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PRIMA FACIE LACK OF NOVELTY:
WHEN PRIOR ART RANGES GIVE RISE TO REBUTTABLE ANTICIPATION

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I. INTRODUCTION

The Court of Appeals for the Federal Circuit has well-established standards for determining whether a claimed numerical range is *prima facie* obvious under 35 U.S.C. § 103,[1] over a prior art reference disclosing a similar range. In instances of *prima facie* obviousness, the patent applicant or patentee (hereafter "claim owner") can rebut such challenge by producing evidence of objective indicia of non-obviousness.[2] By contrast, if the prior art reference discloses a point or a smaller range *within* the claimed range, the prior art conclusively anticipates the claimed range under 35 U.S.C. § 102,[3] and the claim owner cannot rebut such anticipation.[4] It is fair to say that the law on *prima facie* obviousness and conclusive anticipation of claimed numerical ranges is stable.

This stability is not so with the doctrine of *rebuttable anticipation*, which provides a framework for analyzing situations when a prior art range overlaps

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[1] "A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made."

35 U.S.C § 103.

[2] Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

[3] *See* 35 U.S.C § 102(a)(1) ("A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.").

[4] *See generally*, *In re* Haase, 542 Fed. Appx. 962, 967 (Fed. Cir. 2013) ("Substantial evidence supports the Board's finding that Hassick discloses polymers that come within the claim limitations, and the only 'result' required by Mr. Haase's claims is a reduction in turbidity—regardless of how large that reduction is or how well it compares to other results in Hassick. The anticipatory disclosure in Hassick shows a reduction in turbidity. Nothing more is needed." (internal citation omitted)).

with part, or abuts the endpoint, of a claimed range.[5] This doctrine is relatively young.[6] The decisions of the court on rebuttable anticipation have not always been consistent or clear. It is only relatively recently that the court seems to have settled on the requirements for *prima facie* anticipation and its rebuttal.

Curiously, the literature is sparse in its discussion of recent developments in the analysis of novelty or obviousness of overlapping ranges. Some commentators have limited themselves to discussing individual cases.[7] Others have compared different national or regional approaches to the patentability of ranges.[8] The USPTO, in its Manual of Patent Examining Procedure discusses how to analyze overlapping ranges for anticipation, but does not provide a broader overview of the field.[9] No publication has analyzed in detail the doctrine of *prima facie* anticipation of overlapping ranges and its relevance to the overall case law dealing with the subject. This Article aims to fill the gaps.

This Article will provide a contextual and historical survey and analysis of decisions in the area of claimed and prior art numerical ranges. Our analysis will hopefully offer clarity and guidance to the patent law community. We will first provide an overview of the Federal Circuit's well-established standards for determining whether a claimed range is *prima facie* obvious over or whether it is conclusively anticipated by the prior art. These are relatively settled areas of the law. We then analyze situations when the Federal Circuit has applied a *prima facie* anticipation analysis and has explained how to rebut it.

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5 The first decision of the Federal Circuit on *prima facie* anticipation is *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991 (Fed. Cir. 2006). The court clarified its reasoning six years later in *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340 (Fed. Cir. 2012).

6 *See supra* note 5; *see also infra* Sections IV.A and IV.C.

7 Yogeeta B. Jadhav and Courtenay C. Brinckerhoff, *Federal Circuit Considers Patentability of Overlapping Ranges*, FOLEY BLOGS (May 16, 2023), https://www.foley.com/insights/publications/2023/05/federal-circuit-patentability-overlapping-ranges/ [https://perma.cc/Q7WU-9F2F]; Ming He, *Overlapping Ranges in Anticipation and Obviousness*, ICEMILLER: THOUGHT LEADERSHIP (Apr. 25, 2023), https://www.icemiller.com/thought-leadership/overlapping-ranges-in-anticipation-and-obviousness [https://perma.cc/RZC6-88A9] (both of these articles analyze *UCB, Inc. v. Actavis Lab'ys UT, Inc.*, 65 F.4th 679 (Fed. Cir. 2023), discussed below in Sections A and B); *see infra* Section IV.A, *see also infra* Section IV.B.

8 Ke Ke & Xu Houcai, *Study on Novelty of Invention Involving Numerical Ranges*, 1 CHINA PATS. & TRADEMARKS 85, 85–92 (2018).

9 Manual of Patent Examining Procedure § 2131.03 (9th ed. Rev. 07, Feb. 2023).

Finally, this Article includes a flowchart that will help practitioners navigate the many issues that arise when confronting disclosures of ranges in the prior art. The flowchart provides guidance on how to analyze prior art ranges, including those that (1) conclusively anticipate, (2) raise only *prima facie* obviousness, or (3), in a situation of partly overlapping ranges, raise both *prima facie* obviousness and *prima facie* anticipation.

Let us start with *prima facie* obviousness.

II. *PRIMA FACIE* OBVIOUSNESS OVER A PRIOR ART RANGE

One of the central concepts in the law of obviousness of claimed ranges is the idea of the "result-effective variable," which first surfaced in *In re Antonie* (C.C.P.A. 1977).[10] The C.C.P.A. reasoned that if a person of skill in the art (POSA) understands that a claimed variable, such as temperature, concentration, or pressure, affects the result of a claimed composition or process, then it is within the skill of the art to optimize that variable.[11] A claimed range that includes nothing but the result of such optimization would then be *prima facie* obvious. In contrast, "if there is no evidence in the record that the prior art recognized that [a] particular parameter affected the result,"[12] a POSA would not be motivated to optimize the parameter. In such a situation, there is no *prima facie* obviousness. Classic defenses against an obviousness challenge of a claimed range, therefore, include a few possible arguments. One is that a claimed parameter is not result effective and another that the prior art teaches away from the claimed range. A third argument is that, even if *prima facie* obvious, there are unexpected results that flow from the claimed range that do not exist when working within the prior art range.

There are four scenarios that may raise *prima facie* obviousness: (A) the prior art range partly overlaps the claimed range,[13] (B) the prior art range subsumes the claimed range,[14] (C) ranges are disclosed in multiple prior art references and may be combined to create a prior art range,[15] and (D) the prior art

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[10] *In re* Antonie, 559 F.2d 618, 619–20 (C.C.P.A. 1977).

[11] *Id.* at 620.

[12] *Id.*

[13] *See infra* Section A.

[14] *See infra* Section B.

[15] *See infra* Section C.

range is proximal to but does not touch the claimed range.[16] We will now look at each one.

A. THE PRIOR ART RANGE PARTLY OVERLAPS THE CLAIMED RANGE

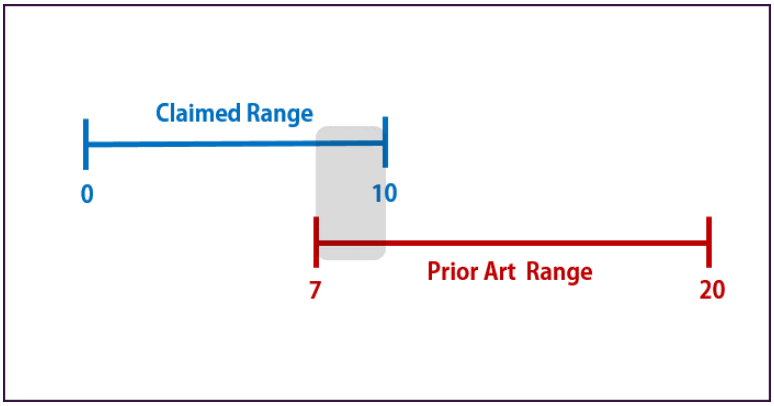

Figure 1. The Prior Art and Claimed Ranges Partly Overlap.

Figure 1 illustrates Scenario II.A. The claimed range (illustrated as 0–10) and the prior art range (illustrated as 7–20) overlap from 7 to 10 (illustrated by the greyed out region). The 2023 decision in *UCB, Inc. v. Actavis Laboratories UT, Inc.* (Fed. Cir. 2023)[17] nicely illustrates the scenario of partly overlapping ranges. *UCB, Inc.* is a case rich with range issues. We will refer to the case throughout this Article, including when we discuss *prima facie* anticipation by an overlapping prior art range,[18] the concept of "envisaging" every point in a range,[19] and the interplay between anticipation and obviousness.[20]

Let us start with *prima facie* obviousness. The invention in *UCB, Inc.* relates to a method of stabilizing rotigotine free base, a drug used to treat Parkinson's disease.[21] The rotigotine is in solid dispersion in a transdermal therapeutic system

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16 *See infra* Section D.

17 UCB, Inc. v. Actavis Lab'ys UT, Inc., 65 F.4th 679 (Fed. Cir. 2023).

18 *See infra* Section A.

19 *See infra* Section B.

20 *See infra* Section D.

21 *UCB*, 65 F.4th at 679.

(TTS) containing polyvinylpyrrolidone (PVP).[22] The several disputes in the case related to the claimed range of PVP per unit of drug. Claim 1 is as follows:

> A method for stabilizing rotigotine, the method 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*.[23]

If normalized per unit of rotigotine, the claimed range of PVP is 0.44 to 0.66.[24] The prior art included a commercial TTS with a normalized amount of PVP at 0.22, as well as disclosure of a method of stabilizing rotigotine by admixing with PVP at a normalized amount of 0.33.[25] Both these items of prior art fall outside and below the claimed range.[26]

The prior art also disclosed a TTS with a range of 0.17 to 0.56 PVP per unit of drug.[27] This range partly overlaps the claimed range.[28] The lower court had held the claims obvious based on the overlap.[29] The Federal Circuit agreed that the PVP ranges were "overlapping,"[30] and concluded that this raised a presumption of obviousness. This shifted the burden of production (but not of persuasion, which always remains with the challenger[31]) to the claim owner to present contrary arguments such as teaching away, or evidence of objective indicia of non-obviousness.

The claim owner argued that the art considered below was not the closest, and that the closest art taught away from the claimed range.[32] The Federal Circuit disagreed and concluded that even if the alternative art were to be considered, it

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22 *Id.* at 684.

23 *Id.* at 685 (emphasis added).

24 *See id.* at 684.

25 *See id.*

26 *See id.*

27 *See UCB*, 65 F.4th at 686.

28 *See id.*

29 *See id.*

30 *Id.* at 690.

31 *Id.*

32 *Id.* at 692.

did not teach away from the claimed range.[33] The court used the occasion to clarify the concept of "teaching away."[34] The allegedly closer art did not '"criticize, discredit, or otherwise dissuade"' a POSA from the claimed range.[35] At best, said the court, the alternative prior art expresses a preference for a different PVP range and that is not sufficient to teach away.[36] The court also held that the claimed and the prior art ranges were "'similar in kind"' and that there were no new or unexpected results when operating in the claimed range.[37] The Federal Circuit affirmed the lower finding that the evidence of commercial success was of limited probative value due to the existence of blocking patents that prevented competitors from entering the field.[38]

In sum, the claim owner was unable to convince the court that there was closer prior art, and even if there was, that it taught away. Moreover, the rebutting evidence the owner presented was unsuccessful in overcoming the *prima facie* case of obviousness.

Importantly for this Article, there was also in *UCB, Inc.* a challenge for anticipation over the same prior art. We will address that below.[39] Let us continue with additional scenarios of *prima facie* obviousness.

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33 *UCB*, 65 F.4th at 691.

34 *Id.*

35 *Id.* at 692.

36 *Id.* at 692–93.

37 *See id.* at 693–695 (holding the district court's findings of similarity of kind and lack of new and unexpected results were not clearly erroneous).

38 *Id.* at 695–697.

39 *See infra* Section IV.A.

