Patent Prosecutors: Take Caution From Recent Federal Circuit Decisions Impacting Claim Construction

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Recent decisions by the U.S. Court of Appeals for the Federal Circuit reemphasize the care that patent prosecutors should take when drafting and prosecuting patent applications at the Patent and Trademark Office.

This article will discuss the cautionary teachings issued by the Federal Circuit in SkinMedica, Inc. v. Histogen Inc., Teva Pharms. USA, Inc. v. Sandoz, Inc., and Bayer Cropscience AG v. Dow Agrosciences LLC. Heeding these instructions will not only strengthen the patents that issue, but also facilitate prosecution at the PTO.

I. Teva v. Sandoz

In Teva,[1] the court evaluated claims directed to a copolymer pharmaceutical product used in treating multiple sclerosis. The copolymer in question was a mixture of individual polymer molecules that have varying molecular weights.

The patents-in-suit asserted by Teva contained two types of claims to the copolymers. The first category of claims described the molecular weight of the copolymer statistically and the court designated these as "Group I claims." The second category of claims used a more straightforward approach, indicating what percentage of molecules within a sample fell within a specific molecular weight range, and the court deemed these "Group II claims."

Turning to the Group I claims, the Federal Circuit recognized that at least three different statistical measures (Mp, Mn and Mw) could describe the molecular weight of the population of copolymers in a sample and that using the various statistical strategies would yield different results. The specification and claims, however, referred only to "molecular weight" without specifying which statistical approach applied.

The patentee also made inconsistent statements regarding the meaning of the term molecular weight during prosecution of two different patents in suit. In prosecuting one patent, the patentee responded to an indefiniteness rejection by stating that 'average molecular weight' referred to the molecular weight at the peak of the molecular weight distribution curve (i.e., describing Mp). In prosecuting a second patent, however, the

[1] *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 2013 BL 198464, 107 U.S.P.Q.2d 1655 (Fed. Cir. 2013) (86 PTCJ 683, 8/2/13).

patentee overcame a similar rejection by arguing average molecular weight meant weight average molecular weight (i.e., describing Mw).

Because the specification and claims did not clearly define the techniques used to measure molecular weight from a statistical perspective, the Federal Circuit held the Group I claims indefinite.

II. SkinMedica v. Histogen

In SkinMedica,[2] the claims-at-issue were directed to pharmaceutical compositions containing "novel conditioned cell culture medium compositions." The claim construction issue at hand focused on the meaning of the three-dimensional cell culture limitation, which was added in response to a rejection over prior art discussing products of two-dimensional cell culture.

Specifically, the Federal Circuit evaluated whether cells grown on beads (the embodiment used by the alleged infringer) qualified as three-dimensional cell culture according to the claims, even though the state of the art as of filing included both two- and three-dimensional culture on beads.

The specification discussed both two-dimensional and three-dimensional culture, touting three-dimensional culture as the preferred embodiment. The specification also mentioned cell lines grown on beads, though it associated them in all instances with two-dimensional culture. For example, the specification taught that "cell lines grown as a monolayer or on beads, as opposed to cells grown in three dimensions, lack the cell-cell and cell-matrix interactions characteristic of whole tissue in vivo." The specification also contained statements equating beads with two-dimensional culture: "[t]he cells are cultured in monolayer, beads (i.e., two-dimensions) or preferably, in three-dimensions." The Federal Circuit relied on these statements to mean that the patentee was departing from the ordinary meaning of three-dimensional culture in favor of one that excluded bead culture.

During the analysis, the Federal Circuit also rejected SkinMedica's argument that a scientific treatise, which was incorporated by reference, expressly discussed the use of beads in three-dimensional cell culture, thereby including this information in the specification. The specification text stating that "[m]ethods of cell and tissue culture are well known in the art, and are described, for example in [the scientific treatise]" failed to indicate any reliance on that passage to define culturing in three-dimensions as including beads, especially in view of the other statements in the specification. Thus, the specification both lacked a reference to any part of the publication and failed to specifically call out the subject matter for incorporation by reference.

