

## Fed. Circ. Instructive On Transitional Phrases In Patent Claims

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Transitional phrases such as "consisting essentially of," "comprising" or "consisting of" define a patent claim's scope as open or closed. This, in turn, controls which unrecited additional components or steps, if any, the claim encompasses. These transitional phrases carry certain presumptions that may be best understood in the context of infringement.

For example, the use of "comprising" creates a presumption that the body of the claim is open — that is, "[t]he addition of elements not recited in the claim cannot defeat infringement."<sup>[1]</sup> But "consisting of" is presumptively closed — that is, the presence of "any elements, steps, or ingredients not specified in the claim" generally forecloses infringement.<sup>[2]</sup>

And, as "a middle ground between the open-ended term 'comprising' and the closed-ended phrase 'consisting of,'"<sup>[3]</sup> there is no infringement of a claim using "consisting essentially of" "where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention."<sup>[4]</sup>

But these presumptions are not absolutes. For example, even though "comprising" presumptively permits the presence of additional, unrecited components, the transitional phrase cannot be used as "weasel word[s] with which to abrogate claim limitations."<sup>[5]</sup> And it "does not displace, or otherwise allow one to disregard, the patent specification."<sup>[6]</sup>

Similarly, although the term "consisting essentially of" presumptively allows for trace amounts of unclaimed ingredients not materially affecting the invention's basic and novel properties, this presumption is overcome where so construing the claim would negate another limitation.<sup>[7]</sup>

The U.S. Court of Appeals for the Federal Circuit addressed the application of traditional transitional phrases and their presumptions in *HZNP Medicines LLC v. Actavis Laboratories UT Inc.*<sup>[8]</sup> and *Amgen Inc. v. Amneal Pharmaceuticals LLC.*<sup>[9]</sup> Although specific to the particular claims at issue, the decisions nevertheless provide key guidance for practitioners drafting claims, alleging infringement or construing claims. The main takeaways follow.



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## **HZNP Medicines v. Actavis Laboratories UT**

A split Federal Circuit panel in HZNP Medicines upheld the U.S. District Court for the District of New Jersey's invalidity decision where the phrase "consisting essentially of" rendered the asserted claims indefinite.[10]

HZNP Medicines and Horizon Pharma USA Inc. sued Actavis Laboratories following its submission of an abbreviated new drug application for a generic version of Horizon's Pennsaid 2%. Horizon alleged that Actavis' proposed drug label infringed Horizon's method-of-use and formulation patents covering the product.

### ***Majority Opinion***

Affirming the decision below, the majority noted that the "consisting essentially of" phrase "permit[s] inclusion of components not listed in the claim, provided they do not materially affect the basic and novel properties of the invention." [11]

First, the majority determined that the formulation patents identify five "basic and novel properties": (1) better drying time, (2) higher viscosity, (3) increased transdermal flux, (4) greater pharmacokinetic absorption, and (5) favorable stability.[12] The majority found that the specification's listing of each of the properties as separate subheadings shows the properties' importance and describes how they improve the prior art.[13]

Second, the court considered whether those properties were definite. Specifically, the majority explained that courts must apply the Nautilus definiteness standard to each of the "basic and novel properties" to assess whether any fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. If any property were indefinite, the phrase "consisting essentially of" would be indefinite as well.

The majority agreed with the district court's determination that the property of better drying time was indefinite because the specification provided two different methods for evaluating better drying time that failed to provide consistent results at consistent times.[14] Thus, the majority concluded that property of better drying time is indefinite, which renders the entire phrase "consisting essentially of" indefinite.

The majority stressed that "the phrase 'consisting essentially of' is not per se indefinite"[15] and the patent owner is not required to "draft claims to an untenable level of specificity." [16] Instead, the majority explained that, "on these particular facts, the district court did not err in determining that the phrase 'consisting essentially of' was indefinite in light of the indefinite scope of the invention's basic and novel property of a 'better drying time.'" [17]

### ***Judge Newman's Dissent***

U.S. Circuit Judge Pauline Newman dissented from the majority's holdings that (1) the claim term "consisting essentially of" rendered the claims indefinite and (2) the knowledge of persons skilled in the art cannot fill any gap in providing the properties of compositions claimed with that term.[18] According to Judge Newman, using "consisting essentially of" does not invalidate claims when the specification describes the claimed formulation's properties, regardless of whether the claims repeat those properties.[19]

