OVERVIEW OF CLAIM DRAFTING ISSUES FOR BIOTECH, CHEMICAL AND PHARMA PATENT APPLICATIONS

By[1]:

Debora Plehn-Dujowich, Ph.D., J.D.[2]

Angela Sebor, Ph.D.[3]

[1] The views and opinions expressed in this paper are solely those of the authors in their private capacity, and do not in any way represent those of their respective employers. This material has been prepared for informational purposes only, and is not intended to provide, and should not be relied on for legal advice. Further, note that Dr. Sebor is not an attorney-at-law.

[2] Debora Plehn-Dujowich is a former Chair of the AIPLA Biotechnology Committee and a former Co-Chair of the International and Foreign Law Committee, and she is presently a Member of the AIPLA Special Committee on Content Curation (invitation only). Debora is Member at Eckert Seamans. See www.eckertseamans.com/our-people/debora-plehn-dujowich

[3] Angela Sebor is the current Chair of the AIPLA Corporate Practice Committee and is a former Chair of the AIPLA Patent Agents Committee. Angela is a Patent Agent and Director Intellectual Property at Tolmar, Inc.

Introduction

While it is impossible to cover all of the various issues related to claim drafting for biotech, chemical and pharma patent applications, this paper will highlight some of the most common issues that may come up:

1. Claim Construction
2. Indefiniteness
3. Markush Groups
4. Dependent Claim Invalidation
5. Product-by-Process Claims
6. Means-Plus-Function Claims
7. Negative Claim Limitations

Claim Construction

The standard for claim construction during U.S. Patent and Trademark Office (USPTO) examination of a patent application is the broadest reasonable interpretation (BRI) of the claim[4]. This is not the standard in the Federal Courts[5], nor for cases before the International Trade Commission (ITC). Moreover, since November 13, 2018, BRI is no longer the standard for post-grant proceedings before the Patent Trial and Appeals Board (PTAB) (*i.e., inter partes* review (IPR), post-grant review (PGR) or covered business method (CBM) proceedings)[6]. Instead, each of these latter proceedings relies on the plain and ordinary (or ordinary and customary) meaning of the claim term, informally referred to as the "Phillips" standard. Both of these standards are viewed in the context of the person of skill in the art (POSITA) at the time of filing. In 2016, the Supreme Court addressed the question of whether the broadest reasonable interpretation standard should apply to IPR proceedings. *Cuozzo Speed Technologies. LLC v. Lee*, No. 15-446, 579 U.S. __ (Jun. 20, 2016). While the Supreme Court ruled that the USPTO's now prior application of BRI to IPR proceedings was reasonable and within the Patent Office's rule making authority, ultimately, the USPTO decided to replace the BRI standard for all post-grant proceedings with the federal court claim construction standard in response to comments from stakeholders and as part of the office's "continuing efforts to improve AIA proceedings"[7].

From a strategic point of view, from the vantage point of drafting claims, the differing claim construction strategies between the USPTO examination process and post-grant and court proceedings probably will not change one's claim drafting strategies. This is so because both

[4] *See Phillips v. AWH Corp.,* 415 F.3d 1303 (Fed. Cir. 2005)
[5] *Id.*
[6] See Federal Register, Vol. 83, No. 197, Thursday, October 11, 2018, "Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board"
[7] *Id.*

standards rely on the person of skill in the art at the time of filing, and both standards consider the claims in view of the specification and also allow the patent practitioner to be his or her own lexicographer. With respect to the BRI standard during examination, the MPEP explicitly constrains the standard to be consistent with ordinary and customary meaning and the specification:

> The broadest reasonable interpretation does not mean the broadest possible interpretation. Rather, the meaning given to a claim term must be consistent with the ordinary and customary meaning of the term (unless the term has been given a special definition in the specification), and must be consistent with the use of the claim term in the specification and drawings. Further, the broadest reasonable interpretation of the claims must be consistent with the interpretation that those skilled in the art would reach. MPEP 2111.