B. THE PRIOR ART RANGE SUBSUMES THE CLAIMED RANGE

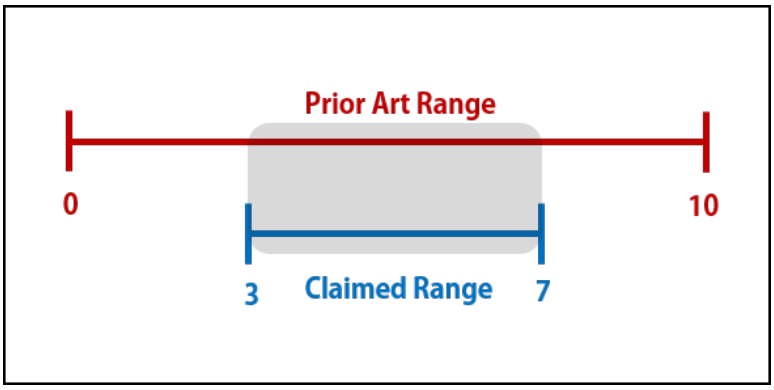

Figure 2. The Prior Art Range Subsumes the Claimed Range.

Figure 2 illustrates Scenario II.B. The prior art range (illustrated as 0–10) subsumes the claimed range (illustrated as 3–7). Alternatively, the claim may also be a single point, say, 5.

The concept of optimizing a prior art range to achieve the claimed range or claimed point takes center stage in the obviousness scenario of subsuming ranges. *In re Peterson* (Fed. Cir. 2003)[40] is a good starting point. The claimed range in *Peterson* is "about 1-3% rhenium," and the subsuming prior art range is "0-7% rhenium."[41] The claimed range is therefore fully encompassed by the prior art range. The court held that the claimed range was *prima facie* obvious over the prior art range.[42]

The court speculated in *dictum* that, in contrast to its holding, there *might* be situations where a prior art range is so large that it is too broad to teach or suggest a subset range.[43] Such a situation, suggested the court, may not give rise to a *prima facie* case of obviousness.[44] The court based its reasoning on the idea of optimization. It recognized that "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum

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40 *See generally In re* Peterson, 315 F.3d 1325 (Fed. Cir. 2003).

41 *Id.* at 1329.

42 *Id.* at 1332.

43 *Id.*

44 *Id.*

combination of percentages."[45] The narrower the disclosed range, the higher the motivation to optimize. The larger the disclosed range, the lesser the motivation to optimize. The *Peterson* holding was based on the conclusion that the prior art range was *not* too large to optimize.[46]

Two years later came *In re Harris* (Fed. Cir. 2005).[47] The claimed invention and the prior art were super alloy compositions with multiple components.[48] Eleven of the claimed components were encompassed by ranges in the prior art.[49] Only one component did not fall entirely within the prior art, and, because of that, anticipation was not raised.[50] For example, four of the eleven subsumed components are as follows:

Table 1. Partial Claim Chart for Claim 1 of U.S. Patent Application No. 09/797,326

Claimed super alloy components	Super alloy components in the prior art
Cobalt about 9–about 10	Up to 10
Tungsten about 8.4–about 8.8	2.0–15.0
Rhenium about 2.8–about 3.1	Up to 4.0
Carbon about 0.06–about 0.08	0.05–0.20

The claim owner took umbrage from the *dictum* in *Peterson* and argued that the range in this case was too large to suggest optimization.[51] The Federal Circuit disagreed.[52] It described the prior art range in *Peterson* as only "somewhat" larger than the claimed one.[53] It then noted that the prior art as well as the claimed range in *Harris* were even narrower than those in *Peterson*, thus leading to a conclusion that, even more so than in *Peterson*, the claim in *Harris* was *prima facie*

45 *Id.*

46 *In re Peterson*, 315 F.3d at 1330.

47 *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005).

48 *Id.* at 1340.

49 *Id.* at 1341–42.

50 *Id.*

51 *Id.* at 1342–43.

52 *Id.* at 1343.

53 *In re Harris*, 409 F.3d at 1343.

obvious.[54] The court evaluated the evidence produced by the claim owner to rebut the *prima facie* case of obviousness and found it wanting.[55]

Six years after *Harris*, the court decided *Genetics Institute v. Novartis Vaccines and Diagnostics, Inc.* (Fed. Cir. 2011),[56] again evaluating the size of the prior art relative to the claim. The facts here are more like those in the *Peterson dicta*, and distinguishable from the holdings in *Peterson* or in *Harris*. *Genetics Institute* presents a case where the "disclosed range [was] so broad [68,000 protein variants] as to encompass a very large number of possible distinct compositions" thus "requir[ing] nonobvious invention."[57] The court in *Genetics Institute* distinguished *Peterson*, where prior art "ranges that are not especially broad invite routine experimentation to discover optimum values."[58]

Galderma Laboratories, L.P. v. Tolmar, Inc. (Fed. Cir. 2013)[59] illustrates a situation where the claim is a single point that is subsumed by the prior art. The main claim is to a topical composition for treating acne, "comprising 0.3% by weight"[60] of adapalene. The prior art disclosed concentration ranges of adapalene for treating acne between 0.01% and 1%.[61] It exemplified different concentrations but not the specifically claimed 0.3%.[62] The prior art also disclosed that 0.1% was an optimal concentration and that higher concentrations increased side effects.[63]

The Federal Circuit did not explicitly discuss whether the concentration of adapalene was result-effective, a situation that would have led a POSA to optimize it.[64] In what appears to be an attempt to preempt such a discussion, the

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54 *Id.*

55 *See id.* at 1342–44 (finding "substantial evidence" that Yoshinari does not teach away nor were any results unexpected).

56 Genetics Inst. v. Novartis Vaccines & Diagnostics, Inc., 655 F.3d 1291 (Fed. Cir. 2011).

57 *Genetics Inst.*, 655 F.3d at 1306 (citing *In re Peterson*, 315 F.3d at 1330 n.1).

58 *Id.*

59 *See generally* Galderma Lab'ys, L.P. v. Tolmar, Inc., 737 F.3d 731 (Fed. Cir. 2013).

60 *Id.* at 734.

61 *Id.* at 735.

62 *Id.*

63 *Id.*

64 *See In re Antonie*, 559 F.2d at 620.

claim owner had argued that the art taught away from 0.3% adapalene.[65] The court, however, rejected the argument.[66] Citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, (Fed. Cir. 2009),[67] the court said that "[a] reference does not teach away . . . if it . . . does not criticize, discredit, or otherwise discourage investigation into the invention claimed."[68] The court added that a "teaching that a composition may be optimal or standard does not criticize, discredit, or otherwise discourage investigation into other compositions."[69] Finally, the production of objective indicia or commercial success did not tilt the result in favor of the claim owner.[70] The court invalidated the claim for obviousness.[71]

A few years later, and in contrast to *Galderma*, the Federal Circuit in *Allergan, Inc. v Sandoz, Inc.* (Fed. Cir. 2015)[72] evaluated a lower court ruling of non-obviousness of a claimed ophthalmic composition containing two specific claimed concentration points: 0.01% bimatoprost and 200 ppm of benzalkonium chloride (BAK).[73] The prior art (Woodward) fully subsumed the two claimed points.[74] Woodward disclosed a range of 0.001–1% bimatoprost and 0–1000 ppm of BAK.[75] Citing *Galderma*, the court asked whether there would have been motivation to select the claimed composition from the prior art range.[76] The claim owner answered that question by showing that the prior art taught away and that the claimed composition showed unexpected results or other objective indicia.[77] Expressly bypassing an inquiry regarding whether the ranges in Woodward were so large as to not even raise *prima facie* obviousness (as per the *dicta* of *Peterson*),

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65 *Galderma Lab'ys*, 737 F.3d at 738–39.

66 *Id.*

67 *See generally* DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314 (Fed. Cir. 2009).

68 *Galderma Lab'ys*, 737 F.3d at 738 (quoting *DePuy Spine*, 567 F.3d at 1327).

69 *Id.* at 739.

70 *Id.* at 738–39.

71 *Id.* at 741.

72 *See generally* Allergan, Inc. v. Sandoz Inc., 796 F.3d 1293 (Fed. Cir. 2015).

73 *Id.* at 1299.

74 *Id.* at 1302.

75 *Id.*

76 *Id.* at 1305.

77 *Id.*

the court went directly to the rebutting evidence presented by the claim owner.[78] It affirmed the lower court's finding that the claim owner had indeed presented "ample evidence of teaching away and unexpected results."[79]

In sum, Federal Circuit case law suggests that, initially, *prima facie* obviousness over a subsuming prior art range depends on the size of the disclosed range and on the relation between the sizes of the subsuming and claimed range or point. The central question is optimization. If, starting with the prior art range, the amount of experimentation to optimize and reach the claimed one is routine and straightforward, then *prima facie* obviousness is likely. That is the lesson from *Peterson* or *Harris*.[80] On the other hand, when, as in *Genetics Institute,* the subsuming range is very large, especially in relation to the claimed range, optimization is not routine, and *prima facie* obviousness is less likely.[81]

The "subsuming" cases we have illustrated also show that arguments of "teaching away" must be marshalled very carefully. Unless a claim owner can produce clear and convincing evidence of "criticizing, discrediting, or discouraging experimentation in," the claimed range, or as in *Galderma* a claimed single point, the defense will fail.[82] The Federal Circuit will dismiss such evidence as simply showing an optimal (*Galderma*) or preferred (*UCB, Inc.*) range and hold that it is not teaching away.[83] When, as in *Allergan*, the evidence convinces the court that teaching away is clearly discouraging experimentation with the claimed value, rebuttal succeeds, and the result is non-obviousness.[84] The same is true for objective indicia of non-obviousness. Evidence of commercial success is a particularly fraught rebuttal, as it may be undermined by a lack of nexus of the success to the claimed invention or by the existence of blocking patents (*UCB, Inc.*).[85]

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78 *Allergan*, 796 F.3d at 1305.

79 *Id.*

80 *See In re Peterson*, 315 F.3d at 1330; *In re Harris*, 409 F.3d at 1343.

81 *See Genetics Inst.*, 655 F.3d at 1306 (citing *In re Peterson*, 315 F.3d at 1330 n.1).

82 *Galderma Lab'ys*, 737 F.3d at 739.

83 *See id.*; *UCB*, 65 F.4th at 692–93.

84 *Allergan*, 796 F.3d at 1305.

85 *UCB*, 65 F.4th at 695–97.

C. RANGES ARE COMBINED FROM MULTIPLE REFERENCES TO CREATE THE CLAIMED RANGE

In *Pfizer Inc. v. Sanofi Pasteur Inc.* (Fed. Cir. 2024),[86] there were several prior art references that had to be combined to reach the claimed range. The invention was of so-called "22F glycoconjugates" within a range of molecular weights.[87] The claimed and prior art ranges were as follows:

Table 2. Partial Claim Chart for Claim 1 of U.S. Patent No. 9,492,559 B2

Claimed range: A serotype 22F glycoconjugate . . .	**Prior Art**
. . . [with] a molecular weight of between 1000 kDa and 12,500 kDa and comprises an isolated capsular polysaccharide from *S. pneumoniae* serotype 22F . . . [88]	No reference teaches a molecular weight for a 22F serotype glycoconjugate. First item: Discloses both a serotype 22F glycoconjugate and the molecular weights for fourteen other serotype *non-22F* glycoconjugates, with molecular weights, ranging from 1303 kDa to 9572 kDa.[89] Second item: Discloses that "saccharide conjugate vaccines retaining a larger size of saccharide can provide a good immune response against pneumococcal disease."[90]

While no reference showed molecular weights for 22F serotype glycoconjugates, there were several molecular weights described for non-22F

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86 *See generally* Pfizer Inc. v. Sanofi Pasteur Inc., 94 F.4th 1341 (Fed. Cir. 2024).

87 *Id.* at 1345.

88 *Id.*

89 *Id.* at 1348.

