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UCB v. Actavis Laboratories (Fed. Cir. April 2023)

Range Limitations to Distinguish from Prior Art

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Overview

- **Discuss MPEP 2173.05(c) Numerical Ranges and Amounts Limitations**

i. NARROW AND BROADER RANGES IN THE SAME CLAIM

ii. OPEN-ENDED NUMERICAL RANGES

iii. EFFECTIVE AMOUNTS

- **Applying Prior Art to Numerical Ranges**

i. § 102 Rejections

ii. § 103 Rejections

- **Discuss New Matter and Ranges**

- ***Discuss UCB v. Actavis Laboratories* (Fed. Cir. April 2023)**

MPEP 2173.05(c) Numerical Ranges and Amounts Limitations

I. NARROW AND BROADER RANGES IN THE SAME CLAIM

It may be considered indefinite when a narrow numerical range falls within a broader range in the same claim when the boundaries of the claim are not discernible.

A narrower range or preferred embodiment may also be set forth in another independent claim or in a dependent claim.

Indefinite claim language examples:

(A) "**a temperature of between 45 and 78 degrees Celsius, preferably between 50 and 60 degrees Celsius**"; and

(B) "**a predetermined quantity, for example, the maximum capacity**."

MPEP 2173.05(c) Numerical Ranges and Amounts Limitations

I. NARROW AND BROADER RANGES IN THE SAME CLAIM

While a single claim that includes both a broad and a narrower range may be indefinite, it is not improper under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C.112, second paragraph, to present a dependent claim that sets forth a narrower range for an element than the range set forth in the claim from which it depends.

For example, if claim 1 reads "**A circuit … wherein the resistance is 70-150 ohms**." and

claim 2 reads "**The circuit of claim 1 wherein the resistance is 70-100 ohms**.", then claim 2 should not be rejected as indefinite.

MPEP 2173.05(c) Numerical Ranges and Amounts Limitations

II. OPEN-ENDED NUMERICAL RANGES

Open-ended numerical ranges should be carefully analyzed for definiteness.

Example 1: When an independent claim recites a composition comprising "**at least 20% sodium**" and a dependent claim sets forth **specific amounts of nonsodium ingredients which add up to 100%,** apparently to the **exclusion of sodium.**

Example 2: A composition claimed to have a theoretical content greater than 100% (i.e., **20-80% of A**, **20-80% of B** and **1-25% of C**).

MPEP 2173.05(c) Numerical Ranges and Amounts Limitations

II. OPEN-ENDED NUMERICAL RANGES

In a claim directed to a chemical reaction process, a limitation required that the **amount of one ingredient in the reaction mixture should "be maintained at less than 7 mole percent"** based on the amount of another ingredient.

The Examiner argued that the claim was **indefinite** because the limitation sets only a maximum amount and is inclusive of substantially no ingredient resulting in termination of any reaction.

The court disagreed holding that the claim was clearly directed to a reaction process: **"[t]he imposition of a maximum limit on the quantity of one of the reactants without specifying a minimum does not warrant distorting the overall meaning of the claim to preclude performing the claimed process."***In re Kirsch,* 498 F.2d 1389, 1394, 182 USPQ 286, 290 (CCPA 1974).

MPEP 2173.05(c) Numerical Ranges and Amounts Limitations

III. EFFECTIVE AMOUNT

The common phrase "**an effective amount**" may or may not be indefinite.

The phrase "**an effective amount** . . . for growth stimulation" was held to be **definite** where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. In re Halleck, 422 F.2d 911, 164 USPQ 647 (CCPA 1970).

The phrase "**an effective amount**" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art.

MPEP 2173.05(c) Numerical Ranges and Amounts Limitations

III. EFFECTIVE AMOUNT

In re Fredericksen, 213 F.2d 547, 102 USPQ 35 (CCPA 1954). The more recent cases have tended to accept a limitation such as “an effective amount” as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim.