From a strategic perspective, a significant practice point is to provide a significantly detailed definition in the specification for claim terms. While there, of course, is always the risk that specifying the definition of a claim in the specification may result in the court adopting a narrower construction than may have been the case if the term was not defined, it is the authors' view that current trends in multiple areas of patent law favor detailed definitions of claim terms.[8] When drafting claims, the careful patent practitioner should consider whether definitions provided in the specification differ from the plain and ordinary meaning of the term, and whether a fallback position for such plain and ordinary meaning should be provided.

Indefiniteness

Another recent change in the law impacting claim drafting is in the area of indefiniteness. In 2014, the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc*., 134 S. Ct. 2120 (2014) overturned the "insolubly ambiguous" test for indefiniteness and replaced it with a "reasonable certainty" standard. Furthermore, in *Teva Pharmaceuticals USA v. Sandoz, Inc.,* No. 2012-1567 (Fed. Cir. June 18, 2015), the Federal Circuit held, applying the new "reasonable certainty" standard, that a claim term that had no default meaning to one of skill in the art and was subject to multiple different meanings was invalid as indefinite. Specifically, the court held that the claim term "molecular weight" could represent any of three different weight measures in the art and that neither the claim itself, the specification, nor the prosecution history specified which of these meanings defined the scope of this term in the claim.

The court stated in the *Teva* decision that:

> Claim 1 of the ′808 patent recites "molecular weight" without specifying the meaning of that term. The parties agree that "molecular weight" could refer to Mp, Mw, or Mn and they agree that each of these measures is calculated in a different way

[8] For example, the uncertainty in Section 101 law favors detailed definitions of claim terms in the specification, thus providing multiple fallbacks. Moreover, the recent change in indefiniteness law holding that a claim term can be invalid if a claim term has no default meaning in the art favors defining claim terms in the specification. *See Teva Pharmaceuticals USA v. Sandoz, Inc.*, No. 2012-1567 (Fed. Cir. June 18, 2015), *infra*

> and would typically yield a different result for a given polymer sample. But the claim on its face offers no guidance on which measure of "molecular weight" the claims cover.[9]

Following this case, in 2017, in *BASF Corp. v. Johnson Matthey Inc. 875 F.3d 1360 (Fed. Cir. Nov. 20, 2017)*, the Federal Circuit opined on whether *functional* language in a claim can provide the requisite "reasonable certainty". In this case, the claim language in question described a chemical reaction performed by a coating in a diesel fuel filtration system, using the phrase "composition…effective to catalyze". The Federal Circuit held that, in this case, a person of ordinary skill in the art would be reasonably certain as to which chemical reactions would perform the recited function. Therefore, while the inquiry is context-specific, functional language can provide reasonable certainty to the person of ordinary skill in the art as to the meaning of a claim term.

To consider indefiniteness when drafting claims, patent practitioners should review their claims and consider whether a skilled person, in light of the specification, would be reasonably certain about the scope of the claim. If not, then perhaps claim term definitions can be added or revised to provide reasonably certainty. If a claim term has more than one ordinary meaning, it is prudent, if not essential, to define all of the ordinary meanings in the specification. And, functional language may not ultimately be indefinite, but that determination will again rely on the person of ordinary skill in the art and whether such functional language would be clear. If not, the specification should be developed to provide that clarity.

Markush Groups

A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." *See Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). Markush groups are covered in MPEP 803.02. The members of the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class.

The Examiner must examine all the members of a Markush group in the claim on the merits if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden. This is the case even if they are directed to independent and distinct inventions. The Examiner should then not require provisional election of a single species. *See* MPEP 802.02.

Multilayer v. Berry Plastics

In *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp*., Nos. 2015-1420, 1477 (831 F.3d 1350, Fed. Cir. Aug. 4, 2016), the Federal Circuit looked at the issue of how to interpret Markush Groups. Multilayer Stretch Cling Film Holdings, Inc. ("Multilayer") brought suit against Berry Plastics Corp. ("Berry"), alleging infringement of at least claim 1 of U.S. Patent No. 6,265,055 ("'055"). The '055 patent relates to multilayered plastic cling wrap films. The

[9] *Id.*

District Court granted Berry's motion for summary judgment of non-infringement based on its claim construction.