The Federal Circuit found that the patentees had disregarded the ordinary meaning of culturing in three dimensions to include beads in favor of a more limited understanding that culturing in three dimensions did not include beads, with beads referring only to two-dimensional culture.

III. Bayer Cropscience v. Dow Agrosciences

In Bayer,[3] the claims at issue recited a recombinant gene comprising a DNA sequence encoding a polypeptide having the biological activity of 2,4-D monooxygenase. 2,4-D oxygenase activity conferred resistance to a commonly-used herbicide.

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[2] *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 2013 BL224978, 108 U.S.P.Q.2d 1001 (Fed. Cir. 2013) (86 PTCJ 890, 8/30/13).

[3] *Bayer Cropscience AG v Dow Agrosciences LLC*, 728 F.3d 1324, 2013 BL 233541, 108 U.S.P.Q.2d 1071 (Fed. Cir. 2013) (86 PTCJ 940, 9/13/13).

At the time the inventors filed the application in question, they did not fully understand the enzymatic reaction conferring resistance on the plant. The inventors appreciated that the enzymatic reaction used oxygen and that at least one oxygen atom was chemically incorporated into the enzyme's substrate (2,4-D), but they did not verify how the reaction used the second oxygen atom. Instead, they assumed that it was incorporated into water.

In the application, therefore, the inventors described the enzyme as a monooxygenase (using one oxygen atom in a product other than water). This assumption proved incorrect. During prosecution, other scientists determined that the enzyme was a dioxygenase (incorporating both oxygen atoms into a product other than water) and the third-party scientists' paper was published during pendency of the application. This publication established that the class 2,4-D oxygenases previously known as monooxygenases were, in fact, 2,4-D dioxygenases.

During litigation, Bayer sought a claim construction that was broader than the ordinary meaning of the word monooxygenase in order to encompass Dow's competitive dioxygenase molecule. The Federal Circuit declined to extend the meaning of that term beyond the ordinary scientific meaning as the specification had not clearly departed from it. Instead, the specification used it in ways consistent with the ordinary meaning, likely because the inventors assumed at that time it was a monooxygenase.

IV. Patent Drafting and Patent Prosecution Guidance

These three cases, taken together, reemphasize the importance of careful patent drafting and prosecution. Specifically, these cases remind patent prosecutors to dig deeper to understand the invention and resist taking the easy road during drafting or prosecution.

Patent prosecutors should clearly define measurement techniques, avoid inconsistent statements, incorporate alternatives during drafting, approach scientific uncertainty thoughtfully, depart from the ordinary meaning of terms only with deliberation, incorporate by reference in an effective way, avoid unnecessary comparisons and take a new view of patent profanity.

A. Clearly Define Measurement Techniques

As demonstrated in Teva, if the claims in an application recite a property or value, take the time to understand from the inventors how they have measured that property or value and whether any alternative approaches exist. Ideally, patent prosecutors should draft an example that demonstrates how to determine whether a sample meets the limitations of the claims.

While Teva provides an extreme example of at least three distinct measurements for a statistical reflection of molecular weight, patent prosecutors should take care to determine with the inventors both whether the art includes different measurement techniques and whether there are any additional factors that might alter determination of a property or value. For example, if reaction conditions such as pH, time, or temperature might affect the determination of a property or value, the application should specify the reaction conditions for the experimental determination of the property or value.

Some drafters intentionally seek ambiguity, but following that approach, as seen in Teva, can dramatically backfire, potentially resulting in invalid claims. Even in more subtle cases, if patent prosecutors do not determine early the reaction conditions for key experiments determining a claimed property or value, the claims may fall prey to an undesired claim construction during litigation or the application may lack written

description for claim limitations necessary to avoid the prior art. Clearly defining measurement techniques, as other approaches suggested here, requires a more thoughtful tack during drafting of the application and a keener understanding of the prior art.