MPEP 2173.05(c) Numerical Ranges and Amounts Limitations

III. EFFECTIVE AMOUNT

In Ex parte Skuballa, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an "**effective amount of a compound of claim 1**" without stating the function to be achieved was **definite**, particularly when read in light of the supporting disclosure which provided guidelines as to the **intended utilities and how the uses could be effected**.

ANTICIPATION

How to determine when a § 102 Rejection should be Applied

ANTICIPATION OF RANGES: MPEP 2131.02 and 2131.03

It is considered **Anticipation** when:

1. A specific example in the prior art is within the claimed range

2. A range (or preferred range) in the prior art is within the claimed range

3. A range in the prior art overlapping the claimed range anticipates if it is determined that claimed range is disclosed with **sufficient specificity**

A Species Will Anticipate a Claim to a Genus

ANTICIPATION- Sufficient Specificity MPEP 2131.03

A range overlapping the claimed range anticipates if it is determined that claimed range is disclosed with **sufficient specificity**. This normally requires either a substantial overlap in the ranges and the same or similar function.

What constitutes "**sufficient specificity**" is **fact dependent.**

ANTICIPATION - Sufficient Specificity

What factors should be considered when making a sufficient specificity analysis?

Are there any differences or similarities between the ranges?

What is the extent of the overlap?

Are the variables predictable or not?

Is there criticality of the claimed range relative to prior art range?

Example

Sufficient Specificity

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

Anticipation - Sufficient Specificity

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

Perricone:

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 more 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.

Anticipation- Sufficient Specificity

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

Medicis:

A cosmetic composition for topical application to the skin or hair containing **0.01 to 20% by weight** of a skin benefit ingredient. One of the fourteen disclosed skin benefit ingredients is **ascorbyl palmitate.**

District court concluded this was sufficient for anticipation.

Anticipation- Sufficient Specificity

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

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 ranges 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."**

Example

When the Prior Art Teaches a Range Overlapping the Claimed Range or Touching

Prior art teaching a range overlapping the claimed range or touching

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

Claims 27 and 31: Method for inhibiting the growth of fungi on fresh leafy and head vegetables.

0-2% CO2 **1-20%** O2 **3-25%** CO/ **>5-25%** CO Balance N2 **29-60º** F

Prior Art: Method of storing fresh leafy and head vegetables in order to maintain their fresh appearance

0-5% CO2 **1-10%** O2 **1-5%** CO Balance N2 **32-40º** F

Prior art teaching a range overlapping the claimed range or touching

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

Federal Circuit held that there were two differences between the claimed invention and the prior art:

1. **The slightly different ranges of carbon monoxide concentration used in the modified atmosphere**

2. **The newly disclosed benefit of inhibiting the growth of fungi**

Prior art teaching a range overlapping the claimed range or touching

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

Federal Circuit held regarding 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.

Prior art teaching a range overlapping the claimed range or touching

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

Patentability cannot be found in the **difference in carbon monoxide ranges** recited in the claims.

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.

Genus-Species Relationships

MPEP 2131.02

"A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus."

***In re Gosteli,* 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989)**

Gosteli claimed a genus of **21** specific chemical species of bicyclic thia-aza compounds in Markush claims.

The prior art reference disclosed **two** of the chemical species.

The parties agreed that **the prior art species would anticipate the claims** unless applicant was entitled to his foreign priority date.

Example

When a Disclosure of a Species Anticipates a Claim to a Genus

ANTICIPATION: When a Disclosure of a Species Anticipates a Claim to a Genus

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

Claim 1. A titanium base alloy consisting essentially by weight of about **0.6% to 0.9%** **nickel**, **0.2% to 0.4%** **molybdenum**, up to **0.2%** **maximum iron**, balance titanium, said alloy being characterized by good corrosion resistance in hot brine environments.

Prior Art disclosed an alloy containing **0.75% Ni** and **0.25% Mo**.

SUMMARY

Regarding **ANTICIPATION**, if the prior art discloses a point within the claimed range, the prior art anticipates the claim.

On the other hand, if the prior art discloses an overlapping range, the prior art anticipates the claimed range only if it describes the claimed range with **sufficient specificity** such that a reasonable fact finder could conclude that there is no reasonable difference in how the invention operates over the ranges.