90 *Id.*

serotype glycoconjugates.[91] The Federal Circuit held that the result-effectiveness of a claimed parameter could still be found even if there was no overlap in ranges, and the prior art had a gap.[92] The court explained that while. . .

> . . . an overlap between a claimed range and a prior art range creates a presumption of obviousness that can be rebutted with evidence that the given parameter was *not* recognized as result-effective, . . . [it] does not mean, however, that the determination whether or not a variable is result-effective is *only* appropriate when there is such an overlap . . . Where [a] gap [in the prior art] includes a parameter not necessarily disclosed in the prior art, it is not improper to consider whether it would have been recognized as result effective.[93]

D. THE PRIOR ART & THE CLAIMED RANGES ARE PROXIMAL, BUT DO NOT TOUCH

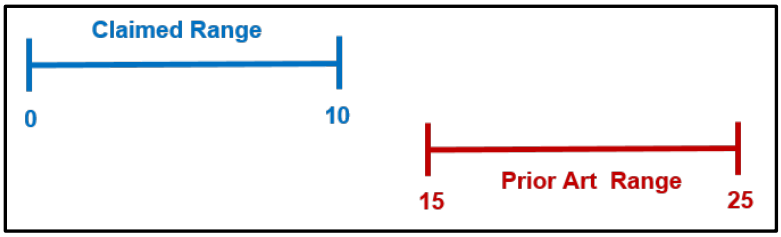

Figure 3. The Prior Art and Claimed Ranges Do Not Touch.

Figure 3 illustrates Scenario II.D. The claimed range (illustrated as 0–10) and the prior art range (illustrated as 15–25) are proximal, but do not abut or overlap.

When the claimed range and prior art range do not overlap, the prior art may render the claimed range *prima facie* obvious *if* the prior art range is proximal to the claimed range. In *Titanium Metals Corp. of America v. Banner* (Fed. Cir. 1985),[94] for example, the range similarities between the claimed alloy of claim 3 and two separate prior art alloys were as follows:

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91 *Id.*

92 *Pfizer*, 94 F.4th at 1348.

93 *Id.* at 1347–48.

94 *See generally* Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 783 (Fed. Cir. 1985).

Table 3. Partial Claim Chart for Claim 3 of U.S. Patent Application No. 455,964

Claim 3 **Alloy comprising:**	**Prior Art** **Two different alloys comprising:**
(i) 0.8% nickel, (ii) 0.3% molybdenum, up to 0.1% iron, and (iii) balance titanium[95]	(A) (i) 0.75% nickel, (ii) 0.25% molybdenum, and (iii) balance titanium[96] (B) (i) 0.94% nickel, (ii) 0.31% molybdenum, and (iii) balance titanium.[97]

The Federal Circuit held that the claimed alloy was obvious over either of the prior art alloys.[98] The court stated that, "[t]he proportions [were] so close that *prima facie* one skilled in the art would have expected them to have the same properties."[99] Moreover, because the claim owner did not provide any evidence rebutting this presumption, the court held that the claimed alloy was unpatentable.[100]

In addition to claim 3, there were in *Titanium Metals* two more claims with ranges: claims 1 and 2.[101] The court held both conclusively anticipated by single point examples in the prior art; *i.e.*, the court held that the claimed ranges read on specifically exemplified alloys.[102] We discuss these two claims next, in Section III.A.

III. CONCLUSIVE ANTICIPATION: THE PRIOR ART FALLS ENTIRELY WITHIN THE CLAIMED RANGE

We will now address two distinct scenarios for conclusive anticipation of a claimed range: (A) the prior art exemplifies a single point falling within the

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95 *Id.* at 776.

96 *Id.* at 777.

97 *Id.* at 783.

98 *Id.*

99 *Id.*

100 *Titanium Metals Corp.*, 778 F.2d at 783.

101 *Id.* at 776.

102 *Id.* at 781–82.

claimed range (Section III.A) and (B) the prior art range is narrower than, and falls entirely within, the claimed range (Section III.B).

A. THE PRIOR ART IS A SINGLE POINT

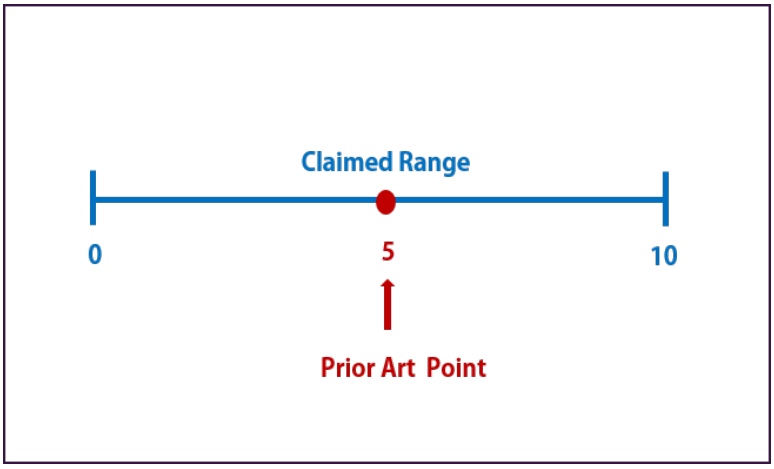

Figure 4. An Exemplified Point in the Prior Art Falls Within the Claimed Range.

Figure 4 illustrates scenario III.A. The prior art exemplifies a point (illustrated as 5) that falls within the claimed range (illustrated as 0-10).

A basic principle of patent law is that when a claim encompasses a range of multiple compositions or points, the claim is anticipated if one of the compositions or points is exemplified in the prior art.[103] For example, in *Titanium Metals*, the court held that claims 1 and 2, which were drawn to a titanium alloy containing 0.6–0.9% nickel and 0.2–0.4% molybdenum, were anticipated by a prior art reference that exemplified a titanium alloy containing 0.75% nickel and

[103] *Titanium Metals Corp.*, 778 F.2d at 781–82; ModernaTX, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352, 1363–64 (Fed. Cir. 2021); *see also* Arbutus Biopharma Corp. v. ModernaTX, Inc., 65 F.4th 656, 665–66 (Fed. Cir. 2023); Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co., 878 F.3d 1336, 1343–44 (Fed. Cir. 2018).

0.25% molybdenum.[104] We already saw above that claim 3 was held invalid for obviousness.[105]

In more recent cases, such as *ModernaTX, Inc. v. Arbutus BioPharma Corp.* (Fed. Cir. 2021),[106] the Federal Circuit has confirmed that if a single prior art reference exemplifies a point that falls within the claimed range, then the prior art reference anticipates the claimed range, and the anticipation is conclusive—that is, it cannot be rebutted.[107] The court held that three claimed ranges were anticipated by a single prior art reference that exemplified at least one composition that fell within each of the ranges.[108]

Table 4. Partial Claim Chart for Claim 1 of U.S. Patent No. 9,364,435 B2

Claim: A lipid composition comprising	**Prior Art**
(i) from 50 mol % to 85 mol % cationic lipid	(i) 50 mol % cationic lipid,
(ii) non-cationic lipid comprising from 13 mol % to 49.5 mol % and	(ii) 48 mol % non-cationic lipid and
(iii) a conjugated lipid that "inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % . . . [109]	(iii) 2 mol % conjugated lipid[110]

The court reasoned that the *Moderna* case was no different from *Titanium Metals*.[111] A 50% cationic lipid fell within the claimed 50–85 % cationic lipid range, a 48% non-cationic lipid fell within the claimed 13–49.5% non-cationic lipid range, and a 2% conjugated lipid fell within the claimed 0.5–2 mol % conjugated lipid

104 *Titanium Metals Corp.*, 778 F.2d at 781.

105 *See supra* Section II.D.

106 *See generally* ModernaTX, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352 (Fed. Cir. 2021).

107 *Id.* at 1363–64; *see also* Arbutus Biopharma Corp. v. ModernaTX, Inc., 65 F.4th 656, 665–66 (Fed. Cir. 2023); Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co., 878 F.3d 1336, 1343–44 (Fed. Cir. 2018).

108 *ModernaTX*, 18 F.4th at 1357, 1363–64.

109 *Id.* at 1356.

110 *Id.* at 1357.

111 *See id.* at 1364.

range.[112] Thus, the court held that the prior art reference anticipated the claims.[113] There was no possibility of rebuttal.

B. THE PRIOR ART IS A RANGE

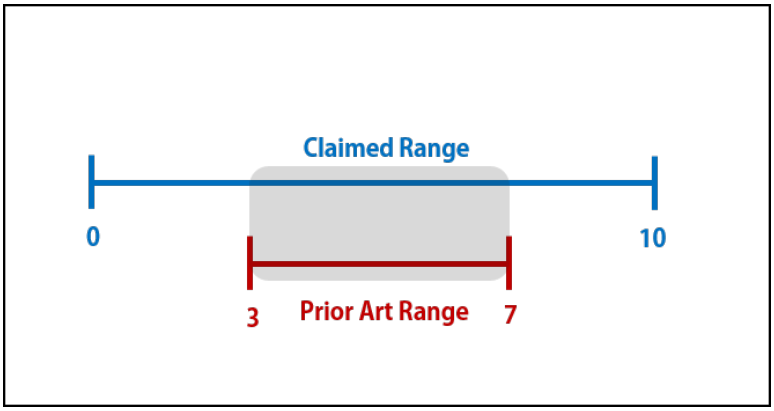

Figure 5. The Prior Art Range Falls Entirely Within the Claimed Range.

Figure 5 illustrates scenario III.B. The prior art is a range (illustrated as 3–7), which falls completely within the claimed range (illustrated as 0–10).

In re Bhagat (Fed. Cir. 2018)[114] illustrates this scenario. The claim is to a lipid-containing formulation with omega (Ω) fatty acids within multiple ranges and ratios:

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[112] *Id.* at 1357.

[113] *Id.* at 1364.

[114] *In re* Bhagat, 726 Fed. App'x 772 (Fed. Cir. 2018).

Table 5. Partial Claim Chart for Claim 65 of U.S. Patent Application No. 12/426,034

Claim: A lipid-containing formulation comprising dosages of:	**Prior Art**
Ω-6 to Ω-3 ratio of 4:1 or greater	Ω-6 to Ω-3 ratio of 4:1 to 6:1
Ω-6 are 4–75% of total lipids	Ω-6 are 4–6%
Ω-3 are 0.1–30% of total lipids	Ω-3 are 0.8–1.2%
Ω-6 are not more than 40 grams[115]	Ω-6 are 8.5 g[116]

The Federal Circuit affirmed the Board's findings that the prior art ranges fell within the claimed ones and conclusively anticipated them.[117]

Let us now turn to the central concern of this Article: *prima facie* anticipation, that is, *rebuttable* lack of novelty.

IV. *PRIMA FACIE* ANTICIPATION OVER A PARTLY OVERLAPPING PRIOR ART RANGE

Over the last twenty years, the Federal Circuit has developed the doctrine of rebuttable anticipation for scenarios when claimed ranges and prior art ranges partly overlap. We will use the term "partly overlapping" for a situation where the endpoint of a prior art range falls within, or abuts one or the other endpoints of, the claimed range. This will distinguish the situation from one where neither endpoint of the prior art range touches the claimed range; we will call the latter situation "fully subsuming."

There are three sub-scenarios of partly overlapping ranges that potentially raise *prima facie* anticipation: (A) portions of the prior art overlap portions of the claimed range; (B) the prior art and claimed ranges abut at only one endpoint, with no other overlap; and (C) the prior art abuts at one endpoint and subsumes the claimed range. These three sub-scenarios are illustrated in Figure 6.

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115 *Id.* at 773–74.

116 *Id.* at 774.

