

Enhancing Efficiencies in Examination



Technology Center 1600



Enhancing Efficiencies

- Inherency
- Ranges
- Routine Optimization



Inherency



Inherency

- The rule that anticipation can be inferred despite a missing element in a prior-art reference if the missing element is either necessarily present in or a natural result of the product or process and a person of ordinary skill in the art would know it (Black's Law Dictionary, 8th Ed. 2004)
- The legal theory of inherency is most commonly applied in a rejection under 35 USC 102 for anticipation
- Inherent feature need not have been recognized in the prior art (Atlas Powder v. IRECO, 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999))



Inherency

- Inherency cannot be established by probabilities or possibilities
- The mere fact that a certain thing may result from a given set of circumstances is not sufficient
- In re Oelrich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981)



In re Runion, 989 F.2d 1201 (Fed. Cir. 1993) (Nonprecedential)

- A claim to a bird feeder with pan for holding the food with an abrasive means for abrading beaks of birds as they feed was rejected over a baking pan for baking bread coated with vegetable grit on all of the surfaces to ensure easy removal of the bread
- Board found that the grit coating of the bread pan performed the function of the claim, i.e. abrading bird beaks
- Court disagreed, determining that a surface described as “rough” or “pebbled” need not necessarily be “abrasive” such that the explanation of the character of the bread pan coating was not consistent with the explanation of the abrasive means in the specification



Inherency

- Structure
- Use
- Advantage or Property



Inherency

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Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003)

- Claim recited descarboethoxyloratidine (DCL)
- DCL is a metabolite formed in the body after administration of loratidine and is a form of loratidine that does not make the user sleepy
- Claim to compound was construed by the court to cover compound in all forms, wherever found



Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003)

- Prior patent disclosed administration of loratidine to patients
- Prior patent did not explicitly disclose DCL and did not expressly refer to metabolites of loratidine
- Evidence showed that DCL is an inevitable consequence of loratidine administration
- Court held that prior art administration of loratidine to patients inherently anticipated claims to the DCL compound



Inherency

- Structure
- Use
- Advantage or Property



Mehl/Biophile International Corp. v Milgraum, 192 F.3d 1362, 52 USPQ2d 1303 (Fed. Cir. 1999)

- Claim recited laser hair removal requiring vertical alignment of the laser light applicator over a hair follicle . . . such that hair regrowth is prevented and scarring of the surrounding skin is avoided
- Prior art relied upon for anticipation:
 - a manual for laser use for tattoo removal
 - a research paper discussing effects of laser energy on melanosomes in guinea pig skin



Mehl/Biophile International Corp. v Milgraum, 192 F.3d 1362, 52 USPQ2d 1303 (Fed. Cir. 1999)

- Court found vertical alignment was not inherent in the laser manual – the manual did not discuss hair follicles and only teaches “aiming” the laser at skin pigmented by a tattoo
- Court found vertical alignment was inherent in research article because the article specifically mentioned disruption of hair follicles and stated that the laser was held in contact with the animals’ skin



Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 77 USPQ2d 1321 (Fed. Cir. 2005)

- Claims recited methods of treating sunburned skin
- Prior patent disclosed the same composition as suitable for general topical application to the skin or hair
- Federal Circuit concluded that sunburned skin is not analogous to all skin surfaces
- Since claim required treatment of sunburned skin, the issue was not whether the prior art's composition would have inherently treat sunburned skin if applied (it would), but whether the prior art disclosed the application of the composition to sunburned skin (it did not)



Inherency

- Structure
- Use
- Advantage or Property



In re Cruciferous Sprout Litigation, 301 F.3d 1343, 64 USPQ2d 1202 (Fed. Cir. 2002)

- Claim recited method of preparing a food product rich in glucosinolates and rich in high Phase 2 enzyme-inducing potential comprising germinating cruciferous seeds and harvesting sprouts to form a food product
- Prior art taught germinating broccoli seeds, harvesting the sprouts and selling them as a food product
- Federal Circuit found that both phrases were limitations of the claim but that the broccoli sprouts of the prior art inherently had the claimed property and therefore inherently anticipated the claims