B. Avoid Inconsistent Statements

In Teva, the patentee made inconsistent statements in two different applications about the methods used to calculate the statistical molecular weight of the population of copolymers. In response to an indefiniteness rejection in one application and a similar rejection in another application, the patentee defined Mp as the molecular weight measurement in one application and Mw in the other. Unable to reconcile the patentees' own statements about the mode for determining molecular weight, the Federal Circuit found the claim term indefinite.

Most patent prosecutors know to avoid inconsistent statements during prosecution, but as attorneys handling prosecution change or even as memories fade over time, patent prosecutors should review or, even better, summarize in short bullet points the arguments they have made in each case in a patent family so as to avoid potentially inconsistent statements. Patent prosecutors can prepare their own summaries or hire a service capable of preparing a prosecution history digest for issued patents in a patent family that remains in active prosecution.

While patent prosecutors may recognize the potential for inconsistent statements when discussing the same or similar rejections across applications (as occurred in Teva), problematic statements can also arise when responding to different prior art or different types rejections that may impact the same or related claim terms. Patent prosecutors, facing multiple challenges, must respond to each rejection successfully, while keeping in mind how their statements can interact with each other.

C. Incorporating Alternatives

While drafting and reviewing an application, patent prosecutors should recursively ask the inventors "what if?" The prosecutor's role in outlining alternative embodiments starkly contrasts with the inventor's role in writing a scientific publication. Patent prosecutors should focus on the working embodiments, as well as asking multiple layers of "what if" questions. Ask the inventors whether competitors could practice techniques in different ways or whether competitors could substitute one material or step with another. Inventors often feel wedded to the embodiments they envisioned, but the patent prosecutor should skillfully ask them to expand their horizons. Patent prosecutors should also encourage inventors to include embodiments that may not function as effectively as the previously-termed preferred embodiment so long as those embodiments would work to carry out the goals of the invention.

Failing to thoroughly consider alternative embodiments impacted the patentees in the Teva case. In Teva, the prosecutor may have even failed to appreciate that there were different ways to measure the molecular weight of a sample statistically.

Patent prosecutors should embrace the technical questions and doubts that they may have. Irrespective of their familiarity with a technology space, patent prosecutors will usually deepen their understanding after asking the right series of questions. Digging deeper to understand alternative embodiments of the application strengthens the application and works best when patent prosecutors recognize their role as inquisitive technical translators, not technical experts. Patent prosecutors should set aside any embarrassment about not knowing all the answers and ask questions until they understand all of the aspects of an invention.

D. Dealing With Scientific Uncertainty and Addressing Assumptions

Bayer teaches patent prosecutors how to deal with scientific uncertainty and technical assumptions. In an ideal scenario, inventors would present the patent prosecutor with an accurate and fully developed narrative around an invention, but pressures to file applications early in our first-inventor-to-file regime and to allow for publication often require patent prosecutors to file applications before the inventors understand the full scientific narrative around a composition or method.

When drafting an application, ask the inventors which aspects of the invention require assumptions and learn the underlying basis for those assumptions. When drafting the application and the claims, avoid using language incorporating assumptions or relying on unconfirmed mechanisms of action. In Bayer, the applicants might have used the term "oxygenase" or explored other language instead of "monooxygenase" as the inventors had not confirmed that the enzyme was in fact a monooxygenase.

In SkinMedica, a similar challenge played out when the prosecutor may have failed to ask whether assumptions made in the application were always true. Specifically, the inventors may have associated beads with two-dimensional culture, yet the patent prosecutor should ask if that correlation holds true in all embodiments. Patent prosecutors should walk the fine line of respecting the knowledge of the inventors while challenging the assumptions they make.

Additionally, instead of relying solely on memory, patent prosecutors should make a list of assumptions to review with the inventors at key points in prosecution, especially before issuance, to ensure that the claims the client will rely upon accurately reflect the current scientific understanding. This approach, however, will only work if the language in the specification is broad enough to support revision to the claims if the original assumption proves incorrect.

