Archetype IP℠
Federal Circuit Friday
www.archetype-ip.com March 2019

In *Forest Laboratories v. SigmaPharm Laboratories* (March 14), the Federal Circuit provided useful examples of two aspects of claim construction: (i) the circumstances under which a limitation not expressly recited can nevertheless be read into a claim; and (ii) the importance of grammar.

A. District Court correctly read a "sublingual or buccal formulation" limitation into a claim that did not recite those words.

The claim at issue recited:

> 1. A pharmaceutical composition comprising as a medicinally active compound:
>
> trans-5-chloro-2-methyl-2,3,3a, 12b-tetrahydro-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole or a pharmaceutically acceptable salt thereof;
>
> wherein the composition is a solid composition and disintegrates within 30 seconds in water at 37° C.

Whether the claim was limited to sublingual or buccal formulations[1] made a difference regarding the scope of the prior art – to help invalidate the claim SigmaPharm had wanted the claim construed to cover *any* dosage form that "disintegrates within 30 seconds in water at 37° C," which would have encompassed a prior art orally-administered tablet.

In general, it is inappropriate to read limitations from the specification into a claim.[2] Here, however, the Federal Circuit agreed with the district court that the claim was limited to sublingual or buccal formulations, based on the following rationale:

- The specification is critically important to understanding the correct claim construction.[3]
- Where the specification states that "the invention" has certain characteristics, those characteristics tend to limit the scope of the claims.[4] The following specification statements supported the narrower construction:
  - "The invention relates to a sublingual or buccal pharmaceutical composition"; and
  - "The invention therefore relates to a sublingual or buccal pharmaceutical."
- The title of the patent ("Sublingual or Buccal Pharmaceutical Composition") supported the narrower construction.[5]

---

[1] Sublingual or buccal formulations are administered by placing under the tongue or in the cheek, and offer different characteristics of onset, peak, and duration of action than orally-administered (*i.e.,* swallowed) dosage forms (sublingual or buccal formulations typically have much faster onset and reduced duration compared to typical oral formulations). *See, e.g.,* ANSEL'S PHARMACEUTICAL DOSAGE FORMS & DRUG DELIVERY SYSTEMS (8th Ed. 2005) p. 162-63.

[2] *See, e.g., 3M Innovative Properties v. Tredegar Corp.,* 725 F.3d 1315, 1321 (Fed. Cir. 2013)("While we construe the claims in light of the specification, limitations discussed in the specification may not be read into the claims."); *Hill-Rom Services v. Stryker*, 755 F.3d 1367, 1372 (Fed. Cir. 2014)(absent "words of manifest exclusion or restriction ... we do not import limitations from the specification into the claims.").

[3] Slip Op. at 5: "[C]laims 'must be read in view of the specification, of which they are a part.'"

[4] *Id.*: "When a patent . . . describes the features of the 'present invention' as a whole, this description limits the scope of the invention."

[5] *Id.* at 5.

- The claim language "disintegrates within 30 seconds in water at 37° C" is exactly how the patent defines "rapid dis-integration," and the specification states that "[p]referred pharmaceutical compositions are solid pharmaceutical compositions which *rapidly disintegrate* in the mouth of a subject, upon insertion into the buccal pouch or upon placement under the tongue."[6] The Federal Circuity found that this disclosure "strongly suggests that the language 'the composition is a solid composition and disintegrates within 30 seconds in water at 37° C' was meant to limit the claim to buccal and sublingual formulations."[7]

Practice Note: The Federal Circuit read the "sublingual or buccal" formulation limitation into the claim without expressly relying on the concepts of "disclaimer" or "lexicography" or otherwise discussing whether the specification statements are "words of manifest exclusion or restriction," and it is hard to see how specification statements that the invention "relates to" sublingual or buccal formulations meet the "exacting standards" of disclaimer and lexicography.[8] This case therefore either (i) represents a situation where the added "sublingual or buccal" limitation represents how a person of ordinary skill would understand the plain and ordinary meaning of the claims when read in the context of the specification and prosecution history, or (ii) demonstrates that "lexicography" and "disclaimer" are *not* the sole exceptions to the general rule of plain and ordinary meaning to a person of ordinary skill.[9]

***

Although not mentioned or relied upon by the Federal Circuit, the district court also looked at the file history, in which the original version of claim 1 recited "suitable for sublingual or buccal administration" but was changed to "wherein the composition is a solid composition and disintegrates within 30 seconds in water at 37° C" in response to the examiner's concern that the original language did not "result in a structural difference between the claimed invention and the prior art."[10] The applicants stated in their response accompanying the amendment that oral administration of "the active compound of the present invention results in serious cardiotoxic affects" and "[t]o obtain the good effects of the compositions of the present invention, it is necessary that the medicine be delivered by sublingual or buccal administration."[11] The district court criticized defendant's assertion that the claim embraces an orally-administered tablet as "expand[ing] its scope to cover the very subject matter that the applicants specifically distinguished their invention from during prosecution and in their patent specification," and found that "the statements made during prosecution demonstrate that the inventors limited the claims to sublingual or buccal compositions."[12]

---

[6] Emphasis added.