Claims 1 and 28 of the '055 patent are reproduced below:

Claim 1

A multi-layer, thermoplastic stretch wrap film containing seven separately identifiable polymeric layers, comprising:

(a) two identifiable outer layers, at least one of which having a cling performance of at least 100 grams/inch, said outer layer being **selected from the group consisting of** linear low density polyethylene, very low density polyethylene, and ultra low density polyethylene resins, said resins being homopolymers, copolymers, or terpolymers, of ethylene and alpha-olefins; and

(b) five identifiable inner layers, with each layer being **selected from the group consisting of** linear low density polyethylene, very low density polyethylene, ultra low density polyethylene, and metallocene-catalyzed linear low density polyethylene resins; said resins are homopolymers, copolymers, or terpolymers, of ethylene and C3 to C20 alpha-olefins;

wherein each of said two outer layers and each of said five inner layers have different compositional properties when compared to a neighboring layer. (emphasis added)

Claim 28

A multi-layer, thermoplastic stretch wrap film containing seven polymeric layers, comprising:

(a) two outer layers, at least one of which having a cling performance of at least 100 grams/inch, said outer layer being **selected from the group consisting of** linear low density polyethylene, very low density polyethylene, and ultra low density polyethylene resins, said resins being homopolymers, copolymers, or terpolymers, of ethylene and alpha-olefins; and

(b) five inner layers, with each layer being **selected from the group consisting of** linear low density polyethylene, very low density polyethylene, ultra low density polyethylene, and metallocene-catalyzed linear low density polyethylene resins; said resins are homopolymers, copolymers, or terpolymers, of ethylene and C3 to C20 alpha- olefins;

wherein at least one of said inner layers comprises a metallocene catalyzed linear low density polyethylene resin with a melt index of 0.5 to 3 dg/min and a melt index ratio of 16 to 80; and wherein each of said two outer layers and each of said five inner layers have different compositional properties when compared to a neighboring layer. (emphasis added)

The District Court's Claim Construction is illustrated in the chart below:

Disputed part of element (b) of claims 1 and 28:	**District court's construction:**
five [identifiable][1] inner layers, with each layer being selected from the group consisting of linear low density polyethylene [(LLDPE)], very low density polyethylene [(VLDPE)], ultra low density polyethylene [(ULDPE)], and metallocene-catalyzed linear low density polyethylene [(mLLDPE)] resins	each of five identifiable inner layers must contain only one class of the following resins, and no other resin(s): linear low density polyethylene [(LLDPE)] resins, very low density polyethylene [(VLDPE)] resins, ultra low density polyethylene [(ULDPE)] resins, or metallocene-catalyzed linear low density polyethylene [(mLLDPE)] resins

The parties had agreed that "at least one of the inner layers of the Accused Films contains blends of resins from the classes of mLLDPE, ULDPE, and LLDPE—all classes of resins separately specified in claims 1 and 28." The Markush group in Claim 1 (b) was construed by the District Court to be ***closed***. Only one of the resins listed in Claim 1(b) could be used to construct each of the five inner layers. Blends of the listed resins were also excluded. Dependent claim 10 was held invalid under 35 U.S.C. §112(d) because it recited "low density polyethylene homopolymers" which was not recited in the Markush group of claim 1, from which it depends.

The Federal Circuit opinion was written by Judge Dyk. He described Markush groups as follows:

> "[a] Markush group lists specified alternatives in a patent claim, typically in the form: a member selected from the group consisting of A, B, and C," where "[i]t is generally understood that . . . the members of the Markush group . . . are alternatively usable for the purposes of the invention"

The following two claim construction issues were identified:

1. Whether the Markush group of element (b) is closed to resins other than the listed four; and

2. Whether the Markush group is closed to blends of the four listed resins.

The Federal Circuit held that the Markush group of element (b) was ***closed*** to resins other than the listed four. However, the court held that the Markush group was ***not closed*** to blends of

the four listed resins. The Federal Circuit held that the district court's grant of summary judgment of non-infringement was predicated on its incorrect construction of claims 1 and 28 as closed to blends of LLDPE, VLDPE, ULDPE, and mLLDPE. The court therefore vacated the grant of summary judgment and remanded for reconsideration of infringement under the correct construction.

