interpret the claims applied in the NSDP rejection. See MPEP 804 (II)(B)(2)(a).
 - The reference patent/application need not be prior art to the claim under examination.
- NSDP rejections based on an obviousness analysis includes the *Graham v. Deere* analysis for each claim:
 - (A) Determine the scope and content of a **reference claim** relative to a claim in the application at issue;
 - (B) Determine the differences between the scope and content of the **reference claim** as determined in (A) and the claim in the application at issue;
 - (C) Determine the level of ordinary skill in the pertinent art; and
 - (D) Evaluate any objective indicia of nonobviousness.



“Shortcut” rationales in NSDP

- MYTH: An NSDP rejection based on an obviousness analysis need not carry out the *Graham v. Deere* analysis for all examined claims.
- REALITY: NSDP rejections based on an obviousness analysis that lack a full analysis for all claims are insufficient.
- Merely pointing out an overlap of claim scope is insufficient.
- Addressing all examined claims and all reference claims in a single sentence is generally insufficient.

NSDP with secondary references

- MYTH: An NSDP rejection may not rely on secondary references.
- REALITY: As with § 103 rejections, examiners are encouraged to rely on secondary references to properly establish obviousness.
- The secondary reference must qualify as prior art.
- Form paragraphs (FP) ¶¶ 8.36 and 8.37 provide appropriate language for relying on a secondary reference.

FP ¶ 8.37

Provisional Rejection, Nonstatutory Double Patenting -
With Secondary Reference(s)

Claim [1] provisionally rejected on the ground of
nonstatutory double patenting as being unpatentable over
claim [2] of copending Application No. [3] **in view of [4]**.
[5]

This is a provisional nonstatutory double patenting
rejection.

*Use FP ¶ 8.36 for a nonprovisional NSDP rejection
with a secondary reference*

To what extent can a reference's specification be consulted when making an NSDP rejection?

- The reference's specification can be used as a dictionary to interpret the reference's claims applied in the NSDP rejection.
- The reference's specification can be used to confirm the scope of the reference's claims.
- Use FP 8.34/8.35/8.36/8.37 as appropriate.

MPEP 804(II)(B)(2)(a)



Addressing potential NSDP where application claims a species encompassed by genus claimed in reference

- **First determine whether a PHOSITA can immediately envisage the species from the genus claimed in the reference patent** without looking to the specification of the reference patent.
 - Follow analysis in MPEP 804 (II)(B)(1). Use FP 8.33 AND either FP 8.34 or 8.35.
- If PHOSITA cannot immediately envisage the species from the genus claimed in the reference patent, **determine whether there is a secondary reference that renders the claimed species obvious** when combined with the genus claimed in the reference patent.
 - Explain why it would have been obvious for PHOSITA to conclude that the examined species is obvious over the reference genus claimed in light of the secondary teaching.
 - See MPEP 804(II)(B)(1) and 804(II)(B)(2). Use FP 8.33 AND either FP 8.36 or 8.37.
- If secondary reference is not found, **determine whether species claimed is obvious over the reference genus claimed without relying on a secondary reference (e.g., admitted prior art in the reference patent if earlier filed)**.
 - Explain why it would have been obvious for PHOSITA to conclude that the examined species is obvious over the reference genus claimed.
 - See MPEP 804(II)(B)(1) and 804(II)(B)(2). Use FP 8.33 AND either FP 8.34 or 8.35.
- If the claimed species is not obvious over the genus claimed in the reference patent, **consider NSDP based on equitable principles**.
 - See discussion in MPEP 804(II)(B)(3). If making an NSDP rejection based on equitable principles (these will be rare), use FP 8.33 AND either FP 8.38 and 8.39, and with Supervisory Patent Examiner approval, get the Technology Center Director signature.

Addressing genus/species situations in an NSDP rejection - Example using immediately envisage analysis

Patent P and Application A share a joint inventor

- **Patent P** claims a composition comprising Compound 9 and an alkali hydroxide.
- **Application A** claims a composition comprising Compound 9 and sodium hydroxide.

Claim 1. A composition comprising Compound 9 and an alkali hydroxide.

Patent P

Claim 1. A composition comprising Compound 9 and sodium hydroxide.

Examined
Application
A



Sample NSDP rejection explanation using an immediately envisage analysis

Patent P claims a composition comprising Compound 9 and an alkali hydroxide. (Claim 1)

Patent P's claim does not recite that the alkali hydroxide is sodium hydroxide.