OBVIOUSNESS

How to determine when a § 103 Rejection should be Applied

Obviousness is considered when

1. **Prior art teaches ranges that overlap or encompass a claimed range**

2. **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)

MPEP 2144.05

Prior art teaching a range overlapping the claimed range or touching

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

Claims 27 and 31: Method for inhibiting the growth of fungi on fresh leafy and head vegetables.

0-2% CO2 **1-20%** O2 **3-25%** CO/ **>5-25%** CO Balance N2 **29-60º** F

Prior Art: Method of storing fresh leafy and head vegetables in order to maintain their fresh appearance

0-5% CO2 **1-10%** O2 **1-5%** CO Balance N2 **32-40º** F

Obviousness: Prior art teaches ranges that overlap or encompass a claimed range

MPEP 2144.05: 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)

Example

When the Prior art teaches ranges that overlap or encompass a claimed range

Obviousness- Prior art teaches ranges that overlap or encompass a claimed range

In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003)

SUPERALLOY COMP.	CLAIM 5	REFERENCE (SHAH)
Rhenium	about 1-3%	0-7%
Chromium	**about 14%**	**3-18%**
Cobalt	about 9.5%	0-20%
Tungsten	**about 3.8%**	**0-18%**
Tantalum	about 2%	0-15%
Molybdenum	**about 1.5%**	**0-4%**
Carbon	about 0.05%	at least 0.002%
Boron	**about 0.004%**	**at least 0.002%**
Aluminum	about 3-4.8%	3-8%
Titanium	**about 3-4.8%**	**0-5%**
Nickel	Balance	Balance

Obviousness: Prior art teaches ranges that overlap or encompass a claimed range

In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003)

The Federal Circuit emphasized:

"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**…"

"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)).

Obviousness: Prior art teaches ranges that overlap or encompass a claimed range (cont'd)

In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003)

The Federal Circuit further emphasized that:

"In light of that case law, we conclude that a 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.

Obviousness: Prior art teaches ranges that overlap or encompass a claimed range (cont'd)

MPEP 2144.08

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 non-obviousness 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);

Summary

Regarding **OBVIOUSNESS**, a presumption of obviousness applies where a claimed range overlaps with a range disclosed in the prior art.

This presumption can be overcome if the prior art

- **teaches away from the claimed range**,
- **the claimed range produces new and unexpected results**, or
- **other evidence demonstrates non-obviousness of the claimed range.**

New Matter and Ranges

New Matter (Written Description) and Ranges

Compliance with the § 112(a) written description requirement is a **question of fact** and is determined on a **case-by-case basis**.

"The 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)

New Matter (Written Description) and Ranges

The following must be considered when determining whether the original disclosure **as a whole** reasonably conveys the range later claimed:

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

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

3. 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: Example

The Examiner found that a specification, as originally filed, describing examples employing **3%, 7%** and **20%** of Rubidium provided sufficient written descriptive support for a range of **3 - 20%** of Rubidium later added in a claim.

The Examiner determined that the values between **3 - 20%** of Rubidium "**would function in the composition in the manner applicant desires**".

UCB v. Actavis Laboratories

(Fed. Cir. April 2023)

UCB v. Actavis Laboratories - Background

UCB:

The drug at issue is **rotigotine**, which is used to treat Parkinson's disease.

The technology at issue relates to **transdermal therapeutic systems** (TTSs), which deliver drugs through the patient's skin and thus avoid complications with oral treatments. Usually administered as a skin patch.

The skin patches contain drugs in an "**amorphous**," i.e., non-crystalline, form because drugs in crystalline form cannot cross the skin barrier.

UCB v. Actavis Laboratories – Background (cont'd)

UCB invented **Neupro® in 2007:** the first U.S. Food and Drug Administration approved patch for treatment of Parkinson's disease.

Original **Neupro®** contains a weight ratio of **rotigotine** to **PVP** of **9:2**.

Original **Neupro®** is covered by several UCB patents, including U.S. Patent Nos. 6,884,434 and 7,413,747 (the Muller patents).