117 *Id.*

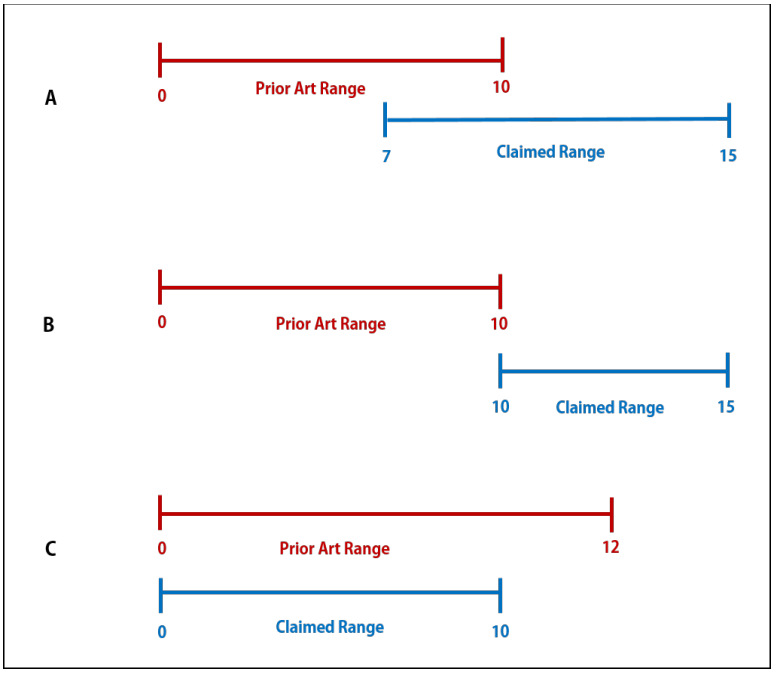

Figure 6. Three Sub-Scenarios That Lead To Prima Facie Anticipation.

Figure 6 illustrates three sub-scenarios discussed in this Section IV. (A) In this sub-scenario, the prior art range (illustrated as 0–10) partly overlaps with the claimed range (illustrated as 7–15); (B) in this sub-scenario, only one endpoint of the prior art range (illustrated as 0–10) and the claimed range (illustrated as 10–15) abut (at endpoint 10); and (C) in this sub-scenario, the prior art range (illustrated as 0–12) abuts one endpoint of and subsumes the claimed range (illustrated as 0–10**).**

The situations illustrated in Figure 6 are oftentimes identical to those where the court reviews lower tribunals' holdings of *prima facie* obviousness. Indeed, there have been several recent cases where the court confronted challenges to claimed ranges based on both *prima facie* obviousness and *prima facie* anticipation.[118]

As we saw in Section II.A, the *prima facie* obviousness analysis of partly overlapping ranges is well-trod ground.[119] The elements of the initial inquiry and the nature of the rebuttal are well-established. However, that has not always been the case with *prima facie* anticipation. The case law in this area developed slowly, and only recently does it seem to have settled around established principles.

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[118] *See generally* Genentech, Inc. v. Hospira, Inc., 946 F.3d 1333 (Fed. Cir. 2020).

[119] *See supra* Section II.A.

Because the analysis of anticipation is essentially the same for the three sub-scenarios in Figure 6, we will not deal with them separately and the following discussion applies to all three. We will describe the basic elements of *prima facie* anticipation, illustrate them with decisions from the Federal Circuit, and discuss the court's recent refinements of the basic framework.

Before we start, however, it should be noted that there is a fourth sub-scenario of "overlapping" ranges: one where the prior art *entirely* subsumes the claimed range. This is illustrated in Figure 2 in Section II.B.[120] In such sub-scenario, the endpoints of the prior art range do not fall within, or abut the endpoints of, the claimed range. The Federal Circuit does not consider such fully subsuming prior art as "partly overlapping" for anticipation purposes.[121] The court analyzes such fully subsuming prior art ranges for anticipation using an "immediately envisaging" framework.[122] And, as described in Section II.B., the court also analyzes such situations under principles of *prima facie* obviousness.[123] We explain the court's anticipation reasoning about fully subsuming prior art in Section IV.A., Subsection 1, under "*Scenario 1: Fully Subsuming Prior Art Range,*" and we also discuss it in Section IV.B.[124]

A. PRIOR ART RANGE ENDPOINTS ARE NOT SPECIFICALLY ANTICIPATORY

The central concept in the anticipation analysis of partly overlapping ranges is that neither of the two endpoints of a prior art range is legally treated as a specifically exemplified value.[125] If a prior art endpoint *were* a specifically exemplified value, and if it fell within or abutted a claimed range, then it would conclusively anticipate the range. We saw such situations in Section III.A,[126] in *Titanium Metals*,[127] and *ModernaT*X.[128] We showed there that when the prior art

120 *See supra* Section II.B.

121 *Atofina*, 441 F.3d at 999.

122 *Id.*

123 *See supra* Section II.B.

124 *See infra* Section IV.A; *see also infra* Section IV.B.

125 *Atofina*, 441 F.3d at 1000.

126 *See supra* Section III.A.

127 *Titanium Metals Corp.*, 778 F.2d at 780–82.

128 *ModernaTX*, 18 F.4th at 1363–64.

exemplifies a point that falls within a claimed range, the prior art conclusively anticipates the claim, and anticipation is not rebuttable.[129]

However, prior art range endpoints are not treated as exemplified points, so they do not *conclusively* anticipate. They do, however, play a special role when they fall within or abut at either end of a claimed range. As shown in Figure 6 (A), (B), and (C), in such situations they create a *prima facie* case of anticipation.[130] Yet except for the three sub-scenarios in Figure 6, prior art range endpoints are considered to be no different than any of the other points in the range. The prior art range is then treated as such: as a range. It is not a series of exemplified points, and, again, with the exception of Figure 6, no particular importance is given to the endpoints. If the prior art endpoints do not touch the claimed range, as in the case of fully subsuming prior art shown in Figure 2, they are treated no differently than the rest of the range and the situation only leads to *prima facie* obviousness.[131]

It was in the seminal case *Atofina v. Great Lakes Chemical Corp.* (Fed. Cir. 2006)[132] that the court held for the first time that the disclosure of a prior art temperature range "is no more a disclosure of the endpoints of the range than it is of each of the intermediate points."[133] A consequence of this concept is that partly overlapping ranges, while not raising conclusive anticipation, raise a rebuttable presumption of anticipation.

The road from *Atofina* to the present day's *prima facie* anticipation framework has been rocky and the legal path has not always been a paradigm of clarity or consistency. We will next discuss several cases that illustrate how the court slowly developed the framework, which now appears to have reached stability.

In *Atofina*, the Federal Circuit dealt with two scenarios: the first was of a fully subsuming prior art range and the second of a partly overlapping prior art range.[134] We will discuss each in turn because the anticipation analysis is different for both.

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129 *See supra* Section III.A.

130 *See supra* at Figure 6.

131 *See supra* Section II.B.

132 *See generally Atofina*, 441 F.3d 991.

133 *Id.* at 1000.

134 *See generally id.*

1. Scenario 1: Fully Subsuming Prior Art Range.

In *Atofina*, the claimed temperature range was 330–450˚C,[135] and in one instance, the prior art range was 100–500˚C.[136] The endpoints of the prior art range neither fall within the claimed one nor do they abut either endpoint of the claimed range. The prior art range entirely subsumes the claimed one. This scenario is identical to those we discussed in Section II.B.[137] in the obviousness context, *e.g.*, in cases like *In re Peterson*,[138] *In re Harris*,[139] *Genetics Institute* (2011)[140], and *Galderma*.[141] Here we ask whether the prior art range anticipates the claimed range.

The Federal Circuit held that the prior art range (100–500˚C) did not anticipate the claimed one (330–450˚C).[142] It explained that "the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus."[143] Had the prior art genus been "small," the court said, perhaps it may have anticipated the claimed range.[144] However, without further elaborating on what it meant by *small*, the court added that "a temperature range of over 100 degrees is not a small genus and the range of temperatures of [the prior art reference] does not disclose [the claimed] temperature range."[145] Without further elucidation, the court held that, "[given] the considerable difference between the claimed range [330–450˚C] and the range in the prior art [100−500˚C], no reasonable fact finder could conclude that the prior art describes the claimed range with *sufficient specificity* to anticipate this limitation of the claim."[146] One may speculate that by "small" the court was analogizing to a line of anticipation cases

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135 *Id.* at 993.

136 *Id.* at 994.

137 *See supra* Section II.B.

138 *In re Peterson*, 315 F.3d at 1329.

139 *In re Harris*, 409 F.3d at 1340.

140 *Genetics Inst.*, 655 F.3d at 1313.

141 *Galderma*, 737 F.3d at 738.

142 *Atofina*, 441 F.3d at 999.

143 *Id.*

144 *Id.*

145 *Id.*

146 *Id.* (emphasis added).

dealing with "envisaging" every element of a limited genus, such as *In re Petering* (Fed. Cir. 1962).[147]

This line of argumentation, *i.e.*, evaluating the size of the prior art range, is reminiscent of the line of cases on *prima facie* obviousness of subsuming prior art ranges: *In re Peterson*,[148] *In re Harris*,[149] *Genetics Institute*,[150] and *Galderma*,[151] which we discussed in Section II.B.[152] There is, however, a crucial difference in the evaluation of the size of a prior art range for *prima facie* obviousness than for anticipation. In *prima facie* obviousness, the question is whether the prior art range is small enough to encourage doing experiments to optimize a result-effective variable.[153] In contrast, for *prima facie* anticipation, the question is specificity; i.e., whether the prior art range is small enough to "immediately envisage" each "member" of the range.[154] There is no inquiry into optimization in an analysis of anticipation.

In sum, the four decisions on *prima facie* obviousness (*Peterson*, *Harris*, *Genetics Institute*, and *Galderma)* taken together with *Atofina* Scenario 1 on anticipation may be seen as generating a spectrum of challenges based on the breadth of subsuming prior art ranges. The challenges go from no *prima facie* obviousness when the subsuming prior art range is too large to optimize (*per* the *dicta* in *Peterson* or the holding in *Genetics Institute);* to *prima facie* obviousness when the subsuming prior art range is not too large to optimize (as *per Harris*); to no

147 *In re* Petering, 301 F.2d 676, 681 (C.C.P.A. 1962) (holding that twenty compounds and a limited number of variations in a generic chemical formula inherently anticipate a claimed species within the genus because "one skilled in [the] art would . . . at once envisage each member" of the genus); *see also* Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 471 F.3d 1369, 1376 (Fed. Cir. 2006) (providing that the prior art cited for anticipation "expressly spelled out a definite and limited class of compounds that enabled a person of ordinary skill in the art to at once envisage *each member* of this limited class" (emphasis added)).

148 *See generally In re Peterson*, 315 F.3d at 1325.

149 *See generally In re Harris*, 409 F.3d at 1339.

150 *See generally Genetics Inst.*, 655 F.3d at 1291.

151 *See generally Galderma*, 737 F.3d at 731.

152 *See supra* Section II.B.

153 *See generally In re* Peterson, 315 F.3d 1325 (Fed. Cir. 2003); *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005).

154 *Atofina*, 441 F.3d at 999.

conclusive anticipation when the subsuming prior art range is not specific enough to immediately envisage the claimed range (as *per Atofina* Scenario 1)[155]; to conclusive anticipation when the size of the subsuming range is specific enough to immediately envisage and therefore anticipate the claimed range (as per *Petering).*

Let us now proceed to *prima facie* anticipation by partly overlapping ranges.