When a genus is so limited such that a person of ordinary skill would have immediately envisaged all of the species of alkali hydroxide—LiOH, NaOH, KOH, RbOH, CsOH, and FrOH from Group I of the periodic table—upon reading the “alkali hydroxide” genus claimed in Patent P, the genus anticipates every species within the genus.

Therefore, claim 1 of Application A is not patentably distinct from claim 1 of Patent P, because claim 1 of Application A is anticipated by claim 1 of Patent P.

Note: Form paragraph 8.34 (Rejection, Nonstatutory Double Patenting - No Secondary Reference(s)) should be used for the entire NSDP rejection.

Patent P and Application A share a joint inventor

Claim 1. A composition comprising Compound 9 and an alkali hydroxide.

Patent P

Claim 1. A composition comprising Compound 9 and sodium hydroxide.

Examined
Application
A



Addressing genus/species situations in an NSDP rejection - Example using a secondary reference

- **Patent Q** claims a tablet comprising Compound 9 and an excipient.
- **Application A** claims a tablet comprising Compound 9 and magnesium stearate.

Patent Q and Application A share a joint inventor

Claim 1. A tablet comprising Compound 9 and an excipient.

Patent Q

Claim 1. A tablet comprising Compound 9 and magnesium stearate.

Examined Application A

uspto®

Sample NSDP rejection explanation using a secondary reference

Patent Q claims a tablet comprising Compound 9 and an excipient. (Claim 1)

Patent Q's claim does not recite that the excipient is magnesium stearate.

Reference Z teaches numerous excipients known to be useful in making pharmaceutical tablets. Reference Z identifies magnesium stearate as one example of an acceptable excipient that does not affect the activity of drugs, including several similar in structure to Compound 9. (Page 452)

A person of ordinary skill would have had a reasonable expectation of success in selecting Reference Z's magnesium stearate as the excipient in Patent Q's tablet because Reference Z teaches that magnesium stearate can be used to make pharmaceutical tablets. The skilled artisan would have been motivated to make the selection because Reference Z teaches that magnesium stearate is an excipient that does not affect drug activity. Because claim 1 of Application A would have been obvious over claim 1 of Patent Q in view of Reference Z, claim 1 of Application A is not patentably distinct from claim 1 of Patent Q.

Note: Form paragraph 8.36 (Rejection, Nonstatutory Double Patenting – With Secondary Reference(s)) should be used for the entire NSDP rejection.

*Patent Q and Application A
share a joint inventor*

Claim 1. A tablet
comprising
Compound 9 and an
excipient.

Patent Q

Reference Z

Exemplifies
magnesium
stearate as
an excipient

Claim 1. A tablet
comprising
Compound 9 and
magnesium stearate.

Examined
Application
A



NSDP based solely on improper timewise extension of patent rights already granted

- NSDP includes rejections based on the equitable principle against permitting an unjustified timewise extension of patent rights (aka NSDP based on equitable principles).
- Two examples in MPEP 804 of NSDP based on equitable principles (rather than based on obviousness analysis or anticipation analysis):
 - *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968)
 - *Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 68 USPQ2d 1865 (Fed. Cir. 2003)
- NSDP rejections based on equitable principles will be rare.

NSDP based solely on improper timewise extension of patent rights already granted (cont.)

- Particular fact pattern in *In re Schneller*:
 - Specification disclosed ABCXY.
 - First-filed patent claimed BCX and ABCX.
 - Later-filed application claimed ABCY and ABCXY.
 - No reason the sole inventor was prevented from presenting claims of later-filed application in first-filed application.
 - Allowance of later-filed application would have improperly extended the “right to exclude” granted in the first-filed patent.

NSDP based solely on improper timewise extension of patent rights already granted (cont.)

- Particular fact pattern in *Geneva v. GlaxoSmithKline*:
 - Earlier patent claimed a compound and the written description disclosed a single utility of that compound as administration to a human in amounts effective for inhibiting β -lactamase.
 - Later patent claimed the earlier patent's disclosed utility as a method of using the compound.
 - The court found that the claims of the later patent and the claims of the earlier patent were not patentably distinct by relying on equitable principles, not an obviousness-type analysis, in reaching its conclusion.

"It 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."

Geneva at 1386.



NSDP based solely on improper timewise extension of patent rights already granted (cont.)

- Each double patenting situation must be decided on its own facts.
- Form paragraph 8.38 (between an issued patent and one or more applications) or 8.39 (provisional rejection) may be used to make an NSDP rejection based on equitable principles.
 - An NSDP rejection based on equitable principles requires Supervisory Patent Examiner approval and a Technology Center Director's signature.
- Contact a double-patenting POC if you believe you are making an NSDP rejection based solely on equitable principles.

