Examination of Ranges

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Objectives

• Applying prior art to numerical ranges
• Determining when a §102, §103 and/or a §102/103 rejection should be applied
• Ranges and new matter
Anticipation is considered when

- Prior art teaches a specific example within a claimed range
- Prior art teaches a range, or preferred range, totally within a claimed range
- Prior art teaches a range overlapping the claimed range anticipates if it is determined that claimed range is disclosed with **sufficient specificity**

MPEP 2131.03
Anticipation: Genus-Species

• 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
Anticipation: Genus-Species

- *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.
Anticipation: Genus-Species

- *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)
  - “A simple calculation will show that, excluding isomerism within certain of the R groups, the limited class we find in Karrer contains only 20 compounds.”
  - “However, we wish to point out that it is not the mere number of compounds in this limited class which is significant here but, rather, the total circumstances involved, including such factors as the limited number of variations for R, only two alternatives for Y and Z, no alternatives for the other ring positions, and a large unchanging parent structural nucleus.”
  - “With these circumstances in mind, it is our opinion that Karrer has described to those with ordinary skill in this art each of the various permutations here involved as fully as if he had drawn each structural formula or had written each name.”
**Anticipation: Genus-Species**

*Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)*

<table>
<thead>
<tr>
<th>Claims</th>
<th>Prior Art</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.6-0.9 Ni</td>
<td>0.75 Ni</td>
</tr>
<tr>
<td>0.2-0.4 Mo</td>
<td>0.25 Mo</td>
</tr>
<tr>
<td>(\leq 0.2) Fe</td>
<td>0 Fe</td>
</tr>
<tr>
<td>Balance Ti</td>
<td>Balance Ti</td>
</tr>
</tbody>
</table>

“When, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is “anticipated” if one of them is in the prior art.”
Anticipation: Genus-Species

*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
MPEP §2131.03 Anticipation of Ranges:

• Prior art which teaches a range overlapping or touching the claimed range anticipates if the prior art discloses the claimed range with sufficient specificity

• Sufficient specificity normally requires that there is substantial overlap in the ranges and the same or similar function
• In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with “sufficient specificity to constitute an anticipation under the statute.”

• What constitutes “sufficient specificity” is fact dependent.
Factors to Consider in a Sufficient Specificity analysis:

- Size of the ranges
- Extent of overlap
- Nature of the variables (e.g., predictable or unpredictable variables)
- Criticality of claimed range relative to prior art range
Factors to Consider Regarding the Criticality of the Claimed Range Relative to the Prior Art Range:

- Does the reference establish the same or different functions or properties within the prior art range relative to the functions or properties of the claimed range?
- Are the data points within the prior art range equivalent to one another?
- Do different criteria (e.g. time, pressure) apply to different points within the prior art range?
- Is the prior art range so limited that the claimed range (species) can be readily envisaged by one of ordinary skill?
Factors to Consider in an Anticipation Analysis:

- “What constitutes a “sufficient specificity” is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broader range, other facts of the case, must be considered when determining whether the narrow range is disclosed with “sufficient specificity” to constitute an anticipation of the claims.”

MPEP §2131.03 II
Factors to Consider in an Anticipation Analysis:

• “If the prior art disclosure does not disclose a claimed range with “sufficient specificity” to anticipate a claimed invention, any evidence of unexpected results within the narrow range may render the claims unobvious.”

• “The question of “sufficient specificity” is similar to that of “clearly envisaging” a species from a generic teaching.”

MPEP §2131.03 II
The patented invention was directed to a method for the treatment of skin damaged or aged by oxygen-containing free radicals, with a composition containing an effective amount of an ascorbyl fatty acid ester.
The claimed ranges of an ascorbyl fatty acid ester varied in breadth from an ‘effective’ amount in claim 1 to particular specific ranges in other claims:

- “up to 10% by weight” in claim 2;
- “from about 0.025% to about 5% by weight” in claim 3;
- “from about 0.025% to about 10% by weight” in claim 22.
The district court found that the Pereira patent anticipated claims 1-19 of the ‘063 patent:

- Pereira taught a cosmetic composition for topical application to the skin or hair, which contains “from 0.01 to 20% by weight” of a skin benefit ingredient.
- Pereira also taught that one of the fourteen skin benefit ingredients is ascorbyl palmitate.
• Claimed amounts of an ascorbyl fatty acid ester:
  an effective amount
  up to 10% by weight
  about 0.025% to about 5% by weight
  about 0.025% to about 10% by weight

• Prior Art:
  0.01 to 20% by weight of a skin benefit ingredient
  one of the fourteen disclosed skin benefit ingredients is ascorbyl palmitate

• District court had concluded this was sufficient for anticipation.
• On appeal, Dr. Perricone argued that “Pereira’s disclosed range of concentration of its skin benefit ingredient only partially overlaps with Dr. Perricone’s claimed range…”

• The court concluded that Pereira’s disclosed range of concentration does not exactly correspond to Dr. Perricone’s claimed range. However, “Pereira’s disclosure nonetheless discloses and anticipates Dr. Perricone’s particular claimed ‘effective amount’ ranges…[since] Pereira’s range entirely encompasses, AND does not significantly deviate from, Dr. Perricone’s claimed ranges.” (underlining added)
Anticipation: Sufficient Specificity

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

- Claimed method for synthesizing difluoromethane 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 synthesized difluoromethane in the presence of 1.1–1.2 moles of oxygen per 100 moles of methylene chloride at a temperature of 150–350 degrees C
Federal Circuit held

- “JP 51-82206 discloses a preferred temperature range of 150 to 350C that slightly overlaps the temperature range claimed in the '514 patent. But that slightly overlapping range is not disclosed as such, i.e., as a species of the claimed generic range of 330 to 450C.”

- “Moreover, the disclosure of a range of 150 to 350C does not constitute a specific disclosure of the endpoints of that range, i.e., 150C and 350C, as Great Lakes asserts. The disclosure is only that of a range, not a specific temperature in that range, and the disclosure of a range is no more a disclosure of the end points of the range than it is of each of the intermediate points. Thus, JP 51-82206 does not disclose a specific embodiment of the claimed temperature range.”
Anticipation: Sufficient Specificity

Federal Circuit held

• “Moreover, the disclosure of a 0.001 to 1.0 percent range in JP 51-82206 does not constitute a specific disclosure of 0.1 percent to 5.0 percent, as Great Lakes asserts. Once again, although there is a slight overlap, no reasonable fact finder could determine that this overlap describes the entire claimed range with sufficient specificity to anticipate this limitation of the claim. The ranges are different, not the same.”
Anticipation: Sufficient Specificity

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

- A process for clarifying water of raw alkalinity less than or equal to 50 ppm
- by adding and blending at least one aluminum polymer include at least an effective amount of 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
ClearValue v. Pearl River Polymers, 668 F.3d 1340, 101 USPQ2d 1773 (Fed. Cir. 2012)

- ClearValue accused Pearl River of infringement of U.S. Patent 6,120,690

- Pearl River argued that the ClearValue patent was invalid in view of U.S. Patent 4,800,039 to Hassick which anticipated the claimed method

- District Court jury found ClearValue patent valid and infringed
ClearValue v. Pearl River Polymers, 668 F.3d 1340, 101 USPQ2d 1773 (Fed. Cir. 2012)

- Hassick taught the use of high molecular weight DADMAC with ACH reduces turbidity in low-alkalinity systems

<table>
<thead>
<tr>
<th>ClearValue Claim</th>
<th>Hassick Patent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3 million MW DADMAC</td>
<td>1-2 million MW DADMAC</td>
</tr>
<tr>
<td>ACH</td>
<td>ACH</td>
</tr>
<tr>
<td>To clarify water with alkalinity of 50 ppm or less</td>
<td>To clarify water with alkalinity of 150 ppm or less</td>
</tr>
</tbody>
</table>
ClearValue v. Pearl River Polymers, 668 F.3d 1340, 101 USPQ2d 1773 (Fed. Cir. 2012)

- ClearValue argued that the broader range of 150 ppm or less did not anticipate the smaller range of 50 ppm or less