[7] *Id.* at 5-6.

[8] *See, e.g., GE Lighting Solutions v. Agilight, Inc.* 750 F.3d 1304, 1309 (Fed. Cir. 2014)("The standards for finding lexicography and disavowal are exacting. To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term,' and 'clearly express an intent to define the term.'" and "[s]imilarly, disavowal requires that 'the specification [or prosecution history] make[ ] clear that the invention does not include a particular feature.'").

[9] *See, e.g., Hill-Rom Services v. Stryker*, 755 F.3d 1367, 1372 (Fed. Cir. 2014):

> Claim terms are generally given their plain and ordinary meanings to one of skill in the art when read in the context of the specification and prosecution history. *See Phillips v. AWH Corp.,* 415 F.3d 1303, 1313 (Fed.Cir.2005) (en banc). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed.Cir.2012).

[10] June 30, 2017 Opinion in District of Delaware Case No. 1:14-cv-0119, pp.14-15.

[11] *Id.* at 17.

[12] *Id.* at 17, 18. This was an application of prosecution history disclaimer.

B. District Court incorrectly read "method for treating tension, excitation, anxiety, and psychotic and schizophrenic disorders" as excluding treatment of bipolar disorder.

The claim at issue recited:

> 4. A method for treating tension, excitation, anxiety, and psychotic and schizophrenic disorders, comprising administering sublingually or buccally an effective amount of a pharmaceutical composition comprising trans-5-chloro-2-methyl-2,3,3a,12b-tetrahydro-1H-dibenz[2,3:6,7]oxepino[4, 5-c]pyrrole or a pharmaceutically acceptable salt thereof.

The accused product was indicated for the treatment of "manic episodes" associated with bipolar disorder.

The district court construed the preamble language ("method for treating tension, excitation, anxiety, and psychotic and schizophrenic disorders") as a limitation and as not including bipolar disorder or manic episodes associated with bipolar disorder because (i) the word "bipolar" does not appear in the claim or the specification, (ii) bipolar disorder was a known disorder at the time of filing (and therefore *could* have been mentioned in the specification and included in the claim), (iii) treatment of bipolar disorder with the same active ingredient was the subject of a later Forest patent application, and (iv) expert testimony indicated that bipolar disorder was distinguishable from the psychotic and schizophrenia disorders that were described in the specification.[13] The focus of the district court's analysis was on whether "bipolar disorder" was within the scope of the claim, not whether the word "excitation" might include treatment of one symptom of bipolar disorder (*i.e.*, manic episodes).[14]

The Federal Circuit revisited the literal scope of the claim, finding that the "claim language and the specification indicate that 'excitation' refers to a symptom rather than a 'disorder'":

> The use of the conjunction "and" before "psychotic and schizophrenic disorders" indicates that "psychotic and schizophrenic disorders" is a distinct item on the list, and that unlike the terms "psychotic" and "schizophrenic," the words "tension," "excitation," and "anxiety" are not describing "disorders."
>
> ***
>
> Moreover, experts for both parties agree that there is no such thing as an "excitation disorder,"... further indicating the claim covers treatment of the symptom "excitation" rather than treatment of an "excitation disorder."

Thus, based on grammar[15] the Federal Circuit concluded that district court "misreads the plain language of the claims and specification" by "treating 'excitation' as being limited to 'excitation disorders,'" and construed "'excitation' to refer to a symptom" of a disease or disorder. The case was remanded for the district court to assess infringement in light of the correct construction.

---

[13] January 29, 2016 Memorandum [Claim Construction] Order in District of Delaware Case No. 1:14-cv-0119, p. 2.

[14] The district court's determination was, essentially, that if "bipolar disorder" was not within the scope of the claim than neither were its symptoms. The district court did analyze whether treatment of manic episodes was *equivalent* to treatment of excitation for doctrine of equivalents purposes, but found "no persuasive objective evidence that those of skill in the art in 1994 considered 'excitation' the *sine qua non* of 'mania' such that the two terms would be equated for purposes of treating a patient" with the claimed active ingredient. June 30, 2017 Opinion in District of Delaware Case No. 1:14-cv-0119, pp. 23-27.

[15] Grammar is an important but seemingly oft-overlooked issue in claim construction. *See, e.g., Credle v. Bond*, 25 F.3d 1566, 1571 (Fed. Cir. 1994)(noting that "grammatical structure and syntax" of the claim can be important evidence for claim construction); *Shire Development LLC v. Watson Pharma.,* 746 F.3d 1326, 1331 (Fed. Cir. 2014)("Looking first to the language of the claims, 'lipophilic' is an *adjective that modifies* matrix" such that "the matrix—not just an excipient within the matrix—must exhibit the . . . lipophilic characteristic.")(emphasis added); *Vasudevan Software v. Microstrategy,* 782 F.3d 671, 680 (Fed. Cir. 2015)(using grammar to interpret prosecution statement by applicants as conjunctive in excluding a set of items from the claim – "The conjunctive interpretation is also consistent with *proper grammar*, where the phrase 'not A, B, or C' means 'not A, not B, and not C.'")(emphasis added).