UCB v. Actavis Laboratories – Background (cont'd)

Problem

- Three months after the original **Neupro®,** it was discovered that a new crystalline form of **rotigotine "Form II**" occurred when **rotigotine** was stored at room temperature.

- After discussions with the FDA, UCB recalled original **Neupro®**.

- Original **Neupro®** remained in limited use in the U.S. under a compassionate-use program, while European regulators agreed to continue marketing original **Neupro®** under **cold-chain conditions** (i.e., refrigerating original **Neupro®**), which prevents Form II crystallization.

UCB v. Actavis Laboratories – Background (cont'd)

Solution to the problem:

In **2012**, the FDA approved a new version of **Neupro®** (reformulated Neupro®), which employs a weight ratio of **9:4 rotigotine to PVP**.

The reformulated **Neupro®** exhibits **long-term stability at room temperature with a two-year shelf-life**.

UCB v. Actavis Laboratories – Background (cont'd)

In **2013**, **Actavis** submitted an Abbreviated New Drug Application (ANDA) to the FDA for approval of a generic version of a **transdermal rotigotine patch**.

In **2014**, **UCB** filed suit for infringement of the '434 Muller patent and U.S. Patent No. 8,232,414.

The district court upheld the validity of the challenged claims of the '434 Muller patent (and some claims of the '414 patent) and granted UCB an injunction preventing approval of Actavis's ANDA which expired in **March 2021**, when the '434 Muller patent expired.

UCB v. Actavis Laboratories

In **2018**, while *UCB I* was on appeal, UCB filed the patent application that matured into the patent-in-suit, the '589 patent.

The '589 patent claims priority from a provisional application filed in December 2009. The patent is entitled "**Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine**" and discusses both **rotigotine Form I and Form II**. *See* '589 patent, col. 1 ll. 47-54, col. 11 l. 66-col. 12 l. 2.

The written description explains that "**PVP is unexpectedly able to stabilize the non-crystalline form of rotigotine and prevent rotigotine from re-crystallization in a solid dispersion . . . thereby imparting sufficient long term storage stability properties to the [TTS], preferably at room temperature**." *Id.* at col. 3 ll. 28-35.

UCB v. Actavis Laboratories

The '589 patent discloses and claims a TTS having a range of rotigotine to PVP ratios by weight of about **9:4** to about **9:6**. Claim 1 is representative:

1. A method for stabilizing rotigotine, comprising
providing a solid dispersion comprising
polyvinylpyrrolidone and
a non-crystalline form of rotigotine free base,
wherein the weight ratio of rotigotine free base to polyvinylpyrrolidone is in a range from about 9:4 to about 9:6.

(Emphasis Added)

UCB v. Actavis Laboratories

The '589 patent's Table 3, shown below, displays results of storage stability testing of samples of **Rotigotine** to PVP ratios ranging from **9:1 to 9:11.**