Judge Newman challenged the majority's distinction between "consisting of" and "consisting essentially of" as "unsupported in precedent." [20] Although she acknowledged precedent that distinguishes the two phrases on the ground that "'consisting of' limits the claimed invention" without "limit[ing] aspects unrelated to the invention," Judge Newman reasoned that "no precedent has held that 'consisting essentially of' composition claims are invalid unless they include the properties of the composition in the claims." [21]

Judge Newman further accused the majority of ignoring the clear and convincing evidence standard for establishing indefiniteness. [22] In her view, no evidence — let alone clear and convincing evidence — showed that persons of ordinary skill in the art would not have understood the components of the composition claims with reasonable certainty. [23]

### **Amgen v. Amneal Pharmaceuticals**

In Amgen, the Federal Circuit addressed the transitional phrases "comprising" and "consisting of," reversing the U.S. District Court for the District of Delaware's construction of two Markush group limitations as closed to items other than those listed. [24]

Amgen had asserted U.S. Patent No. 9,375,405, which is directed to a rapid dissolution formulation of cinacalcet. [25] Representative claim 1 recites in relevant part:

1. A pharmaceutical composition comprising:

(a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg; ...

(c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and

(d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovidone, sodium starch glycolate, croscarmellose sodium, and mixtures thereof. [26]

A critical issue below was construction of the binder and disintegrant Markush groups in elements C and D. Amgen argued that the Markush groups recited in elements C and D should be construed as open-ended, but the district court disagreed. The district court held that "Amgen ha[d] not overcome the very strong presumption that the Markush groups for the binder and disintegrant elements are closed to unrecited binders and disintegrants." [27]

Following a bench trial on infringement, the district court determined that Amneal does not infringe the asserted claims because, although Amneal uses a binder and disintegrant product falling within the respective Markush groups, it also uses a binder product and disintegrant product outside the Markush groups. Thus, Amneal's product does not literally meet the binder and disintegrant claim limitations. [28]

### **Federal Circuit Decision**

On appeal, Amgen argued that the claim's use of the "comprising" term "renders the claim open-ended,

even when other language restricts the scope of particular claim elements." [29] Amgen next pointed to the phrase "at least one" found in the binder and disintegrant limitations, arguing that the "consisting of" term "only applies to the group from which 'at least one' binder or disintegrant must be selected." [30]

Amgen also compared the binder and disintegrant limitations' use of "at least one" to element A's Markush group that did not. Amgen argued that this "at least one" language "would be meaningless if the groups are closed to additional binders and disintegrants and meaningless in view of the claim's recitations of 'mixtures thereof' within the Markush group." [31]

In response, the defendants argued that, inter alia, Amgen "failed to overcome the strong presumption that a claim term set off with 'consisting of' is closed to unrecited elements." [32]

Agreeing with Amgen and reversing the district court's construction, the Federal Circuit reiterated the "strong presumption" that a claim term introduced with "consisting of" is closed to unrecited elements and held that the facts in this case were distinguishable. [33]

The Federal Circuit explained that there is "no language in Amgen's claims indicating that every binder or disintegrant in the claimed formulation must be within the Markush groups, because the claim recites 'at least one' binder or disintegrant 'selected from the group consisting of' various excipients." [34] Thus, the plain language "requires 'at least one' of the Markush members and certainly does not indicate that the only binders and disintegrants in the claimed formulation are those listed in the groups." [35]

According to the Federal Circuit, use of the phrase "comprising" reinforces that additional binders and disintegrants not recited in the Markush group may be present in the claimed formulation. [36] As the court noted, the term "comprising" is "the standard transition term used to make clear that the claim does not preclude the presence of components or steps that are in addition to, though not inconsistent with, those recited in the limitations that follow." [37]

Accordingly, the claim's plain language confirms that the formulation must include at least one of the listed binders and disintegrants and may include unlisted binders and disintegrants.

## **Takeaways**

The Federal Circuit's opinions highlight issues that may arise in using transitional phrases to define the scope of an invention. With this backdrop, practitioners should be mindful of the following key points and guidelines when using these phrases to avoid potentially rendering a claim indefinite or opening a claim up to a prior art attack.