Highlights and Guidance

- The Examiner must provide rationale or evidence to support a conclusion of inherency in order to present a *prima facie* case
- Once the Examiner presents a *prima facie* case to support a conclusion of inherency, the burden shifts to the Applicant to show that there is no inherency



Highlights and Guidance

- Claims to products, compositions or articles of manufacture that are claimed functionally may not be patentable if the evidence indicates that a prior art product, composition or article of manufacture that meets all required structural limitations is suitable for or capable of performing the claimed function



MPEP Citations

- 2112 – Requirements of rejections based on inherency
 - 2112.01 – Composition, product and apparatus claims
 - 2112.02 – Process claims
- 2131.01 – Multiple references may be used in a 102 rejection to support the primary reference to show inherency – supportive reference(s) may be post-filing



Ranges



Ranges

- Anticipation is considered when
 - An embodiment in the prior art falls within a claimed range
 - Prior art teaches a range overlapping or touching a claimed range if the prior art discloses the claimed range with sufficient specificity
- Obviousness is considered when
 - Claimed ranges overlap or lie inside ranges disclosed by the prior art



Genus-Species Relationships

- Disclosure of a Species Anticipates a Claim to a Genus
 - *In re Slayter*, 276 F.2d 408, 125 USPQ 345 (CCPA 1960)
 - *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989)
 - *Ex parte A*, 17 USPQ2d 1716 (BPAI 1990)
- Number of other species disclosed is immaterial
- Whether or not the species is preferred is immaterial



Genus-Species Relationships

- *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)
 - Generic claim was anticipated by prior art patent disclosing generic formula due to substituent preferences which effectively reduced the members of the genus to those that could be “at once envisage[d]” by one skilled in the art.



Genus-Species Relationships

- *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978)
 - Disclosure of genus of compounds in the prior art used to reject claim to a specific peripheral blood pressure increasing compound
 - Court distinguishes *In re Petering* but still finds that genus anticipated the claimed compound



Embodiment in the prior art falls within a claimed range

- Titanium Metals v. Banner, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)
 - Claim to a titanium alloy consisting essentially by weight of about 0.6%-0.9% Ni, 0.2%-0.4% Mo, up to 0.2% Fe and the balance Ti was anticipated by prior art disclosing a titanium alloy containing 0.75% Ni and 0.25% Mo
 - Court cites *In re Petering* as authority



Prior art teaches a range overlapping or touching a claimed range

- In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)
- Rejection was made under 35 USC 103

| Claims 27 and 31 | Prior Art |
|---|---|
| Method for <u>inhibiting the growth of fungi</u> on fresh leafy and head vegetables | Method of storing fresh leafy and head vegetables in order to maintain their fresh appearance |
| <u>0-2% CO₂</u> | 0-5% CO ₂ |
| 1-20% O ₂ | 1-10% O ₂ |
| 3-25% CO / >5-25% CO | 1-5% CO |
| Balance N ₂ | Balance N ₂ |
| 29-60° F | 32-40° F |



Prior art teaches a range overlapping or touching a claimed range

- Federal Circuit held
 - Patentability cannot be found in the difference in carbon monoxide ranges recited in the claims.
 - Case law in which the difference between the claimed invention and the prior art is a range or other variable within the claims have consistently held that in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range



Prior art teaches a range overlapping or touching a claimed range

- Atofina v. Great Lakes Chemical Corporation, 441 F.3d 991, 78 USPQ2d 1417 (Fed. Cir. 2006)
 - Patented method claims required the presence of 0.1–5 moles oxygen per 100 moles methylene chloride at a temperature of between 330 and 450 degrees C
 - Great Lakes process used 1.1–1.2 moles of oxygen per 100 moles of methylene chloride at a temperature of 150–350 degrees C

| <u>Atofina Patent</u> | JP 51-82206 |
|---|---|
| 0.1 – 5 m O ₂ /100 moles CH ₂ Cl ₂ | 0.001 – 1.0 m O ₂ /100 moles CH ₂ Cl ₂ |
| At a temperature of 330 – 450°C | At a temperature of 100 – 500°C |



Prior art teaches a range overlapping or touching a claimed range

Atofina v. Great Lakes Chemical Corporation, 441 F.3d 991, 78 USPQ2d 1417 (Fed. Cir. 2006)