2. Scenario 2: Partly Overlapping Prior Art Range.

The prior art in *Atofina* also disclosed a preferred range of 150–350˚C, which partly overlapped the claimed range of 330–450˚C.[156] This is sub-scenario (A) in Figure 6: one of the endpoints of the prior art range (350˚C), fell within the claimed range. Expanding on its earlier statement that endpoints are not specific enough for anticipation, the court held that the "slightly overlapping range is not disclosed as such, *i.e.*, as a species of the claimed generic range of 330 to 450˚C."[157] The court concluded that the endpoint did not anticipate the claimed range.[158]

That, however, was not the end of the matter. *Atofina* was a first, tentative step to the development of *prima facie* anticipation. There was more to *Atofina* than what the court *said* in its 2006 opinion. Certain crucial facts and their impact on the decision were not spelled out until almost six years later, in *ClearValue, Inc. v. Pearl River Polymers, Inc.* (Fed. Cir. 2012).[159] The invention in *ClearValue* is a process of clarifying turbid water with certain polymers.[160] The claim requires the starting unclear water to have raw alkalinity "less than or equal to 50 ppm."[161] The prior art disclosed a broader range of water alkalinity: "150 ppm or less."[162] The prior

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155 It is of interest that the Federal Circuit in *Atofina* reversed the lower court's holding of anticipation in Scenario 1, yet refrained from commenting that the facts of Scenario 1 could also lend themselves to an analysis of *prima facie* obviousness under 35 U.S.C. § 103. Because obviousness was not raised on appeal, the Federal Circuit remained silent.

156 *Atofina*, 441 F.3d at 993–94.

157 *Id.* at 1000.

158 *Id.*

159 ClearValue, Inc. v. Pearl River Polymers, Inc., 668 F.3d 1340 (Fed. Cir. 2012).

160 *Id.* at 1342.

161 *Id.* at 1344.

162 *Id.*

art abutted the claimed range at 0°C and also entirely subsumed it. This is sub-scenario (C) in Figure 6.[163]

Citing *Atofina*, the claim owner in *ClearValue* argued that "150 ppm or less" is too large a genus to anticipate the "less than or equal to 50 ppm" narrowly-claimed subgenus.[164] The Federal Circuit agreed with this premise and held that there was no conclusive anticipation.[165] Instead, the court held the claim *prima facie* anticipated.[166] Wishing to distinguish the facts in *ClearValue* from those in *Atofina*, the Federal Circuit supplemented the reasons why it had held that there was no anticipation in *Atofina*.[167] The court, citing to *Atofina's* Joint Appendix and to Atofina's patent—although not to the actually reported *opinion*—said that "the evidence [in *Atofina*] showed 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."[168] It explained that, in *Atofina's* patent specification, the claim owner had argued that "'only a narrow temperature range enables' the process to operate as claimed, and that problems occur when operating the reaction either below . . . or above [the claimed range]."[169] The *ClearValue* court added that during the prosecution history "Atofina described [its claimed] temperature range as 'critical.'"[170] The court also cited to a comparative example that "shows that a temperature [outside the claimed range] does not allow' the . . . reaction to operate as claimed."[171]

These previously unmentioned details are more than a minor oversight in the *Atofina* opinion. The issue of the criticality of a claimed range when compared to a partly overlapping prior art range has since become a central aspect of the analyses of *prima facie* anticipation. Because it is the combination of both decisions that sets forth the framework for *prima facie* anticipation, we will refer to the combination of *Atofina* and *ClearValue*, as "*Atofina*/*ClearValue*."

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163 *See supra* at Figure 6.

164 *ClearValue*, 668 F.3d at 1344.

165 *Id.* at 1345.

166 *Id.*

167 *Id.* at 1344–45.

168 *Id.* at 1345.

169 *Id.* at 1344–45.

170 *ClearValue*, 668 F.3d at 1345.

171 *Id.*

Let us summarize how *Atofina*/*ClearValue* changed the law. If the prior art range fully subsumes the claimed range, that is, if neither of the endpoints of the prior art touches the claimed range, there is complete overlap, but the ranges do not "partly overlap." Therefore, there is no rebuttable anticipation. If the prior art range is "small" there might be conclusive anticipation under principles of "immediately envisaging" law. Otherwise, there is only *prima facie* obviousness. If, however, either of the prior art endpoints touches the claimed range, there is *prima facie* anticipation. We will have more to say in Section IV.D. about proving criticality of a claimed range as rebuttal evidence to *prima faci*e anticipation.

Meanwhile let us look in more detail at a threshold question: What role does the doctrine of "immediately envisaging" a claimed range play in its anticipation by partly overlapping prior art?

B. THE ROLE OF "IMMEDIATELY ENVISAGE" IN ANALYSIS OF ANTICIPATION BY A RANGE

As we showed in Section II.B., when we discussed the obviousness analysis in *UCB, Inc.*,[172] the case deals with partly overlapping ranges.[173] The claim is to a TTS system of rotigotine free base mixed with polyvinylpyrrolidone (PVP).[174] The claimed PVP range, when normalized per unit of rotigotine, is 0.44 to 0.66.[175] The prior art disclosed a TTS with range of 0.17 to 0.56 PVP per unit of drug.[176] This range partly overlaps the claimed range and is thus illustrated by sub-scenario (A) in Figure 6. We saw in Section II.B. that the Federal Circuit held the claims obvious based on the overlap.[177] However, the court also analyzed an anticipation rejection over the same prior art.

The Federal Circuit in *UCB, Inc.* reversed the lower court's finding, which, based on the "immediately envisage" decision in *Kennametal, Inc. v. Ingersoll Cutting Tool Co.* (Fed. Cir. 2015),[178] had ruled that the partly overlapping range of

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172 *UCB*, 65 F.4th at 689–92 (discussing obviousness as related to the patent at issue.).

173 *See supra* Section II.B.

174 *UCB*, 65 F.4th at 684.

175 *See id.*

176 *See id.*

177 *See supra* Section II.A.

178 *See* Kennametal, Inc. v. Ingersoll Cutting Tool Co., 780 F.3d 1376, 1383 (Fed. Cir. 2015) (discussing the affirmation of the boards conclusion based off the immediately envisage standard).

the prior art anticipated the claimed range of PVP.[179] The lower court had reasoned that a POSA could "immediately envisage" every point of the prior art range, including the endpoints.[180] Supported by expert testimony, the lower court had found that a POSA would limit its consideration to only half and whole integers in the prior art range.[181] In a revealing footnote, the Federal Circuit commented on the difficulty of concluding what and how many discrete points might be "envisaged" within a range, even a small range.[182] The court pointed out, in a slightly dismissive tone, that the expert testimony contradicted the very specification of the patent, which had at least one example with a ratio of 1.6, neither an integer nor a half integer.[183]

Even more harshly, the court held that misapplying the "immediately envisage" test of *Kennametal* to partly overlapping ranges was an error of law.[184] Anticipation in such a scenario must follow the *Atofina*/*ClearValue* analysis, not the "immediately envisage" analysis. Yet since evaluating the factual framework of *prima facie* anticipation under *Atofina*/*ClearValue*—especially evaluating rebutting evidence of criticality—would have necessitated remand, the Federal Circuit sidestepped this framework and, as we have seen above, decided the case on obviousness instead.[185]

It is clear that in a scenario where the prior art range fully subsumes a claimed range or point, such as Scenario 1 in *Atofina*, cases on "immediately envisaging" like *In re Petering*,[186] *Kennametal*,[187] and *Eli Lilly & Co.*[188] can be applied

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179 *UCB*, 65 F.4th at 687.

180 *Id.* at 687–88.

181 *Id.* at 688.

182 *See id.* at 688 n. 3 (explaining the contradiction between what a person of ordinary skill in the art would find versus what the patent discloses).

183 *Id.*

184 *Id.* at 688.

185 *See UCB*, 65 F.4th at 689.

186 *In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962) (explaining that a person skilled in the art could envisage a narrower subclass within the broader disclosure).

187 *See generally* Kennametal, Inc. v. Ingersoll Cutting Tool Co., 780 F.3d 1376, 1376 (Fed. Cir. 2015).

188 *See generally* Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 471 F.3d 1369, 1369 (Fed. Cir. 2006).

in anticipation analysis. If a POSA can immediately envisage every element of a small genus, the anticipation by the small genus is conclusive.

However, the *UCB, Inc.* court's criticism of the lower court for using the "immediately envisage" line of cases—rather that the *Atofina*/*ClearValue* framework in partly overlapping ranges, such as Scenario 2 in *Atofina*—raises an interesting question: should the anticipation analysis of partly overlapping ranges be solely evaluated on the *Atofina*/*ClearValue* framework? That is, should the analysis be limited to the issue of criticality and rebuttal evidence demonstrating criticality? Or is there still room to apply "immediately envisaging" case law to partly overlapping ranges and not only to fully subsuming ranges?

Our view is that anticipation analysis in partly overlapping ranges does not need to be done solely on *Atofina*/*ClearValue* and that there is room for "immediately envisaging" case law. This view is informed by a later case, *OSRAM Sylvania, Inc. v. American Induction Technologies, Inc.* (Fed. Cir. 2012).[189] This decision was handed down the same year as, and ten months after, *ClearValue*.[190] The claim in *OSRAM Sylvania* is to an electric lamp assembly with a tube containing a buffer gas "at a pressure less than 0.5 torr."[191] The prior art described a lamp where the gas pressure was "1 torr or less."[192] In other words, as in *ClearValue*, the prior art range abutted the claimed range at zero torr; i.e., this is the partly overlapping sub-scenario (C) in Figure 6.[193] On a Motion for Summary Judgement (MSJ), the lower court ruled that the prior art conclusively anticipated the narrower claimed range.[194]

Relying entirely on both *Atofina* and *ClearValue*, the Federal Circuit reversed and ordered trial on the issue.[195] However, the court did not exclude the possibility of using "envisaging" case law. The court instructed the lower court to hear testimony on "how one of ordinary skill in the art would understand the relative size of [the prior art] genus or [claimed] species."[196] Note that the question as to the relative sizes of the prior art and claimed ranges is treated by the Federal

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189 *See generally* OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc., 701 F.3d 698 (Fed. Cir. 2012).

190 *See generally id.*

191 *Id.* at 701.

192 *Id.*

193 *See supra* at Figure 6.

194 *OSRAM Sylvania*, 701 F.3d at 703.

195 *Id.* at 709.

196 *Id.* at 706.

Circuit as an issue of fact.[197] The court recognizes that whether a POSA can identify specific points within a prior art range so that it is specific enough for conclusive anticipation may vary from technology to technology.[198] It seems that the court left the door open to the possibility that, at trial, the evidence might show that a POSA in this particular lamp technology would be able to immediately envisage specific points of the prior art genus.[199]

Given *OSRAM Sylvania*, we are of the opinion that in a scenario where the prior art range partly overlaps—that is, a prior art endpoint abuts or falls within the claimed range, as in Scenario 2 in *Atofina*—"immediately envisage" case law may still be applied as a first step in the analysis. If the prior art range is small enough, and a POSA can envisage individual points, the anticipation is conclusive, and no further inquiry is needed. If, under the facts, a POSA cannot immediately envisage each point of the range, the court must move on to an *Atofina*/*ClearValue prima facie* anticipation analysis.

That is where the lower court in *UCB, Inc.* erred. Its ruling that the prior art range was small enough to allow a POSA to envisage the claimed range was reversed by the Federal Circuit as clear error.[200] And since the lower court did not then carry out a full *Atofina*/*ClearValue* analysis, the Federal Circuit held that the lower court had committed an error of law.[201] Since, in *UCB, Inc.*, the prior art range was large and did not lend itself to immediately envisaging individual points, the case had to be decided on the *Atofina*/*ClearValue* framework.[202] However, rather than deciding the anticipation question on appeal or remanding for further proceedings, the Federal Circuit affirmed the lower court on obviousness, held the claims invalid, and the case ended.[203]

It would appear then that after *Atofina*/*ClearValue*, *UCB, Inc.* and *OSRAM Sylvania*, the framework for analyzing anticipation by partly overlapping ranges follows three steps:

- If specific points within a prior art range are exemplified, or if the prior art range is "small enough" so that a POSA can immediately envisage each

197 *Id.* at 705–06.