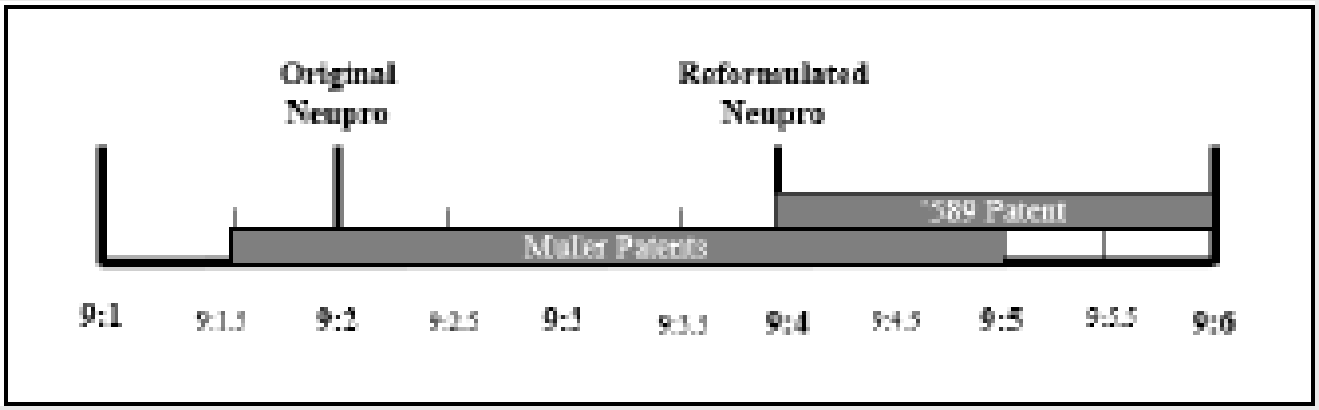
TABLE 3

Results from storage stability testing of sample Nos. 1-9 at 25° C./60% RH (+ = crystals, – = no crystals)

	Sample No.								
	1	2	3	4	5	6	7	8	9
Rotigotine:PVP [weight ratio]	9:1	9:1.6	9:2	9:3	9:4	9:6	9:8	9:11	9:4
0 weeks	+	+	–	–	–	–	–	–	–
1 week	+	+	+	+	–	–	–	–	–
4 weeks	+	+	+	+	–	–	–	–	–
8 weeks	+	+	+	+	–	–	–	–	–

UCB v. Actavis Laboratories

A comparison of the Muller patents, the '589 patent, and original and reformulated **Neupro®** is depicted below



UCB v. Actavis Laboratories – New Litigation

March 2019 - UCB again filed a lawsuit against Actavis, accusing Actavis's same ANDA of infringement asserting the '589 patent, which would delay FDA approval of a generic for nine additional years until the '589 patent expires in December 2030.

July 2019 - in response to Mylan Technologies, Inc. seeking to market its own generic version of Neupro®, UCB also filed a lawsuit against Mylan alleging infringement of the '589 patent and U.S. Patent No. 10,350,174.

UCB v. Actavis Laboratories - District Court Decision

In **March 2021**, the month UCB's injunction expired, the district court ruled on Actavis's invalidity defenses.

Applying the "at once envisage" framework for anticipation articulated in *Kennametal, Inc. v. Ingersoll Cutting Tool Co., 780 F.3d 1376, 1381 (Fed. Cir. 2015)*, **the district court found that the Muller patents anticipate all asserted claims.**

- Separately, **the district court held that the asserted claims would have been obvious in view of multiple prior art references, including the Muller patents**.

UCB v. Actavis Laboratories - Discussion

On appeal, UCB argues that the district court erred in its anticipation analysis because, contrary to our precedent, it applied *Kennametal* to an overlapping ranges case.

UCB also argues that the district court's obviousness analysis is incorrect because, broadly, the district court (1) impermissibly relied on hindsight in its analysis; and (2) improperly disregarded evidence of objective indicia of nonobviousness. *See* Appellant's Br. 49-73.

UCB v. Actavis Laboratories - Novelty Analysis

UCB argues that the district court committed legal error by applying the wrong law—*Kennametal* and the "immediately envisage" line of cases—in its anticipation analysis.

Questions of fact decided by the district court are reviewed for clear error. Id. **"A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed."** United States v. U.S. Gypsum Co., 333 U.S. 364, 395, 68 S. Ct. 525, 92 L. Ed. 746 (1948).

A court's application of an improper standard to fact "may be corrected as a matter of law."

UCB v. Actavis Laboratories - **Novelty Analysis** (cont'd)

In finding that the Muller patents anticipate the asserted claims of the '589 patent, however, the district court did not apply the traditional framework for analyzing **overlapping ranges**.

Instead, the district court relied on the *Kennametal* **"immediately envisage"** line of cases to identify discrete points in Muller's range and analyzed those discrete points as a point-within-a-range case.

Specifically, the district court relied on testimony from two Actavis experts.

Expert 1: A POSA would read Muller's range to teach "a few examples" of TTSs with specific weight ratios, including **9:4 and 9:5** weight ratios of **rotigotine to PVP**.