MPEP 804 (II)(B)(3)



NSDP and art rejections

- MYTH: If I properly reject the invention claimed in **Application A** as obvious under 35 U.S.C. 103 over **Reference Z**, I do not need to make a NSDP rejection over claims in **Patent X** in view of **Reference Z** because applicants would automatically overcome that rejection by overcoming my 103 rejection.
- REALITY: If the invention claimed in **Application A** is patentably indistinct as shown by the NSDP analysis over the claims in **Patent X** in view of **Reference Z**, it is an error to omit the NSDP rejection even if the section 103 rejection is compliant.



Overcoming an NSDP rejection based on anticipation analysis

- The following are options for applicants to overcome an NSDP rejection based on **anticipation** analysis:
 - A. Amendment to the examined claims such that the reference claims no longer anticipate
 - B. Cancellation of the relevant reference claims
 - C. An approved TD in the examined application

*Evidence of secondary considerations is **NOT** an option*

*A statement that a TD will be submitted when NSDP is the sole outstanding issue is **NOT** an option*



Knowledge pre-check: overcoming an NSDP rejection based on obviousness analysis

- Which of these are options for applicants to overcome an NSDP rejection based on **obviousness** analysis?

Select all that apply.

- A. Amendment to the examined claims such that the reference claims no longer render the examined claims obvious
- B. Cancellation of the relevant reference claims
- C. Evidence of unexpected results, properly presented
- D. An approved TD in the examined application

*A statement that a TD will be submitted when NSDP is the sole outstanding issue is **NOT** an option*



Filing of terminal disclaimer

- MYTH: As soon as applicant files a TD over a reference application/patent, the NSDP rejection over that application/patent must be withdrawn.
- REALITY: The TD is not effective to overcome an NSDP rejection until it has been approved.
 - Contact the Patent Legal Research Center for TD review if there is no approval in the file.
 - Examiners should not review TDs for compliance **BUT** should confirm that the reference numbers on the TD are correct.



Terminal disclaimer filed in reference application/patent

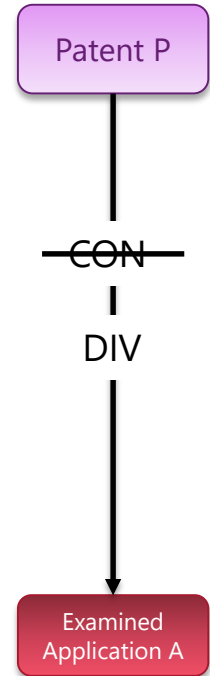
- MYTH: If a TD was approved in **Patent P** over **Application A**, then no TD needs to be submitted in **Application A** to overcome NSDP over **Patent P**.
- REALITY: A TD is only effective to overcome a NSDP rejection in the application in which it was filed.

Changing status from CON to DIV

- **Patent P** had a restriction requirement, and **Application A** was filed as a CON.
- **Application A** claims a nonelected invention from **Patent P**'s restriction.
- The examiner makes a compliant NSDP rejection in **Application A** over claim(s) of **Patent P**.
- Applicants reply with a corrected ADS, and a corrected filing receipt identifies **Application A** as a DIV of **Patent P**.
- The examiner **need not** evaluate the corrected ADS before dropping the NSDP rejection.

Claim: A tablet comprising Compound 9 and an excipient.

Benefit chain



Claim: A method of treating indigestion comprising administering a tablet comprising Compound 9 and an excipient.

FALSE.

Changing status from CON to DIV

- Examiners should look to the most recent filing receipt.
 - Document code: APP.FILE.REC
- Examiners are not to evaluate an ADS or act inconsistently with the most recent filing receipt.
- If an application was originally filed as a CON, but a corrected filing receipt identifies it as a DIV, then 35 U.S.C. 121's prohibition on NSDP may apply.
- The most recent filing receipt is the USPTO's information of record and **always** should be treated as accurate.

MPEP 211.02(a); 503; 601.05(a), part (II)



Earlier issuing patent

- MYTH: If **Patent X** was filed before **Application A**, NSDP over claims of **Patent X** is not available because there will be no improper timewise extension.
- REALITY: Improper timewise extension is only one issue addressed by NSDP.
- A TD filed in **Application A** to overcome a proper NSDP rejection ensures that the patent issuing from **Application A** is only enforceable while commonly owned with **Patent X** and also provides notice to the public that the patent issuing from **Application A** is tied to **Patent X**.
- Examiners should not speculate about when a patent's term will end because PTA calculations are complex.



Thank you!

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