198 *Id.* at 706.

199 *See id.*

200 *UCB*, 65 F.4th at 689.

201 *Id.*

202 *Id.* at 687–89.

203 *Id.* at 689.

point, the range is conclusively anticipated; *i.e.*, the anticipation is non-rebuttable. The validity analysis ends.

- However, if the prior art range is not small—and since partly overlapping endpoints are just endpoints and not specific examples—the prior art range raises a *prima facie* case of anticipation.

- And, since anticipation is only presumed, it can be rebutted by demonstrating that the range as claimed is critical for the operation of the invention.

As demonstrated by this three-step analysis of anticipation, the case law seems to have achieved a certain level of stability. It is interesting, from a historical perspective, to understand whether the *Atofina/ClearValue* approach to *prima facie* anticipation reflected by steps (2) and (3) arose from earlier decisions or was a breakthrough in the court's thinking. We believe that it was a breakthrough.

C. LOOKING BACK AT THE DEVELOPMENT OF *PRIMA FACIE* ANTICIPATION

The idea that the endpoints of prior art ranges are not specifically anticipatory first arose as *dictum* in *In re Malagari* (C.C.P.A. 1974).[204] The C.C.P.A. seemed intrigued by Malagari's argument that "the disclosure of the endpoint of a prior art range ought to be given no greater significance as prior art than individual points within the range disclosed by a prior art reference."[205] Yet the court's interest was academic. Because it decided the case on § 103, not § 102 grounds, this prescient comment was *dictum*.[206]

Two relevant Federal Circuit decisions preceding *Atofina/ClearValue* suggest, however, that the formulation of *prima facie* anticipation was not in the court's mind before *Atofina/ClearValue*. The first case is *Atlas Powder Co. v. Ireco Inc.* (Fed. Cir. 1999)[207] and the second is *Perricone v. Medicis Pharmaceutical Corp.* (Fed. Cir. 2005).[208]

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[204] *In re* Malagari, 499 F.2d 1297, 1303 (C.C.P.A. 1974).

[205] *Id.* at 1302–03.

[206] *See id.*

[207] *See generally* Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342 (Fed. Cir. 1999).

[208] *See generally* Perricone v. Medicis Pharm. Corp., 432 F.3d 1368 (Fed. Cir. 2005).

The claim in *Atlas Powder* is to a blasting composition with percentage ranges of several components.[209] The following table is taken from the court's decision:[210]

Table 6. Partial Claim Chart for Claim 1 of U.S. Patent No. 4,111,727 and its reissue, U.S. Patent No. RE 33,788

	Claimed Ranges	**Prior Art #1**	**Prior Art #2**
Composition contents:			
Water-in-oil Emulsion	10–40%	20–67%	30–50%
Solid Ammonium Nitrate	60–90%	33–80%	50–70%
Emulsion contents:			
Ammonium Nitrate	70–90%	50–70%	65–85%
Water	About 3–15%	About 15–about 35%	7–27%
Fuel Oil	About 2–15%	About 5–about 20%	2–27%
Emulsifier	0.1–5%	About 1–5%	0.5–15%

The claimed ranges partly overlap the prior art ranges. These are scenarios that, under *Atofina*/*ClearValue*, would result in *prima facie* anticipation. Yet the Federal Circuit affirmed the lower court's finding of conclusive anticipation.[211] Citing *Titanium Metals*, the court held that the claim "read on" the prior art.[212] It added that "when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim."[213] The only element of the claim that warranted further analysis was not in the claimed numerical ranges or their criticality. That is because the claim contains another—functional—limitation, that "sufficient

[209] *Atlas Powder Co.*, 190 F.3d at 1343–44.

[210] *Id.* at 1345.

[211] *Id.* at 1350.

[212] *Id.* at 1346, 1350 (citing *Titanium Metals Corp.*, 778 F.2d at 781).

[213] *Id.* at 1346 (citing *Titanium Metals Corp.*, 778 F.2d at 780–82).

aeration is entrapped to enhance sensitivity to a substantial degree."[214] This limitation is not expressly disclosed in the prior art. The court analyzed this limitation in detail and held that it was met inherently by the prior art.[215] It seems clear to us, therefore, that the court in *Atlas Powder* treated the endpoints of the prior art ranges as specifically anticipatory numbers.

The second case, *Perricone*, was decided a mere three months before *Atofina*.[216] There were several claims at play in the '063 patent. Claim 9 is to a method of treating damaged skin by topically applying a composition containing "an effective amount of an ascorbyl fatty acid ester in a dermatologically acceptable" carrier.[217] The closest prior art, Pereira, disclosed a dermatological composition with "'from 0.01 to 20% of . . . [a]scorbyl palmitate.'"[218] The court affirmed the lower court's decision that the Pereira range was an "'effective amount,'"[219] as required by claim 9. We take no issue with this conclusion. We also take no issue with the court's decision on two of the three dependent claims. Claim 3 requires "from about 0.025% to about 5% by weight" and claim 22 requires "from about 0.025% to about 10% by weight."[220] The Pereira prior art range fully subsumes these two claimed ranges. As we have seen from *Atofina* Scenario 1, fully subsuming prior art does not raise *prima facie* anticipation in that it is not considered by the court to be a partial overlap. Yet it is not clear that the rather large subsuming ranges of Pereira conclusively anticipate under the "immediately envisaging" case law. The court certainly did not say so. Its holding that these prior art subsuming ranges anticipate the claimed narrower range seems, to us, to be less than rigorous.[221]

There was a third dependent claim in *Perricone*: claim 2, which requires "up to 10% by weight" of the fatty acid ester.[222] We will focus on claim 2 because the court's decision reveals that the court, at this time, had not yet formulated the

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214 *Atlas Powder Co.*, 190 F.3d at 1344.

215 *Id.* at 1349.

216 *See generally Perricone*, 432 F.3d 1368.

217 *Id.* at 1373.

218 *Id.* at 1376 (citing U.S. Patent No. 4,981,845 A, col. 1, ll. 55–68 (issued Jan. 1, 1999)).

219 *Perricone*, 432 F.3d at 1377 (citing U.S. Patent No. 4,981,845 A, col. 14, ll. 30–40 (issued Jan. 1, 1999)).

220 *Id.* at 1377.

221 *See id.* at 1377–79.

222 *Id.* at 1377.

Atofina/*ClearValue* framework for *prima facie* anticipation. Logic requires that the amount of the critical fatty acid ester in the claim not be zero, less the claim convert into nothing but a composition comprising a dermatological carrier. Therefore, we must conclude that the limitation of "up to 10% by weight" means a range from a non-zero amount to 10% of the active fatty acid ester. When looked at this way, the claimed range and the Pereira range of 0.01 to 20% partly overlap. Yet the court held that the claim was conclusively anticipated by Pereira.[223] Had the court applied its later *Atofina*/*ClearValue* analysis, it would have held claim 2 *prima facie* anticipated and required evidence of criticality of the claimed range over the range in Pereira.

The decisions in *Atlas Powder* and *Perricone* lead us to conclude that *Atofina*/*ClearValue* was a breakthrough in the case law. *Atofina*/*ClearValue* established a novel framework for viewing and analyzing anticipation of claimed ranges that partly overlap with ranges in the prior art. Having reached this conclusion, let us now look at cases decided in the wake of *Atofina*/*ClearValue*. We will focus especially on proof of criticality as rebutting evidence.

D. CRITICALITY AS PART OF THE *ATOFINA*/*CLEARVALUE* FRAMEWORK

Let us examine how the Federal Circuit has gone from the *Atofina*/*ClearValue* concept of claimed range criticality to where we are today. The road is bumpy and goes through several decisions: *Atofin*a[224] itself, *ClearValue*,[225] *OSRAM Sylvania*,[226] *Ineos USA LLC v. Berry Plastics Corp.*,[227] and *Genentech, Inc. v. Hospira, Inc*.[228]

Recall the basic facts in *Atofina*. There was one prior art range (150–350˚C) that partly overlapped the claimed range (330–450˚C).[229] The opinion made no mention of any criticality of the claimed range compared to the prior art.[230] The

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223 *Id.*

224 *See generally Atofina*, 441 F.3d at 991.

225 *See generally ClearValue*, 668 F.3d at 1340.

226 *See generally OSRAM Sylvania*, 701 F.3d at 698.

227 *See generally* Ineos USA LLC v. Berry Plastics Corp., 783 F.3d 865 (Fed. Cir. 2015).

228 *See generally* Genentech, Inc. v. Hospira, Inc., 946 F.3d 1333 (Fed. Cir. 2020).

229 *Atofina*, 441 F.3d at 993.

230 There is only one mention of criticality in *Atofina*, and it is in the section on Infringement. *Id.* at 997. It refers to the criticality of using a chromium catalyst alone, not in combination with other metals. *Id.*

initial explanation behind the no anticipation holding in *Atofina* was based solely on the large size of the prior art ranges.[231] As we have seen, it was the court in *ClearValue* that added the element of "criticality" to the *Atofina* decision.[232]

Looking back, the court in *ClearValue* explained that it had based its decision of no anticipation in *Atofina* on two premises: *first*, the prior art range was too large; and *second*, the claim owner showed that the claimed range was critical.[233] You may recall that this post-decision reconstruction of the *Atofina* holding was based entirely on evidence in that case's Joint Appendix. After this clarification, the court used "criticality" as the main basis for distinguishing the facts in *ClearValue* from those in *Atofina*.[234] The court held that, in *ClearValue*, the claim owner had not properly rebutted the *prima facie* anticipation.[235] Unlike *Atofina*, there was no argument or proof of criticality. The claim owner in *ClearValue* did not argue that the "less than or equal to 50 ppm" limitation in claim 1 was critical, nor did they argue that the method claimed "work[ed] differently at different points within the prior art range of 150 ppm or less."[236]

In *OSRAM Sylvania*,[237] decided a few months after *ClearValue*, the Federal Circuit fully embraced the *Atofina*/*ClearValue* framework. The court reversed a Motion for Summary Judgment (MSJ) that the lower court had entered in favor of the challenger.[238] It instructed the lower court to consider evidence of the relative sizes of claimed and prior art genus and subgenus ranges.[239] It also instructed the lower court to consider evidence of criticality: in particular, whether "the limitation of less than 0.5 torr is central to the invention claimed . . . and that a

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231 *Id.* at 999.

232 *ClearValue*, 668 F.3d at 1345.

233 *Id.*

234 *Id.*

235 *Id.*

236 *Id.*

237 *See OSRAM Sylvania*, 701 F.3d at 705–06 (explaining the Federal Circuit's decisions in *Atofina* and *ClearValue* and applying them to the evidence presented at hand).

238 *Id.* at 709.

239 *Id.* at 706.

lamp would operate differently at various points within the range disclosed in the [prior art].[240]

Three years later came *Ineos*.[241] As in *OSRAM Sylvania*, the lower court had terminated the case on a MSJ, and the Federal Circuit was asked to review the decision.[242] The invention was a lubrication agent that improves the operability of bottle caps.[243] The claim and prior art are as follows:

Table 7. Partial Claim Chart for Claim 1 of U.S. Patent No. 6,846,863 B2

Claimed ranges A lubricating agent comprising:	**Prior art** Lubricating agent includes:
[Limitation 2] 0.05 to 0.5% by weight of at least one saturated fatty acid amide[244]	[A] total quantity of *at least* 0.1 part by weight per 100 parts by weight of polyolefin, in particular of *at least* 0.2 parts by weight, quantities of *at least* 0.4 parts by weight being the most common ones; the total quantity of lubricating agents *does not exceed* 5 parts by weight, more especially 2 parts by weight, *maximum values* of 1 part by weight per 100 parts by weight of polyolefin being recommended.[245]

The main issue in dispute concerned anticipation of claim limitation [2], a range of 0.05 to 0.5% of an amide.[246] In addressing this issue, the Federal Circuit, citing *Atofina*, held that the prior art terms, "at least," "does not exceed," and "maximum values" denote range endpoints, not specific examples. [247] The court

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240 *See id.* at 706, 709 (explaining the lower court's failure to correctly apply *Atofina* and *Clearvalue* and therefore consider evidence of criticality and remanding the matter for trial).