Judge Dyk distinguished the case at hand with *Abbot v. Baxter* (Fed. Cir.). The court in *Abbott* held that if a Markush claim recites "a member selected from the group consisting of A, B, and C," the claim is presumed to permit the member to be one and only one of A, B, or C, and to **exclude** mixtures or combinations of A, B, and C.

The Federal Circuit in *Multilayer v. Berry* looked at the specification of the '055 patent for guidance in construing the claims. Judge Dyk noted that the specification repeatedly and consistently referenced blends in describing any and all resins, including the four resins in element (b). He also noted that the specification discussed blending the resins in order to achieve a desired range of physical or mechanical properties. Thus, he concluded that blends were included in the Markush group.

Shire Development, LLC v. Watson Pharmaceuticals, Inc

In *Shire Development, LLC v. Watson Pharmaceuticals, Inc*. (848 F.3d 981, Fed. Cir. Feb. 10, 2017), the Federal Circuit also looked at the issue of how to interpret Markush Groups. Shire sued Watson for infringing claims 1 and 3 of Shire's U.S. Patent No. 6,773,720 (the '720 patent).

The District Court found that Watson did infringe. However, the Federal Circuit ***reversed*** and found that Watson did not infringe because of its interpretation of a Markush group in the claims.

Claim 1:

1. Controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, comprising:

an *inner lipophilic matrix* consisting of *substances selected from the group consisting of* unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycerids, waxes, ceramides, and cholesterol derivatives with melting points below 90° C., and wherein the active ingredient is dispersed both in said [sic] the lipophilic matrix and in the hydrophilic matrix;

an *outer hydrophilic matrix* wherein the lipophilic matrix is dispersed, and said outer hydrophilic matrix consists of compounds selected from the group consisting of polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrins, pectins, starches and derivatives, alginic acid, and natural or synthetic gums;

optionally other excipients…

Watson's ANDA formulation contained two matrices, an inner lipophilic matrix, and an "extragranular space" that the D.C. recognized as the outer hydrophilic matrix. This outer matrix contained magnesium stearate as a lubricant.

However, magnesium stearate is not a member of the Markush group of claim 1 (b) and is lipophilic rather than hydrophilic. The court therefore held that there was ***no infringement***.

Thus, even though the claim preamble recited "**comprising**…" the Markush groups in the subsequent claim clauses, each reciting "selected from the group **consisting** of" were construed as being *closed*. The Federal Circuit held that use of the term "consisting of" creates a very strong presumption that the claim element is closed and therefore excludes any elements or steps not specified in the claim. Overcoming this presumption requires the specification and prosecution history to unmistakeably manifest an alternative meaning such as when the patentee acts as its own lexicographer.

Amgen, Inc. v. Amneal Pharmaceuticals, LLC

In *Amgen, Inc. v. Amneal Pharmaceuticals, LLC*. Nos. 2018-2414, 2019-1086 (2020 U.S. App. LEXIS 245, Fed. Cir. Jan. 7, 2020), the issue of how to interpret Markush Groups was again reviewed by the Federal Circuit, only this time with a different result.

Amgen sued Amneal for infringing claims 1, 2-4, 6, 8-12, and 14-18 of Amgen's U.S. Patent No. 9,375,405 (the '405 patent). The District Court found that Amneal did not infringe. The Federal Circuit ***reversed*** and remanded because it found that the District Court interpreted Amneal's claims incorrectly.

The claim at issue recited:

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;

(b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof,

(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 crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof,

wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

Amneal's ANDA states that its product uses "Opadry" as a binder. It was undisputed that Opadry is a composite product comprised of HPMC, polyethylene glycol ("PEG") 400, and PEG 8000. HPMC is listed in the binder Markush group of claim 1. The Markush group was construed as being open due to the "at least one" claim language.

The court held that "[b]ecause the district court erred in its analysis of the binder in Amneal's formulation, we vacate its finding that Amneal does not infringe the asserted claims because of the identity of Opadry. On remand, the court should consider whether Amneal's formulation contains "from about 1% to about 5% by weight" of HPMC, irrespective of the HPMC's pairing with PEG."

