

Why Fed. Circ. Should Explain Treatment Of Prior Art Ranges

By **Ben Katzenellenbogen and Paul Stewart** (May 31, 2023)

The U.S. Court of Appeals for the Federal Circuit recently **issued** a decision in *UCB Inc. v. Actavis Laboratories UT Inc.* regarding the patentability of claimed ranges where the prior art discloses overlapping ranges.

The Federal Circuit reiterated prior holdings that prior art disclosure of a point within the claimed range necessarily anticipates the claimed range, while prior art disclosure of an overlapping range creates a prima facie case of anticipation that may be rebutted by establishing the criticality of the claimed range. In particular, the Federal Circuit reiterated that prior art disclosure of a range is not a disclosure of the endpoints of the range.

Unfortunately, the Federal Circuit again failed to provide any explanation or justification for its treatment of the endpoints in prior art ranges — other than a citation to earlier cases that recited the same conclusion without any meaningful justification.

This article discusses the facts and holding of the recent case, as well as reviewing the earlier cases. The case may bring greater clarity and certainty to this area of law, and reduce the likelihood that district judges will erroneously analyze cases involving ranges, if the Federal Circuit were to provide a more robust theoretical underpinning for its treatment of endpoints in the prior art.

The Federal Circuit's Recent Analysis

The recent case of *UCB v. Actavis* was a Hatch-Waxman case involving an abbreviated new drug application seeking U.S. Food and Drug Administration approval to sell a generic version of a pharmaceutical called rotigotine, which is used to treat Parkinson's disease.

Drugs can be delivered through the patient's skin to avoid potential complications with pills or other oral treatments. To facilitate this, the patent claims a stable crystal form of rotigotine that is shelf-stable at room temperature for two years. The brand name of the drug is Neupro.

The increased stability is purportedly provided by having a particular ratio of rotigotine to a chemical called polyvinylpyrrolidone. The prior art, referred to as the Muller patents, disclosed a range of ratios from 9-1.5 to 9-5. The original Neupro used a ratio of 9-2 and fell within the range disclosed in the Muller patents.

The patent at issue, U.S. Patent No. 10,130,589, referred to as the '589 patent, discloses and claims a range of ratios from about 9-4 to about 9-6. The reformulated Neupro used a ratio of 9-4 and fell within the range disclosed and claimed in the '589 patent.

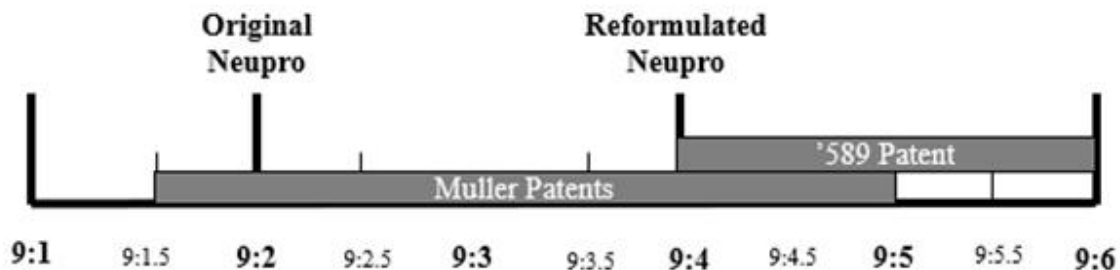
Stripping away all the technical details, the prior art disclosed the range of 1.5 to 5, and the patent claimed a range of 4 to 6. The UCB opinion included the following illustration of the overlapping ranges.



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A comparison of the Muller patents is depicted. The ranges of rotigotine to PVP ratios disclosed in the Muller patents and the '589 patent overlap from about 9:4 to 9:5 and include the ratio in reformulated Neupro. (Court Documents)

The defendant conceded infringement, such that the only issue was validity in light of the prior art. The district court found the claims invalid as both anticipated and obvious.

The Federal Circuit began by reciting prior holdings regarding ranges, including that the anticipation analysis depends on whether the prior art discloses a point within the claimed range or discloses a range that overlaps with the claimed range.

The Federal Circuit stated that, if the prior art discloses a point within the claimed range, the prior art anticipates. However, if the prior art discloses an overlapping range, the prior art presents a prima facie case of anticipation that can be rebutted by establishing the claimed range is "critical to the operability of the claimed invention."

The Federal Circuit held that the district court erred by treating the prior art Muller patents as disclosing a series of points because "the disclosure of a range is not a disclosure of the endpoints of the range or other discrete points within the range."

The Federal Circuit rejected as unnecessary an invitation to affirm the finding of anticipation on alternate grounds. The Federal Circuit affirmed the judgment of invalidity by affirming the finding of obviousness.

The Basis for Treating Endpoints as Different From Other Disclosed Points

The Federal Circuit's recent UCB decision did not explain why a disclosure of a range is not a disclosure of the endpoints — or any other points within the range. Nor did it explain why endpoints within a claimed range may not anticipate, while other points within a claimed range automatically anticipate when disclosed individually and not as part of a range.

Rather, the Federal Circuit stated these were settled issues of law and cited its 2015 decision in *Ineos USA LLC v. Berry Plastics Corp.*

The cited *Ineos* decision similarly — and equally unsatisfactorily to the authors — merely presented as settled law the proposition that "the disclosure of a range ... does not constitute a specific disclosure of the endpoints of that range." The lack of explanation in *Ineos* was particularly perplexing for multiple reasons.