241 *See generally Ineos*, 783 F.3d at 865.

242 *Id.* at 866.

243 *Id.* at 867.

244 *Id.*

245 *Id.* (emphasis added).

246 *Id.*

247 *See Ineos*, 783 F.3d at 869 (explaining how the lower court erred in its conclusion as to the anticipation of claim limitation 2 because the phrases "at

confirmed that disclosure of such endpoints does not constitute conclusive anticipation.[248] However, relying on *Atofina/ClearValue*, the court focused its attention on criticality:

> [W]hen the prior art discloses a range, rather than a point, the court must evaluate whether the patentee has established that the claimed range is critical to the operability of the claimed invention. Here, however, Ineos failed to put forth facts in opposition to summary judgment that created a genuine issue of material fact about the criticality of the range of limitation. There is no evidence that the operability of the bottle cap would be improved by the claimed range.[249]

The court distinguished *OSRAM Sylvania*, where it had reversed the MSJ because the claim owner *had* produced evidence that the claimed range was critical—and the evidence had to be considered on remand.[250] In *Ineos*, by contrast, the Federal Circuit affirmed the MSJ.[251] At best, Ineos had produced one inventor's testimony stating that the range claimed in limitation [2] "is critical to avoid unnecessary manufacturing costs and the appearance of undesirable blemishes on the bottle caps."[252] The court, however, held that this evidence was not related to the claimed invention:

> [Even] if true, this has nothing to do with the operability or functionality of the claimed invention. Ineos has not established any relationship between avoided cost and prevention of undesirable blemishes, and the claimed invention's slip properties or elimination of odor and taste problems . . . While we do not rule out the possibility that testimony concerning reduced

least" and "does not exceed" clearly disclose ranges, not particular individual values).

248 *Id.*

249 *Id.* at 871.

250 *Id.* at 870.

251 *Id.* at 871.

252 *Id.* at 870.

> manufacturing costs could be relevant where a method of manufacture claim is at issue, this is not the case before us.[253]

Through its decisions in *ClearValue*, *OSRAM Sylvania*, and *Ineos* the Federal Circuit has reached a consistent level of analysis on the role of criticality. In order to successfully rebut *prima facie* anticipation by partly overlapping ranges in the prior art, the proof of criticality must be "central to the invention claimed,"[254] and must be "related to the operability or functionality of the claimed invention."[255]

Let us now look at the interesting instances where the prior art simultaneously raises *prima facie* anticipation and *prima facie* obviousness.

E. Interplay between *Prima Facie* Anticipation & *Prima Facie* Obviousness

In situations of partly overlapping prior art ranges, both *prima facie* anticipation and *prima facie* obviousness can co-exist. As we have discussed in the previous sections, if the partly overlapping prior art range is small relative to the claimed range and individual points can be readily envisaged, the result may be conclusive anticipation, and the case ends. If the partly overlapping prior art range is relatively large compared to the claim, then both *prima facie* anticipation and obviousness can arise at the same time, and both must be rebutted by the claim owner. The *prima facie* anticipation challenge can be rebutted with evidence of criticality and the *prima facie* obviousness challenge can be rebutted by evidence of objective indicia of non-obviousness. The potential simultaneity of both challenges has only recently been analyzed by the Federal Circuit.

Genentech provides an illustration of the interplay between anticipation and obviousness.[256] Claim 1 is as follows:

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253 *Ineos*, 783 F.3d at 871.

254 *See OSRAM Sylvania*, 701 F.3d at 706 (explaining that the district court's finding of anticipation warrants reversal because it failed to consider evidence of criticality that was "central to the invention claimed in the '905 patent").

255 *See Ineos*, 783 F.3d at 871 (finding that Ineos had not shown a genuine issue of material fact about the criticality of the range of limitation because its evidence was not related to the "operability or functionality of the claimed invention").

256 *See Genentech*, 946 F.3d at 1337–42 (discussing both *prima facie* anticipation and obviousness challenges and stating that both can be rebutted by the claim

> A method of purifying a protein which comprises CH_2/CH_3 region, comprising subjecting a composition comprising said protein to protein A affinity chromatography at a temperature in the range *from about 10˚C to about 18˚C*.[257]

A prior art reference, which also taught a method for purifying proteins comprising a CH_2/CH_3 region by protein A affinity chromatography, disclosed that "[a]ll steps are carried out at room temperature (18–25˚C)."[258] This is sub-scenario (B) in Figure 6.[259] On appeal from the PTAB, the Federal Circuit reviewed two rejections each of claims 1 and 5: one based on *prima facie* anticipation and the other on *prima facie* obviousness.[260]

The court held that because the prior art and the claimed ranges partly overlapped at 18˚C, the claims were *prima facie* anticipated by the prior art.[261] Citing *E.I. DuPont de Nemours & Co. v Synvina C.V.* (Fed. Cir. 2018)[262] and *Galderma*,[263] the court explained that the burden of production of evidence showing criticality then fell upon the claim owner.[264] Interestingly, these two cases deal with *prima facie* obviousness, not *prima facie* anticipation.[265] The clear implication is that, whether in *prima facie* obviousness or *prima facie* anticipation, the shifting of the burden of production is identical. As we will discuss below, although these rebuttals share a commonality, they are not identical.

In *Genentech*, the claim owner did not put forth any evidence that the claimed range resulted in different outcomes or that other ranges would be inoperable. The claim owner only argued that the prior art range of 18–25˚C was limited to the laboratory room, not to the actual chromatographic column.[266] The

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owner through showing evidence of criticality of the claimed range of the invention).

257 *Id.* at 1336 (emphasis added).

258 *Id.* at 1337 (internal quotations omitted).

259 *See supra* at Figure 6.

260 *Genentech*, 946 F.3d at 1335.

261 *Id.* at 1338–40.

262 *See generally* E.I. DuPont de Nemours & Co. v. Synvina C.V., 904 F.3d 996, 1008 (Fed. Cir. 2018).

263 *Galderma Lab'ys*, 737 F.3d at 738.

264 *Genentech*, 946 F.3d at 1338.

265 *See generally E.I. Dupont*, 904 F.3d at 996; *Galderma Lab'ys*, 737 F.3d at 731.

266 *Genentech*, 946 F.3d at 1339.

Federal Circuit disagreed and affirmed the PTAB's ruling that the abutting temperature also applied to the columns.[267] The court concluded that the *prima facie* anticipation remained unrebutted and held that both claims 1 and 5 were anticipated.[268]

The PTAB had also rejected claims 1 and 5 (and others) based on *prima facie* obviousness over the same prior art reference and raised the same issue of overlap at 18°C.[269] It is rare for the Federal Circuit to review additional grounds of claim rejections when it has already affirmed invalidity on a ground like anticipation—yet it did so in this case.[270] The court concluded that, because the prior art reference disclosed an overlapping but different range than the claimed range, *prima facie* obviousness also existed.[271]

Since the court was now dealing with obviousness, it first asked the standard obviousness inquiry in range situations: Is the temperature of protein A chromatography result-effective?[272] The answer was yes.[273] There was sufficient evidence that the temperature of chromatography was known to be result-effective, and thus a POSA would have been motivated to optimize the temperature.[274] The court then looked at objective indicia of non-obviousness.[275] The claim owner presented evidence of industry praise.[276] The court, however, did not find it persuasive because it failed to show a nexus between the praise and the claim.[277] Claims 1 and 5 were not solely held anticipated; they were also held obvious over the same prior art.[278]

A more recent case, *UCB, Inc.*, also dealt with simultaneous anticipation and obviousness. You will recall that the Federal Circuit held that by misapplying the "immediately envisage" test of *Kennametal*, the lower court erred and turned a

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267 *Id.* at 1339–40.

268 *Id.* at 1340.

269 *Id.* at 1340–41.

270 *Id.*

271 *Id.* at 1341.

272 *Genentech*, 946 F.3d at 1341.

273 *Id.* at 1342.

274 *Id.* at 1341–42.

275 *Id.* at 1342.

276 *Id.*

277 *Id.*

278 *Genentech*, 946 F.3d at 1342.

case of ranges (where the endpoints are not specific anticipations) into a case of exemplified points within the range.[279] This was error, said the court, yet it did not do its own analysis of range versus range, thus sidestepping the *Atofina*/*ClearValue* framework.[280] Instead, the court analyzed obviousness and held the claim invalid under § 103, affirming on that ground alone.[281]

The Federal Circuit has recognized that in certain scenarios of partly overlapping ranges, such as those in *Genentech* or *UCB, Inc.*, there can be simultaneous *prima facie* anticipation and obviousness—and both presumptions must be subsequently rebutted by the claim owner. The issues we wish to analyze are: What evidence can be mustered for the rebuttals? How different is the evidence of rebuttal for *prima facie* anticipation from that of *prima facie* obviousness? We discuss these questions next.

V. REBUTTING *PRIMA FACIE* OBVIOUSNESS AND *PRIMA FACIE* ANTICIPATION

Let us start with evidence of criticality to rebut *prima facie* anticipation. There are several ways that a claim owner may try to show that their claimed range is critical.

In *Atofina*, the claim owner pointed to statements in its patent specification and in its prosecution showing that the range was critical to operability, and the court found such evidence persuasive.[282] The court in *ClearValue* added that a claim owner may also argue or demonstrate that their invention will not work outside of the claimed range.[283] The claim owner can also argue that the prior art does not enable the claimed range.[284]

Logically, the claim owner can rely on trial testimony to show that the claimed range is critical. As we have seen, for any evidence of criticality to be

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279 *UCB*, 65 F.4th at 687–88.

280 *Id.* at 687–89.

281 *Id.* at 697.

282 *See Atofina*, 441 F.3d at 998–1000.

283 *ClearValue*, 668 F.3d at 1345 (contrasting *ClearValue*, where no considerable difference between the claimed range and range in the prior art were found, from *Atofina* where considerable difference between the claimed range and the range in the prior art precluded a finding of anticipation).

284 *See id.* ("ClearValue [does not] argue that the [prior art] reference fails to teach one of ordinary skill in the art how to use the claimed invention, i.e., that [it] is not enabled to the extent required to practice claim 1.").

persuasive, however, it must be associated with the "operability or functionality of the claimed invention."[285]

In contrast, a presumption of obviousness of a claimed range can be rebutted with classical evidence of objective indicia of non-obviousness.[286] These include criticality of the range, a proof that, as discussed, overlaps with the evidence necessary to rebut *prima facie* anticipation. Criticality for non-obviousness is usually shown by demonstrating unexpected results when operating within, but not outside, the claimed range.[287]

Other objective indicia of non-obviousness could also be used to show criticality in rebutting anticipation. For example, it may be possible to show long-felt but unresolved needs that were only resolved when working within the claimed range but not outside it. Also available would be failure of others, skepticism, copying by competitors, and commercial success—all when operating within, but not outside, the claimed range. Commercial success is a classic, but classically fraught, objective indicia of non-obviousness.[288] To turn evidence of commercial success into evidence of criticality, the claim owner must demonstrate that the invention is commercially successful due to the claimed range, but not to features outside it.[289] However, this is not a simple task considering that evidence of commercial success is often readily negated by the existence of blocking patents, as in *UCB, Inc.*,[290] or by a lack of nexus between the claim and the success, as in *Genentech*.[291]

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285 *Ineos*, 783 F.3d at 870–871 (explaining that the testimony that Ineos attempted to use to show the criticality of a claimed range was unpersuasive as it had "nothing to do with the operability or functionality of the claimed invention" (internal quotation marks omitted)).