- Claims required the presence of 0.1–5 moles oxygen per 100 moles methylene chloride at a temperature of between 330 and 450 degrees C
- Prior art disclosed 0.001-1.0 moles of oxygen per 100 moles of methylene chloride at a temperature of 100–500 degrees C

| Claims | Prior Art |
|---|---|
| 0.1 – 5 m O ₂ /100 moles CH ₂ Cl ₂ | 0.001 – 1.0 m O ₂ /100 moles CH ₂ Cl ₂ |
| At a temperature of 330 – 450°C | At a temperature of 100 – 500°C |



Prior art teaches a range overlapping or touching a claimed range

- Federal Circuit held
 - The disclosure of a range of 150 to 350C preferred temperature range did not constitute a specific disclosure of the endpoints of that range and that the disclosure was only that of a range, not a specific temperature in that range
 - The disclosure of a range is no more a disclosure of the endpoints of the range than it is of each of the intermediate points.
 - “Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim.”



Prior art teaches a range overlapping or touching a claimed range

ClearValue v. Pearl River Polymers, 668 F.3d 1340, 101 USPQ2d 1773 (Fed. Cir. 2012)

- Claim recited a process for clarifying water of raw alkalinity less than or equal to 50 ppm by adding ACH with a high molecular weight quaternized ammonium polymer comprising DADMAC having a molecular weight of at least approximately 1,000,000 to approximately 3,000,000
- Prior art taught the use of high molecular weight DADMAC with ACH reduces turbidity in low-alkalinity systems

| Claim | Prior Art |
|--|---|
| 1-3 million MW DADMAC | 1-2 million MW DADMAC |
| ACH | ACH |
| To clarify water with alkalinity of 50 ppm or less | To clarify water with alkalinity of 150 ppm or less |



Prior art teaches a range overlapping or touching a claimed range

- ClearValue argued that the broader range of 150 ppm or less did not anticipate the smaller range of 50 ppm or less citing Atofina
- Federal Circuit distinguished Atofina for several reasons
 - The Atofina patent disclosed that the claimed narrower range was critical to the success of the practice of the claimed method
 - Comparative examples in the Atofina patent support this conclusion, showing that a temperature of 300 degrees did not allow the synthesis reaction to operate as claimed
 - Combined with the evidence disclosed above and the considerable difference between the claimed Atofina range and the prior art range, a finding of anticipation in Atofina was precluded



Highlights and Guidance

- A range limitation is a genus limitation but a range limitation is a literal claim limitation
- Embodiments disclosed in the prior art that fall within the claimed range (and meet all the other limitations of the claim) will anticipate the claim
- But when only ranges are disclosed in the prior art, the disclosed ranges must be considered to determine whether they anticipate the claimed range
- Overlapping ranges also raises potential issues of obviousness



Highlights and Guidance

- When a prior art range overlaps or encompasses a claimed range, evidence of criticality of the claimed range appears to impact the determination of anticipation as well as obviousness



MPEP Citations

- 2131.03 – Anticipation of Ranges
- 2144.05 – Obviousness of Ranges
- 2144.05(I) – Overlap of Ranges



Routine Optimization



Routine Optimization

- Routine optimization may be the basis for a rejection under 35 USC 103



In re Aller, 220 F.2d 454, 105 USPQ 233 (CCPA 1955)

- Claimed process for production of phenols using sulfuric acid with acetone as a by-product was identical to prior art **except** for lower temperatures and higher sulfuric acid concentrations
- Claims: 25 - 70% H₂SO₄ at 40 - 80° C
- Prior Art: 10% H₂SO₄ at 100 ° C
- Prior art phenol yield was 75% while Appellants showed phenol yields from 83.7 – 100%
- Prior art acetone yield was about 60% while Appellants' acetone yield was 71 - 88%



In re Aller, 220 F.2d 454, 105 USPQ 233 (CCPA 1955)

- The court held that it would have been expected that the reaction rate would have been slowed at a known rate when the temperature was reduced, and that the reaction rate would have been accelerated at a known rate by an increase in acid concentration
- No evidence of a critical temperature range or acid concentration