Expert 2: A skilled artisan would see five or so examples, including "1.5, 2, 3, 4, and 5, maybe you would even go to half integers, but a POSA would not expect to look in more granular detail than that to calculate the range" as taught by Muller.

UCB v. Actavis Laboratories - **Novelty Analysis** (Cont'd)

The district court's analysis also improperly extends *Kennametal, 780 F.3d at 1381-83*.

The court's fact finding that a POSA would only consider half and whole integers contradicts the specification of the '589 patent. Table 3 of the '589 patent, for example, discloses a ratio of **1.6**, neither an integer nor a half integer.

Kennametal does not stand for the proposition that a reference missing a limitation can anticipate a claim if a skilled artisan viewing the reference would "at once envisage" the missing limitation.

Rather, Kennametal addresses whether the disclosure of a limited number of combination possibilities discloses one of the possible combinations.

UCB v. Actavis Laboratories - Obviousness Analysis

The district court held the asserted claims obvious based on two separate grounds, including that:

1. the claimed range of weight ratios of rotigotine to PVP overlap with that disclosed in the Muller patents and UCB failed to rebut this prima facie case of obviousness; and
2. the prior art's 9:2 and 9:3 TTS examples as modified by Muller's teachings of a range of 1.5% to 5% PVP render the claims obvious.

"**Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness**."

"A factual finding is only clearly erroneous if . . . we are left with the definite and firm conviction that a mistake has been made."

UCB v. Actavis Laboratories - Obviousness Analysis

UCB contends that a different reference **Tang** is the actual closest prior art because (unlike the Muller patents) Tang addresses the stability problem.

Further, UCB contends that Tang **teaches away** from the claimed range, thus establishing non-obviousness of the claimed range.

Tang is directed to TTSs with "a therapeutic agent in a stable amorphous form."

It teaches "**the importance of the weight ratio of the polymeric stabilizer to the therapeutic agent in stabilizing the therapeutic agent**." *Id.* None of Tang's working examples include **rotigotine** as the active ingredient. And Tang does not disclose the Tg of **rotigotine**.

UCB also asserted the claimed weight ratio range of "**from about 9:4 to about 9:6**" exhibited **unexpected results** and introduced evidence to establish commercial success.

UCB v. Actavis Laboratories - District Court Decision Analysis

The district court found that the Muller patents, and not Tang, are the closest prior art.

To support this finding, the court reasoned:

1. Tang does not disclose working examples with **rotigotine**;

2. Tang does not disclose the **Tg of rotigotine**; and

3. The Muller patents are the closest prior art because, unlike Tang, they disclose and claim a TTS with a range of R:PVP ratios including about **9:4** to **9:5**.

UCB v. Actavis Laboratories-Decision on Appeal Analysis

The district court did not clearly err in rejecting UCB's argument that Form II changed the state of the art, thus rendering all pre-Form II prior art, including the Muller patents, irrelevant.

For e.g, in addition to the expert testimonies, a medical doctor specializing in Parkinson's disease published an article showing that there were no crystallization issues with original Neupro® when treating over 100 patients.

One of the experts also explained how the success of cold-chain storage for original Neupro® in Europe indicated that a "relatively small adjustment" of the of R:PVP ratios was needed.

Thus, the district court's determined that due to the similarities in Form I and Form II, no cataclysmic change rendered pre-Form II prior art unusable.

UCB v. Actavis Laboratories - Conclusion

The range of **R:PVP** ratios in the Asserted Claims in this case and the like range in the Muller Patents' claims significantly overlap and there is **no meaningful difference** in how a POSA would view them.

The district court viewed Tang as simply teaching **an alternative invention** not teaching away.

Tang expresses a preference for a higher PVP percentage (a 9:18 rotigotine to PVP weight ratio), but it does not teach away from the claimed range neither does it discredit or discourage.

District court found that the claimed invention did not establish unexpected results. “Results obtained in the alleged invention and those in prior art, like the '747 Muller patent, are "**similar in kind . . . [and] with similar levels of stability (i.e., lack of crystallization)**."

Any Questions?