E. When Necessary Clearly Depart From the Ordinary Meaning of a Term

Even though the patentees in Bayer did not intend to depart from the ordinary meaning of the term monooxygenase, primarily because they incorrectly assumed that their enzyme was a monooxygenase, this case still provides an important caution for patent prosecutors seeking to depart from the ordinary meaning of a claim term. In order to successfully depart from the ordinary meaning of a claim term, the specification must present a clear message that the patent gives a different meaning to the claim term.

Review all of the occurrences of the claim term in the application and ensure that all support the intended definition. The Bayer court evaluated the various occurrences of the monooxygenase term in the specification and made determinations as to whether each supported the ordinary meaning or the alternative definition purported by the patentee.

Yet, on the other hand, the patentee in SkinMedica may not have wanted to depart from the ordinary meaning of the term three-dimensional cell culture. Therefore, even when using terms in accordance with their ordinary meaning, patent prosecutors should review usage carefully to make sure the specification does not depart from the ordinary meaning. In either event, departing from the ordinary meaning or using terms in accordance with it, patent prosecutors should review the usage of claim terms very carefully throughout the specification.

F. Incorporating by Reference in an Effective Way

In SkinMedica, the patent drafter incorporated a technical treatise on laboratory procedures for cell and tissue culture in the application for the premise that cells may be cultured in any manner known in the art. Many patent prosecutors use this "catch all" approach to avoid the cumbersome repetition of techniques well known to the person of ordinary skill in the art. Yet we see in SkinMedica that the Federal Circuit found ineffective the general reliance on a long technical treatise for the teaching of unspecified methods of cell and tissue culture.

Incorporation by reference can still serve a useful role in patent applications, but patent prosecutors should carefully outline why they are relying on a particular reference. In SkinMedica, a more useful incorporation by reference could have named the specific culturing techniques and referenced sections in the treatise discussing those techniques.

Patent prosecutors should stop viewing incorporation by reference as a shortcut or a get-out-of-jail-free card that can allow them to reach into a treatise for any teaching once the need presents itself. Instead, patent prosecutors should do the hard work of delineating the scope of the application early on.

G. Avoiding Unnecessary Comparisons

While making comparisons comes naturally to patent prosecutors (comparing the claims to the prior art or comparing a competitor's product to the claims), patent prosecutors should shy away from unnecessary comparisons and make sure that scientific underpinning supports all of the comparisons made in an application.

In SkinMedica, the specification referenced cell lines grown as a monolayer or on beads, as opposed to cells grown in three-dimensions. Setting up the contrasting comparison between beads and three-dimensional growth contributed to the Federal Circuit's decision to construe the term "three-dimensional" to exclude beads. Yet at the time the application was filed, one of ordinary skill in the art could use beads in either two-dimensional or three-dimensional cell culture approaches.

Patent prosecutors should carefully review both materials from the inventors and their own writing to locate any comparisons. Once patent prosecutors have located all of the comparisons in an application, they should challenge each one to make sure they understand the reason for the comparison and that the comparison accurately reflects the technical state of the art.

H. Taking a New View of Patent Profanity

Patent prosecutors recognize that certain kinds of terms can lead to an unnecessary narrowing of the claims during claim construction. Yet the list of "patent profanity" continues to expand. As discussed above, in SkinMedica, the specification referenced cell lines grown as a monolayer or on beads, as opposed to cells grown in three-dimensions. Using the phrase "as opposed to" and contrasting beads and three-dimensional growth helped the Federal Circuit construe the term three-dimensional to exclude beads.

While many patent prosecutors recognize that terms such as invention, preferred, chief, majority, critical, essential, necessary, solely, only, main, significant (in the general sense, not the statistical sense), principal, important, fundamental, etc., can present significant risks, avoiding patent profanity requires more than eliminating a list of "bad words" from the application. Unfortunately, even the term patent profanity suggests

this dangerously simplified approach. Instead, avoiding patent profanity requires drafters to consider whether any of language that they are using might unduly limit the scope of any claim terms in an undesirable way.

This brings patent prosecutors back to the central goal of asking as many questions as possible to gain a deeper understanding of the prior art and the present invention, so that the prosecutor can then draft and prosecute the broadest invention possible in view of the prior art and the other requirements of the patent statute.

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