Practice Points for Markush Groups:

- *Take care to include all desired compounds in a Markush group*
- *Make sure that any compound recited in a dependent claim is also listed in the Markush group of the independent claim*

Dependent Claim Invalidation

The court in *Multilayer v. Berry* also looked at the issue of whether a dependent claim is proper. 35 U.S.C. §112(d) states that:

> *(d)* REFERENCE *IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then* ***specify a further limitation*** *of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.*

MPEP 608.01(N) discusses dependent claims and covers rejections under 35 U.S.C. §112(d).

In Multilayer v. Berry, dependent claim 10 of the '055 patent was held invalid under 35 U.S.C. §112(d) because it recites low "density polyethylene homopolymers" which was not recited in the Markush group of claim 1, from which it depends.

Another case that looked at the issue of dependent claim invalidation is *Pfizer, Inc. v. Ranbaxy Laboratories Ltd*., 457 F.3d 1284 (Fed. Cir. 2006). The patent at issue was directed to the active ingredient in Lipitor®. Dependent salt claim 6 was held to be invalid for failing to further limit its base claim; the base claim was not open to salts. The claims can be summarized as follows:

1. Compound A or Compound B; or pharmaceutically acceptable salt thereof.

2. Compound A.

6. The hemicalcium salt of the compound of claim 2.

Base claim 2 was not open to salts, and therefore dependent claim 6 was an improper dependent claim since it referred to a "salt." Thus, Section 112, 4th paragraph is an independent ground for holding a patent claim invalid.

Product-by-Process Claims

Product-by-process claims are not limited to the manipulation of the recited steps. *See* MPEP 2113. Rather, product by process claims are limited only by the structure implied by the steps.

In re Thorpe was a seminal case that held that determination of a product-by-process claims' patentability is based on the product itself, and not by the steps of the process:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Th*orpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

The Federal Circuit has also held that "[b]ecause validity is determined based on the requirements of patentability, a patent is invalid if a product made by the process recited in a product-by-process claim is anticipated by or obvious from prior art products, even if those prior art products are made by different processes." *Amgen Inc. v. F. Hoffman-La Roche Ltd*., 580 F.3d 1340, 1370 n 14, 92 USPQ2d 1289, 1312, n 14 (Fed. Cir. 2009).

However, in the context of an infringement analysis, a product-by-process claim is only infringed by a product made by the process recited in the claim. *Id*. at 1370 ("a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim").

Means Plus Function Claims

Means plus function claims, or claims invoking 35 U.S.C. §112(f), are often thought of in the context of the computer/software fields, where claiming by function may be more practical than claiming a particular structure. However, means plus function claims are a claim type that the practitioner in the biotech/pharma/chemical arts field may also consider as a strategy that, if done properly, may allow the drafter to capture equivalents of a particular structure, material or act that is disclosed in the specification. The statute reads:

> *An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.*

MPEP 2181(I) sets forth a three-prong analysis for determining whether or not a claim is a "means plus function" claim:

1. The claim limitation must use the term "mean", "step" or an equivalent term (*e.g.,* a generic placeholder for such term);

2. The term from (1) is modified with functional language, typically linked to transitional language, such as "for" or "such that"; and

3. The term from (1) is <u>not</u> modified by sufficient structure, material or acts for performing the claimed function.

Under the first prong, terms that can be used as a "generic placeholder" instead of the traditional "means for" language can include, for example, "mechanism for," "module for," "device for," "unit for," "component for," "element for," "member for," "apparatus for," "machine for," or "system for". The absence of the "mean", "step" or equivalent (generic placeholder) language will trigger a rebuttable presumption that 35 USC § 112(f) does not apply.

Under the second prong, it must be clear that the element in the claims is set forth, at least in part, by the function it performs and not by a structure, material or acts for performing the claimed function. Use of transitional phrases like "for" or "such that" assist with the drafting of the functional language.