- In support, ClearValue cited Atofina v. Great Lakes
Anticipation: Sufficient Specificity

• Federal Circuit found that verdict was not supported by substantial evidence and reversed
• 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 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 was precluded
• Federal Circuit distinguished *Atofina* for several reasons
  
  “We explained that the prior art’s teaching of a broad genus (i.e. broad temperature range) does not disclose every species in that genus. In Atofina, the evidence showed that one of ordinary skill would have expected the synthesis process to operate differently outside the claimed temperature range, which the patentee described as ‘critical’ to enable the process to operate effectively. Based on this ‘considerable difference’ between the prior art’s broad disclosure and the ‘critical’ temperature range claimed in the patent, we held that ‘no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim.’”
Anticipation: Sufficient Specificity

• Federal Circuit pointed to the following basis for concluding anticipation in ClearValue
  – ClearValue did not argue that the 50 ppm limitation was critical or that the claimed method operates differently at different points within the prior art range of 150 ppm or less
  – ClearValue did not argue that Hassick failed to enable the disclosed method
  – Hassick provides an example at 60-70 ppm, but the Federal Circuit is clear to note that this example does not anticipate
  – It is the disclosure of the range of 150 ppm or less, which, when combined with the lack of allegation of criticality or evidence demonstrating any difference across the range, that anticipates
Obviousness is considered when

- Prior art teaches ranges that overlap or encompass a claimed range
- Prior art teaches a range that touches the claimed range at one end point

*In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976)*
*In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)*
**Obviousness: Overlapping Ranges**

*In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)*

- Rejection affirmed was made under 35 USC 103 instead of 35 USC 102

<table>
<thead>
<tr>
<th>Claims</th>
<th>Prior Art</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method for inhibiting the growth of fungi on fresh leafy and head vegetables</td>
<td>Method of storing fresh leafy and head vegetables in order to maintain their fresh appearance</td>
</tr>
<tr>
<td>0-2% CO₂</td>
<td>0-5% CO₂</td>
</tr>
<tr>
<td>1-20% O₂</td>
<td>1-10% O₂</td>
</tr>
<tr>
<td>3-25% CO / &gt;5-25% CO</td>
<td>1-5% CO</td>
</tr>
<tr>
<td>Balance N₂</td>
<td>Balance N₂</td>
</tr>
<tr>
<td>29-60° F</td>
<td>32-40° F</td>
</tr>
</tbody>
</table>
Obviousness: Overlapping Ranges

• Federal Circuit held that there were two differences between the claimed invention and the prior art
  – the slightly different ranges of carbon monoxide concentration used in the modified atmosphere; and
  – the newly disclosed benefit of inhibiting the growth of fungi
• Federal Circuit held
  – With regard to the new benefit, the general rule that discovering a new benefit for an old process is applicable in this case to the extent that the claims and the prior art overlap

  – what Woodruff terms as a “new use” (preventing fungal growth) is at least generically encompassed by the prior art purpose of preventing the deterioration of leafy and head vegetables.
• 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.
Overlap of Ranges

- “A prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a *prima facie* case of obviousness.” *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379,1382-83 (Fed. Cir. 2003)
### In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003)

<table>
<thead>
<tr>
<th>Superalloy comp.</th>
<th>Claim 5</th>
<th>Reference (Shah)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhenium</td>
<td>about 1-3%</td>
<td>0-7%</td>
</tr>
<tr>
<td>Chromium</td>
<td>about 14%</td>
<td>3-18%</td>
</tr>
<tr>
<td>Cobalt</td>
<td>about 9.5%</td>
<td>0-20%</td>
</tr>
<tr>
<td>Tungsten</td>
<td>about 3.8%</td>
<td>0-18%</td>
</tr>
<tr>
<td>Tantalum</td>
<td>about 2%</td>
<td>0-15%</td>
</tr>
<tr>
<td>Molybdenum</td>
<td>about 1.5%</td>
<td>0-4%</td>
</tr>
<tr>
<td>Carbon</td>
<td>about 0.05%</td>
<td>at least 0.002%</td>
</tr>
<tr>
<td>Boron</td>
<td>about 0.004%</td>
<td>at least 0.002%</td>
</tr>
<tr>
<td>Aluminum</td>
<td>3-4.8%</td>
<td>3-8%</td>
</tr>
<tr>
<td>Titanium</td>
<td>about 3-4.8%</td>
<td>0-5%</td>
</tr>
<tr>
<td>Nickel</td>
<td>Balance</td>
<td>Balance</td>
</tr>
</tbody>
</table>