First, the opinion asserted without explanation that the prior art's use of the phrases "at

least" a lower value and "does not exceed" a higher value set forth minimum and maximum amounts and clearly disclosed ranges, not particular individual values.

Second, regarding another limitation, Ineos found, again without analysis, that disclosure in the prior art that a claimed ingredient was optional was a disclosure of a specific point, 0%, not a range. As 0% was within the claimed range of 0% to 0.15%, Ineos found the disclosure rendered any evidence of criticality irrelevant.

Ineos offered no explanation why "at least" X discloses a range, but language such as "optionally containing" X discloses a point. Ineos also did not address whether disclosing "0% or more" of X would disclose a point or a range.

Ineos cited the Federal Circuit's 2006 *Atofina v. Great Lakes Chemical Corp.* decision as the basis for treating endpoints of a range differently than other points disclosed in the prior art. However, *Atofina* also failed to provide any explanation for the distinction.

In *Atofina*, the Federal Circuit simply announced that the prior art "disclosure of a range of 150 to 350°C does not constitute a specific disclosure of the endpoints of that range, i.e., 150°C and 350°C."

The Federal Circuit added that "[t]he 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 endpoints of the range than it is of each of the intermediate points."

The Federal Circuit's holding in *Atofina* may have been straightforward, but the Federal Circuit provided neither case citation nor logical explanation. The opinion appeared to simply treat it as unassailably obvious that each point in a range, including the endpoints, is not disclosed.

Potential Criticisms

The Federal Circuit's assertion is not beyond criticism. There are multiple reasons one could argue that the endpoints of a range are different from other points within the range.

For example, consider a disclosure of a composition containing from X to Y amount of an ingredient. One could argue the two endpoints, X and Y, are expressly disclosed examples or species, while other points within the range are merely inherently disclosed or a genus defined by the upper and lower ends of the range.

The Federal Circuit has frequently analyzed express disclosures differently from inherent disclosures, and disclosures of species differently from disclosures of genera.

A related argument has to do with the number of points disclosed by a range. There is ordinarily an infinite number of potential values disclosed within a range. For example, the range between 1 and 3 contains 2. It also contains 1.5 and 2.5. It also contains 1.1, 1.2, 1.3, etc.

As a result, it is far easier to disclose an infinite number of points by reciting a range than it is to test even a small percentage of that infinite number of points.

The Federal Circuit has expressed concern about the validity of some claims where the number of encompassed options significantly exceeds the number of options tested by the inventors.

One could argue that whether disclosing a range meaningfully discloses possession of each value within the range raises a different question than whether disclosing the endpoints X and Y meaningfully discloses possession of the two endpoints.

One could also argue that disclosing the range of X to Y suggests that the composition has the same — or at least sufficiently similar — properties at all amounts of ingredient between X and Y.

It may further suggest that all points within the range are the same — or at least similar — because using a little less ingredient, or using a little more, will not make a significant difference. As long as the amount of ingredient is between X and Y, the effect of differing amounts of ingredient will not be critical.

In contrast, identifying X and Y as the endpoints of the range may suggest that there is something critical about X and Y. For example, the disclosed invention may not work if the amount of ingredient is less than the lower endpoint X or more than upper endpoint Y. Thus, there are potentially relevant distinctions between the endpoints and the other values within a range.

Indeed, the Federal Circuit in 2012 addressed a related issue in *ClearValue Inc. v. Pearl River Polymers Inc.*

In *ClearValue*, the Federal Circuit characterized *Atofina* as involving evidence that one of ordinary skill would have expected the claimed process to operate differently outside the claimed temperature range, which the patentee described as critical to enable the process to operate effectively.

In *ClearValue*, the Federal Circuit was discussing an expectation of differences between values inside and outside the claimed range, not the prior art range. But in many cases, the prior art range may itself have established some critical difference from the prior art.

The Federal Circuit has not offered an explanation for presuming that the prior art ranges are not critical or even material.

Potential Resolution

The Federal Circuit's analysis in *Atofina* may have originated with a concern that there was only de minimis overlap between the prior art ranges and the claimed ranges.

For example, the prior art disclosed a range of 100 to 500 degrees Celsius, which the opinion characterized as much broader than and fully encompassing the claimed range of 330 to 450 degrees Celsius.

The prior art also disclosed a preferred range of 150 to 350 degrees Celsius, which the opinion characterized as only slightly overlapping the claimed range.

Regarding another limitation, the prior art disclosed a range of 0.001 to 1.0%, which the opinion characterized as having a slight overlap with, but not falling within, the claimed range of 0.1 to 5%.

The Federal Circuit may have been focusing more on concerns about raw scope or perceived fairness than doctrinal consistency or explanation.

In later cases citing *Atofina*, the Federal Circuit often found other grounds on which to affirm findings of invalidity. Thus, even where the Federal Circuit found the district court's analysis was legally erroneous, the Federal Circuit often affirmed the judgment.

As a result, the Federal Circuit may not have been concerned with exploring the theoretical basis for treating endpoints and other points within a disclosed range the same, or for distinguishing between disclosure of endpoints to a range and points that are not part of a range.

Particularly if the Federal Circuit faces a case where these distinctions could make a difference to the outcome, it would be helpful if the Federal Circuit takes the time to more thoroughly explore the basis for this decades-old precedent.

To the extent the Federal Circuit can provide a compelling explanation for the framework it promulgated, it would facilitate uniformity and make it easier for district court judges to correctly apply the law.

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