Under the third prong, if the "means" term is modified by a sufficient structure, material or acts that form the claimed function, then 35 USC §112(f) will not apply. Indeed, if one of ordinary skill in the art, upon reading the specification, would understand a term to have a sufficiently definite meaning that it is clearly the name for the structure that performs the function, even when the term covers a broad class of structures or identifies the structures by their function, then 35 USC §112(f) will not apply. According to MPEP 2181(I)(C):

> *To determine whether a word, term, or phrase coupled with a function denotes structure, examiners should check whether: (1) the specification provides a description sufficient to inform one of ordinary skill in the art that the term denotes structure; (2) general and subject matter specific dictionaries provide evidence that the term has achieved recognition as a noun denoting structure; and (3) the prior art provides evidence that the term has an art-recognized structure to perform the claimed function. Ex parte Rodriguez, 92 USPQ2d 1395, 1404 (Bd. Pat. App. & Int. 2009) (precedential). "The standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1349, 115 USPQ2d 1105, 1111 (Fed. Cir. 2015).*

Therefore, to use means plus function language in a claim, the specification must set forth adequate disclosure showing what is meant by this functional language. When this is done properly, the broadest reasonable interpretation (BRI) of such a claim will include the structure, material or act described in the specification that performs the entire claimed function and importantly, will

also include *equivalents* of the disclosed structure, material or act. However, if the claim, or the specification, is not drafted properly, indefiniteness rejections can be applied under 35 U.S.C. §112(b) and/or written description rejections can be applied under 35 U.S.C. §112(a). Furthermore, the BRI of a means plus function claim can cause a claim to read on prior art, where not using such language (*e.g.,* just claiming the actual structure, material or act disclosed in the specification) may have been free of the art. Finally, 35 U.S.C. §112(f) requires a combination of elements and therefore, care must be taken not to make the "means for" the only limitation in the claim.

An example of effective means plus function claiming in a pharmaceutical case is illustrated in *Ex parte Gleave*, Appeal 2012-004973 (P.T.A.B. Jan. 22, 2014). In this case, an original claim to a pharmaceutical composition drafted using more standard drafting techniques, was redrafted to invoke 35 U.S.C. §112(f). Specifically, where the original claim broadly claimed a "therapeutic agent effective to achieve a desired therapeutic benefit, the means plus function claim recited (a) a "means for" performing a specific technical function, and (b) a pharmaceutically acceptable carrier. The specification disclosed particular structures that performed the recited specific technical function and ultimately, the Patent Trial and Appeals Board ruled that the claim therefore covered not only these particular structures, but also equivalents that are effective to perform the same function. Using means plus function language has to be done in a thoughtful manner, but it can be effective.

Negative Claim Limitations

Negative claim limitations are sometimes introduced during prosecution to try to avoid prior art. However, care should be taken to ensure that there is proper support in the specification for any negative claim limitations. In a recent Federal Circuit decision (*Novartis Pharmaceuticals v. Accord Healthcare Inc*. Fed. Cir. 2022), the court held that the negative limitation "absent an immediately preceding loading dose" added during prosecution to overcome prior art failed to satisfy the written description requirement of 35 U.S.C. §112(a). Claim 1 of the Novartis patent at issue (U.S. Pat. No. 9,187,405) recites:

> **Claim 1.** A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising orally administering to said subject 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol, in free form or in a pharmaceutically acceptable salt form, at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen.

The court explained that for negative claim limitations, there is adequate written description when, for example, "the specification describes a reason to exclude the relevant [element]." *Santarus, Inc. v. Par Pharm., Inc*., 694 F.3d 1344, 1351 (Fed. Cir. 2012). A reason to exclude an element may be found in statements in the specification expressly listing the disadvantages of using that element, for example. *Id*, at 1351.

However, according to the court the '405 specification "discloses neither the presence nor absence of a loading dose."

According to MPEP 2173.05(i):

> *Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984).*

Therefore, to include a negative limitation in a claim, care must be taken to ensure that it has adequate support in the specification. Support may be in the form of a description of reasons to exclude the element, or it may be in the form of a list of alternative elements. However, the lack of any description of an element in the specification may not be sufficient support for a negative claim limitation excluding the element.

Conclusion

The learning process never ends. As the USPTO, the PTAB and the federal courts continue to provide guidance on claim construction and other issues, patent practitioners will have to continue to update their best practices for claim drafting.