All of the claimed ranges of the application are encompassed by the ranges of the reference.
The Federal Circuit emphasized that:

• “In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness…
The Federal Circuit also emphasized that:
• We also held that a *prima facie* case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skill in the art would have expected them to have the same properties.”

(citing *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985); and *In re Malagari*, 499 F.2d 1297, 182 USPQ 549 (CCPA 1974)).
The Federal Circuit also emphasized that:

- “In light of that case law, we conclude that a \textit{prima facie} case of obviousness was made out in this case.
  
  - Selecting a narrow range from within a somewhat broader range disclosed in a prior art reference is no less obvious than identifying a range that simply overlaps a disclosed range.
  
  - In fact, when as here, the claimed ranges are completely encompassed by the prior art, the conclusion is even more compelling than in cases of mere overlap.”
However, if the reference’s disclosed generic range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the nonobviousness of a claimed species. *Id.*

See also: *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); *MPEP 2144.08.*
Great Lakes argued that the ranges of oxygen to methylene chloride and temperature disclosed in JP 51-82206 encompassed and therefore anticipated the limitations in the Atofina patent.

District Court relied on *Titanium Metals* to support a finding of anticipation of the Atofina patent by JP 51-82206.

Federal Circuit disagreed and reversed the decision, finding the Atofina patent valid and infringed, distinguishing the facts from those in *Titanium Metals*.

<table>
<thead>
<tr>
<th>Atofina Patent</th>
<th>JP 51-82206</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 – 5 m O₂ /100 moles CH₂Cl₂</td>
<td>0.001 – 1.0 m O₂ /100 moles CH₂Cl₂</td>
</tr>
<tr>
<td>At a temperature of 330 – 450°C</td>
<td>At a temperature of 100 – 500°C</td>
</tr>
</tbody>
</table>
Obviousness: Encompassed Ranges

• Federal Circuit held
  – “Titanium Metals stands for the proposition that an earlier species reference anticipates a later genus claim, not that an earlier genus anticipates a narrower species.”
  – “Here, the prior art, JP 51-82250, discloses a temperature range of 100 to 500C which is broader than and fully encompasses the specific temperature range claimed in the '514 patent of 330 to 450C.
  – “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.”
102/103 Rejection

• 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.
Obviousness of Ranges:

- Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties.

- *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)

MPEP 2144.05
• Applicants may attempt to rebut a *prima facie* case of obviousness based on ranges by showing the criticality of the claimed range. See *MPEP §716.02 - §716.02(g)*.

A *prima facie* case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.

*In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)
Evidence pertaining to secondary considerations must be taken into account whenever present; however, it does not necessarily control the obviousness conclusion.

- *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372, 82 USPQ2d 1321, 1339 (Fed. Cir. 2007)
- *Leapfrog Enterprises Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162, 82 USPQ2d 1687, 1692 (Fed. Cir. 2007)
- *Cubist Pharm. v. Hospira*, 805 F.3d 1112 (Fed. Cir. 2015)

MPEP §2145
A 35 USC §§ 102/103 combination rejection is permitted if it is unclear if the reference teaches the range with “sufficient specificity.” The examiner must, in this case, provide reasons for anticipation as well as a reasoned statement regarding obviousness.
102/103 Rejection

• 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.
35 USC §112(a):

- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.
New Matter and Ranges

• The test for determining compliance with the written description requirement of 35 USC §112(a) later claimed subject matter is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language.
New Matter and Ranges

- Compliance with the §112(a) written description requirement is a question of fact and is determined on a case-by-case basis. 
  
  *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976)

- “[T]he level of detail required [in the specification] to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.”