286 *See, e.g.*, JORGE A. GOLDSTEIN, U.S. BIOTECHNOLOGY PATENT LAW § 10:7 (2024).

287 *See* Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311 (Fed. Cir. 2006). A presumption of obviousness in partly overlapping prior art and claimed ranges can be overcome if it can be shown that ". . . the claimed range produces new and unexpected results." *Id.*

288 *See, generally,* JANICE M. MUELLER, PATENT LAW ch. 5, § H.2 (5th ed. 2016).

289 *Ormco Corp.*, 463 F.3d at 1312.

290 *UCB*, 65 F.4th at 695–97 (explaining that evidence of UCB's ritigotine TTS patent commercial success was weak because of the existence of blocking patents dissuading competitors from developing other ritigotine TTS).

291 *Genentech*, 946 F.3d at 1342 (explaining that Genentech's evidence of commercial success based on a selection of a presentation of its claimed method at the American Chemical Society's National Meeting in 2005 was insufficient as evidence of criticality due to a lack of nexus between the claim

While criticality of the claimed range is common to rebutting both *prima facie* cases of obviousness and of anticipation, there are defenses that will work in one but not the other. For example, non-recognition of a claimed range parameter as "result-effective" works in rebutting *prima facie* obviousness but not in rebutting *prima facie* anticipation.[292] Teaching away, while a good argument to defend against obviousness, is not available for anticipation.[293] In contrast, while lack of enablement is a good argument to defend against anticipation based on a single item of prior art,[294] lack of enablement of any one item of prior is not available for *prima facie* obviousness based on a combination of multiple items.[295]

VI. CONCLUSION

The Federal Circuit has long- and well-established standards for determining whether a claimed range is *prima facie* obvious or conclusively anticipated over a prior art reference disclosing a similar range. We have tried in this article to clarify the more recently minted doctrine of *prima facie* anticipation over a prior art range.

The law regarding *prima facie* anticipation of ranges is nuanced. After *Atofina* the endpoints of ranges are not treated as exemplified values. When a prior art endpoint falls within, or abuts the endpoint of, a claimed range, it does not conclusively anticipate but instead raises a *prima facie* case of anticipation. That

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and the success because Genentech could not prove that the presentation was selected due to the claimed method).

[292] *In re Haase*, 542 Fed. App'x at 967.

[293] *ClearValue*, 668 F.3d at 1344 (quoting *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998)) ("Although this alleged teaching away would be relevant to an obviousness analysis, 'whether a reference teaches away from [an] invention is inapplicable to an anticipation analysis.'").

[294] *See id.* ("To anticipate a patent claim under 35 U.S.C. §102, 'a reference must describe…each and every claim limitation and enable one of skill in the art to practice an embodiment of the claimed invention without undue experimentation.'").

[295] *See* Raytheon Techs. v. Gen. Elec. Co., 993 F.3d 1374, 1380 (Fed. Cir. 2021) ("To render a claim obvious, the prior art, taken as a whole, must enable a skilled artisan to make and use the claimed invention [citation omitted]. In general, a prior art reference asserted under § 103 does not necessarily have to enable its own disclosure, i.e., be 'self-enabling,' to be relevant to the obviousness inquiry.").

was not always the case, as demonstrated by *Atlas Powder*[296] and *Perricone*,[297] two cases preceding *Atofina*, in which the court appeared to still be treating prior art endpoints as conclusively anticipatory.[298]

The doctrine of rebuttable anticipation arose tentatively, almost *sub silentio*, in *Atofina*. Yet the concept of demonstrating criticality of the claimed range to rebut the presumption did not crystallize in the court's reasoning until six years later in *ClearValue*. Both cases established what we call the *Atofina*/*ClearValue* framework. By distinguishing its reversal of the MSJ in *OSRAM Sylvania* from its affirmance of the MSJ in *Ineos*, the Federal Circuit has also clarified what it does or does not consider convincing evidence of criticality to successfully rebut *prima facie* anticipation.

The following flowchart should provide a useful recap for orienting future range analyses:

[296] *See generally Atlas Powder Co.*, 190 F.3d at 1342.

[297] *See generally Perricone*, 432 F.3d at 1368.

[298] *Atlas Powder Co.*, 190 F.3d at 1346–50; *Perricone*, 432 F.3d at 1375–77.

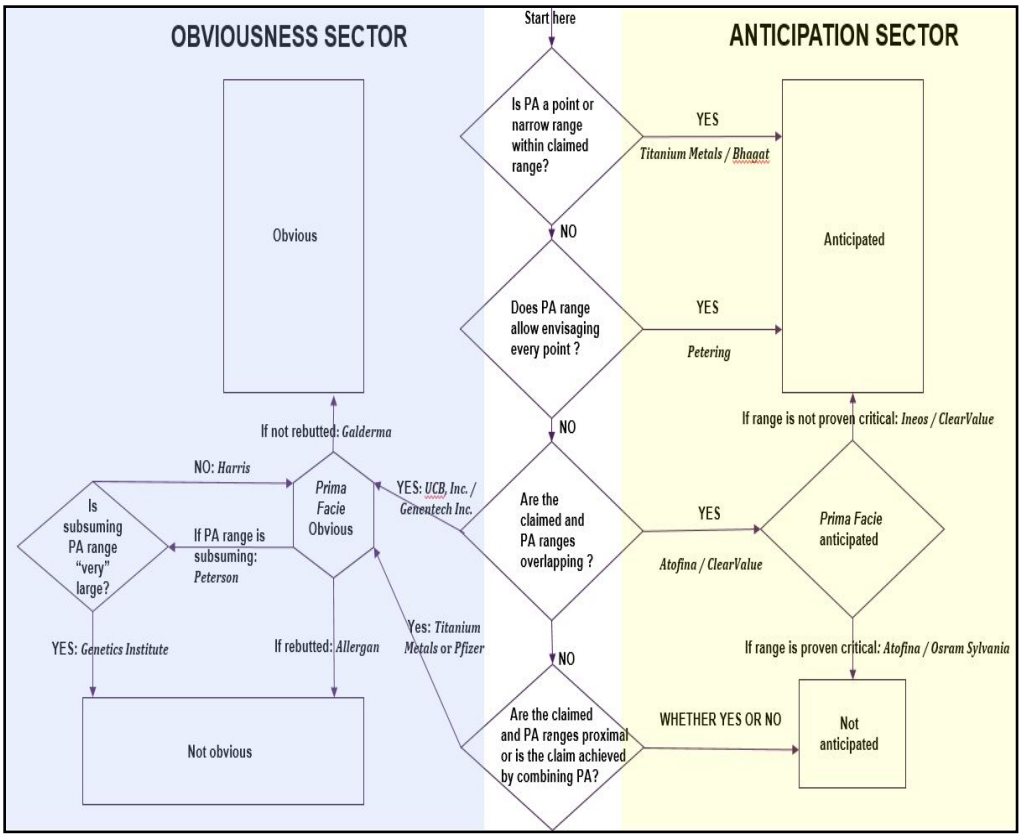

Figure 7. Range Analyses Flowchart.

The central column of the flowchart shows four diamonds, each representing a decision point. Starting at the center top, each diamond poses one or more queries about the relation between the claimed and prior art (PA) ranges. For example: Does the prior art range allow envisaging every point? Do the ranges overlap? Are the prior art and claimed ranges proximal? The answer to each query leads either to the left or to the right sectors of the flowchart. To the left of the chart is the OBVIOUSNESS SECTOR and to the right is the ANTICIPATION SECTOR. Within each sector, and depending on sub-queries, the reasoning flows either to the top of each (for a finding of anticipation or of obviousness), or to the bottom of each (for a finding of no anticipation or non-obviousness).

The flowchart distinguishes among four general circumstances.

First, focusing on the top right-hand corner of the chart, there are two instances of conclusive (*i.e.*, non-rebuttable) anticipation, flowing off the first and second diamonds, respectively. The two instances are found in the ANTICIPATION SECTOR of the chart. They are: (1) when the prior art discloses a

point or a smaller range *within* the claimed range (*Titanium Metals, Bhagat*); and (2) when the prior art range *fully* subsumes the claimed range and the prior art range is "small"—*i.e.*, when a POSA can "at once envisage each member" of the prior art range (*Petering*). In both instances, the prior art conclusively anticipates the claimed range, and the claim owner cannot rebut such anticipation. As we have discussed, the determination regarding whether a claimed range is "small" under the "immediately envisage" anticipation analysis is highly fact-dependent—and, in most instances, such facts will be best supported by carefully crafted expert testimony.

Second, focusing on the fourth diamond in the central column of the chart, there are two range circumstances where only *prima facie* obviousness—but neither *prima facie* (*i.e.*, rebuttable) anticipation nor conclusive anticipation—may apply. The two range circumstances are found in the OBVIOUSNESS SECTOR of the flowchart. They are: (1) when the prior art range and claimed range are *proximal*, but do not abut or overlap (*Titanium Metals*); and (2) when the prior art range is "created" by combining multiple references (*Pfizer*). These are well-established legal principles.

Third, focusing on the third diamond in the central column of the flowchart, i.e., when the claimed and prior art ranges partly overlap, both *prima facie* anticipation (*Atofina*/*ClearValue*) and *prima facie* obviousness (*UCB, Inc.* and *Genentech*) apply. These simultaneous possibilities lead to both the ANTICIPATION and OBVIOUSNESS SECTORS of the chart. The rebuttal for either differs depending on which is challenged: (1) *prima facie* obviousness based on an overlapping prior art range (as in *UCB, Inc.* or *Genentech*), can be rebutted with classical evidence of non-obviousness, including objective indicia of non-obviousness (*Allergan*). In contrast, (2) *prima facie* anticipation based on a partly overlapping prior art range (as in *Atofina,* **Scenario 2**) can be rebutted with evidence of criticality (*Atofina, Osram Sylvania*).

When analyzing *Osram Sylvania* in Section IV.B., we concluded that where the prior art range partly overlaps the claimed range, "immediately envisage" case law may still be applied as a *first* step in an anticipation analysis. But, if a POSA *cannot* immediately envisage each point of the range, the court must apply a *prima facie* anticipation analysis under *Atofina*/*ClearValue*.

Fourth, as shown in the lower portion of the OBVIOUSNESS SECTOR, when the prior art fully subsumes the claimed range, *prima facie* obviousness may apply (*Peterson*). However, following *Atofina* **Scenario 1,** there is no *prima facie* anticipation, only *prima facie* obviousness.

In both obviousness and anticipation analysis, the size of the prior art range is relevant, but for different reasons. Still focusing on the lower portion of the OBVIOUSNESS SECTOR, in the evaluation of "size" in obviousness analysis

the central question is optimization: if the prior art range is so large that a POSA would *not* be motivated to optimize it, there is no *prima facie* obviousness (*Genetics Institute*). However, if the prior art range is small enough to encourage experimentation to optimize a result-effective variable, *prima facie* obviousness exists (*Harris*). In contrast, for anticipation analysis the definition of "size" relates to the doctrine of immediately envisaging every point of a prior art range (*Petering*).

As we discussed in Section V., where both *prima facie* obviousness and *prima facie* anticipation are raised based on partly overlapping ranges, the prudent claim owner may want to use evidence of criticality to rebut both of them.

As we have shown, the prior art may raise instances of *prima facie* obviousness, conclusive anticipation, rebuttable anticipation, or simultaneous *prima facie* anticipation and obviousness. We hope that this article has provided practitioners with the proper framework for contesting or defending the multiple issues that arise on the patentability of claims with ranges.