In re Orfeo, 440 F.2d 439, 169 USPQ 487 (CCPA 1971)

- Claims: process of producing refrigerant comprising condensing a mixture consisting of CHF_3 and CClF_3 having CHF_3 in the range of about 20-75 mole %
- Prior Art: CHF_3 and CClF_3 each had been used individually as refrigerants
- Prior Art: method of preparing fluorochloro-hydrocarbons resulting in a mixture of CClF_3 and CHF_3 having desirable temperature ranges and suitable for use as refrigerants
- The examiner asserted routine optimization to find claimed amounts of refrigerants



In re Orfeo, 440 F.2d 439, 169 USPQ 487 (CCPA 1971)

- Rule 132 affidavit showed that the use of the CHF_3 / CClF_3 mixture as a refrigerant produces a new and unexpected reduction in power requirements lower than the individual power requirements of CHF_3 or CClF_3
- The Board stated that improved refrigeration was expected in view of known lower boiling point of the combination
- The court found “no indication that the lower boiling point is directly responsible for the lower power requirement, and, to the contrary, it appears that there are numerous factors (some of them not fully comprehended) which lead to the unexpectedly low power requirement of the [mixture].”



Highlights and Guidance

- MPEP 2144.05 - Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical
- If the prior art recognizes that the known effect is attributed to a claimed parameter, then it is logical to conclude that changes to that parameter produce expected results



Highlights and Guidance

- Results that are unexpected in view of the disclosure of the prior art must be considered and may overcome an examiner's finding of obviousness



MPEP Citations

- 2144 – Supporting A Rejection under 35 USC 103
- 2144.05(II) – Optimization of Ranges
- 2144.05(II)(A) – Optimization Within Prior Art Condition or Through Routine Optimization
- 2144.05(II) – Only Result-Effective Variables Can Be Optimized



Enhancing Efficiencies

- Be consistent with specification and/or art as appropriate in interpreting the claims
- Look for the best evidence at time of first office action
- Pick the most appropriate statute based on the evidence
- Clearly identify the issue(s) that are the basis of the rejection(s)



102/103 Rejection

- MPEP 706.02(m) - Form Paragraph 7.27
- Claim [1] rejected under [35 U.S.C. 102](#) ([2]) as anticipated by or, in the alternative, under [35 U.S.C. 103\(a\)](#) as obvious over [3].

Examiner Note:

1. This form paragraph is NOT intended to be commonly used as a substitute for a rejection under [35 U.S.C. 102](#). In other words, a single rejection under either [35 U.S.C. 102](#) or [35 U.S.C. 103\(a\)](#) should be made whenever possible using appropriate form paragraphs [7.15](#) to [7.19](#), [7.21](#) and [7.22](#).



102/103 Rejection

- Examples of circumstances where this paragraph may be used are as follows:
 - a. When the interpretation of the claim(s) is or may be in dispute, i.e., given one interpretation, a rejection under [35 U.S.C. 102](#) is appropriate and given another interpretation, a rejection under [35 U.S.C. 103\(a\)](#) is appropriate. See [MPEP §§ 2111- 2116.01](#) for guidelines on claim interpretation.
 - b. When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See [MPEP §§ 2112- 2112.02](#).
 - c. When the reference teaches a small genus which places a claimed species in the possession of the public as in *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), and the species would have been obvious even if the genus were not sufficiently small to justify a rejection under [35 U.S.C. 102](#). See [MPEP §§ 2131.02](#) and [2144.08](#) for more information on anticipation and obviousness of species by a disclosure of a genus.



102/103 Rejection

- Examples of circumstances where this paragraph may be used are as follows:
- d. When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also [MPEP § 2113](#).
- e. When the reference teaches all claim limitations except a means plus function limitation and the examiner is not certain whether the element disclosed in the reference is an equivalent to the claimed element and therefore anticipatory, or whether the prior art element is an obvious variant of the claimed element. See [MPEP §§ 2183- 2184](#).
- f. When the ranges disclosed in the reference and claimed by applicant overlap in scope but the reference does not contain a specific example within the claimed range. See the concurring opinion in *Ex parte Lee*, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993). See [MPEP § 2131.03](#).



Thank You!

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