  *See Ariad Pharmaceuticals., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)
New Matter and Ranges

The factors to be considered in determining whether the original disclosure as a whole reasonably conveys the range later claimed:

• An explicit and/or implicit disclosure of a generic range in the application disclosure as originally filed encompassing or relating to newly claimed ranges

• Specific, preferred, and/or exemplified embodiments in the original disclosure relating to newly claimed ranges

• An explicit or implicit disclosure in the application as originally filed relating to particular ranges or parameters being part of the inventor’s invention
New Matter and Ranges

- An explicit or implicit disclosure in the application as originally filed relating to direction or guidance for obtaining such particular ranges

- The complex and/or unpredictable nature of the claimed invention or the claimed range

- Any evidence or admission indicating that the newly claimed range is a different invention than the range originally described
Ex parte Jackson, 110 USPQ 561 (Bd. App. 1956)

• The BPAI found that the specification, as originally filed, describing examples employing 4%, 15% and 20% of cadmium provided sufficient written descriptive support for a range of 4% to 20% of cadmium later added in a claim.

• The BPAI determined that the values between 4% and 20% of cadmium “would function in the composition in the manner applicant desires”.
In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976)

• Amended claims to a solids content range of “between 35% and 60%,” within the described broad range of 25% to 60% solids along with specific embodiments of 36% and 50%.

• The court found that such an amendment did not constitute new matter
New Matter and Ranges

• In light of the fact that the Specification as originally filed describes “employing solids contents within the range of 25-60% along with specific embodiments of 36% and 50%, we are of the opinion that, as a factual matter, persons skilled in the art would consider a process employing a 35-60% solids content range to be part of appellants’ invention.”

• “To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was the first with the genus when he filed.”
New Matter and Ranges

• The court opined “there is no evidence, and the PTO does not contend otherwise, that there is in fact any distinction, in terms of the operability of appellants’ process or of the achieving of any desired result, between the claimed lower limit [35%] of solids content and that disclosed [36%] in the...application.”
Example 1

• Applicant files an application with a claim to a compound that includes an additive in an amount of 1-100 ppm

• The specification has examples which include 4 and 8 ppm

• The examiner finds art with the same compound and with the same additive in an amount of 40-50 ppm and rejects the claim
New Matter and Ranges

• Applicant amends the claim to recite the compound with the additive in an amount of 62.5-100 ppm

• There is no literal support for 62.5 ppm

Question:
• Should a rejection under 35 USC §112(a) be made?
Answer:

• The rejection under 35 USC §112(a) should likely not be made. Literal support for the new endpoint is not required. However, the rejection under 35 USC §112(a) may be appropriate if the examiner has a reason to doubt that the disclosure of the broader range describes the narrower range, i.e., the broader and narrower ranges are different inventions.
Example 2

- Applicant files an application with a claim to a compound that includes an additive in an amount of 30-60 ppm.

- There are no examples provided in the specification.
New Matter and Ranges

• The examiner finds prior art directed to the same compound having the same additive present in an amount of 15-85 ppm.
• The prior art does not disclose an example containing the additive.
• The examiner makes a 35 USC §103 rejection after the analysis concludes there is not sufficient specificity to support a 35 USC §102 rejection.
• Applicant files an amendment to the claim limiting the amount of additive to 40-50 ppm.
• With the claim amendment, applicant also files a 1.132 declaration showing unexpected results at 40-50 ppm relative to the broader originally disclosed range of 30-60 ppm.
• The evidence strongly supports the assertion that unexpected results are present within the narrower range of 40-50 ppm.
New Matter and Ranges

Questions:
- Should the 35 USC §103 rejection be dropped?
- Should a new matter rejection be made?
New Matter and Ranges

• The rejection under 35 USC §103 should be dropped in this case because applicant has overcome the *prima facie* case of obviousness.

• A rejection under 35 USC §112(a) should be made in this case because applicant is now alleging that the newly claimed range is a different invention than the originally disclosed range since the newly claimed range has properties unique from the originally disclosed range.
Highlights

• A range limitation is a genus 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
• A range limitation is a claim limitation

• 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 raise issues of obviousness
• 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.
Thank You!

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