First, although the phrase "consisting essentially of" does not render the claim per se indefinite, each basic and novel property of the claimed invention that follows must satisfy the Nautilus definiteness standard. Consequently, practitioners may wish to avoid the use of such language and its associated risk particularly where it is not required to overcome a prior art reference.

Second, use of the phrase "consisting of" when preceded by other transitional language such as "comprising" or the phrase "at least one" does not preclude the presence of unrecited elements in whole or in part that following the phrase "consisting of."

Example claims 1A to 1D below illustrate the effect of different transitional phrases on the likely scope of the claim in view of the Federal Circuit's analysis.

1A. A composition comprising:

- (a) an active pharmaceutical ingredient; and
- (b) at least one excipient selected from the group consisting of A, B, C, and D.

1B. A composition comprising:

- (a) an active pharmaceutical ingredient; and
- (b) an excipient selected from the group consisting of A, B, C, and D.

1C. A composition consisting of:

- (a) an active pharmaceutical ingredient; and
- (b) an excipient selected from the group consisting of A, B, C, and D.

1D. A composition consisting essentially of:

- (a) an active pharmaceutical ingredient; and
- (b) an excipient selected from the group consisting of A, B, C, and D.

Despite the difference in wording, the composition in claim 1A and 1B would likely be interpreted to include the active pharmaceutical ingredient and not exclude unlisted excipients. In contrast, the composition in claim 1C would likely be interpreted to exclude an unlisted excipient.

Further, claim 1D would be interpreted to include components not listed in the claim (as opposed to claim 1C) provided they do not materially affect the basic and novel properties of the invention. However, it would further require an assessment of the basic and novel properties of the claimed formulations to determine if the claim is definite. Thus, practitioners should be mindful of the claim's scope and narrow it only as much as is required to meet the requirements of patentability.

As illustrated in *HZNP Medicines and Amgen*, the well-accepted meanings of these transitional phrases will not be disturbed absent clear indication in the intrinsic evidence that the patentee intended otherwise. Consequently, practitioners should take care in using these phrases to ensure that the issued claim's scope is as intended.

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- [1] *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371–72 (Fed. Cir. 2005).
- [2] *Shire Dev., LLC v. Watson Pharm., Inc.*, 848 F.3d 981, 984 (Fed. Cir. 2017).
- [3] *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).
- [4] *Yoon Ja Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1319–20 (Fed. Cir. 2006).
- [5] *Liberty Ammunition, Inc. v. United States*, 835 F.3d 1388, 1399 (Fed. Cir. 2016) (quoting *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007)).
- [6] *Raytheon Co. v. Sony Corp.*, 727 F. App’x 662, 672 (Fed. Cir. 2018)
- [7] See, e.g., *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 61 (Fed. Cir. 2002), cert. granted, judgment vacated on other grounds, 537 U.S. 802 (2002), on remand, 347 F.3d 1355 (Fed. Cir. 2003).
- [8] Nos. 2017-2149, -2152, -2153, -2202, -2203, -2206, slip op. (Fed. Cir. Oct. 10, 2019).
- [9] Nos. 2018-2414, 2019-1086, slip op. (Fed. Cir. Jan. 7, 2020).
- [10] This article does not address the Federal Circuit’s ruling on induced infringement.
- [11] *HZNP Meds.*, slip op. at 22 (internal citations omitted).
- [12] *Id.* at 23.
- [13] *Id.*
- [14] *Id.* at 29-30.
- [15] *Id.* at 24.
- [16] *Id.* at 33.
- [17] *Id.*
- [18] Dissent at 2.
- [19] *Id.* at 5-6.
- [20] *Id.* at 9-10.
- [21] *Id.* at 10.
- [22] *Id.* at 11.
- [23] *Id.*

[24] Id. at 19, 28.

[25] Id. at 2.

[26] Id. at 4.

[27] Id.

[28] Id. at 8.

[29] Id. at 12.

[30] Id. at 12-13.

[31] Id. at 13.

[32] Id.

[33] Id.

[34] Id. at 17-18.

[35] Id. at 18

[36] Id.

[37] Id.