

# Tips on How to Properly Construe Patent Claims

## Sound Understanding of the Patent Landscape Remains Crucial to Bringing a Drug to Market

John P. Iwanicki

In patent law, the claim is the name of the game. For emerging and established biotechnology and pharmaceutical companies alike, it is ground zero for determining freedom-to-operate for pro-

posed commercial products or methods.

One must interpret (or construe) the meaning of the claims in third-party patent rights in order to determine whether a proposed product or method infringes those third-party patent rights or whether they are invalid. Likewise, understanding the

meaning of claims during prosecution will help ensure that issued claims cover commercial embodiments or, if need be, accused products or methods.

This is crucial, especially for the biotech and pharmaceutical industries where so much investment is needed to bring a drug product to market. Sound freedom-to-operate and market exclusivity decisions depend on a proper understanding of the patent landscape, and this begins with the



John P. Iwanicki ([jiwanicki@bannerwitcoff.com](mailto:jiwanicki@bannerwitcoff.com)) is a senior partner in the chemical and biotechnology practice groups at Banner & Witcoff. Web: [www.bannerwitcoff.com](http://www.bannerwitcoff.com).

claims, or numbered paragraphs, at the end of the patent.

Although the Supreme Court in *Markman v. Westview Instruments*, 517 U.S. 370 (1996) has given the job of claim interpretation to federal district court judges as a matter of law, companies must understand the canons of claim construction to help guide legal strategy in obtaining, enforcing, or avoiding patent rights before getting to court. The United States Court of Appeals for the Federal Circuit case of *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) established important principles to help guide district courts and patent owners alike in construing claim language. Adhering to these principles in construing claims before litigation begins will help shift the odds in your favor that a district court will reach a similar conclusion on the meaning of claims.

### PHOSITA

Claims are to be construed from the perspective of the hypothetical person having ordinary skill in the art at the time of the invention (sometimes referred to as the PHOSITA) in the particular technology field. The first step, therefore, is to determine the education and skill level of the PHOSITA.

This is not a one-size-fits-all analysis, but is tailored to the particular technology field and the complexity of the invention. Technology fields that are considered complex or high tech generally dictate higher education and skill-level requirements for the PHOSITA, compared with technology fields that are considered less complex.

It is important to keep in mind that the education and skill-level requirements are determined at the time of the invention and not at the time of enforcement of the patent, which can occur many years after the time of the invention when an industry has evolved and become much more sophisticated and complex.

Also, while the education and skill level of inventors are often relied upon to define the PHOSITA, some courts have held that an inventor is one of extraordinary skill in the art and is not one of ordinary skill in the art.

To ascertain the meaning of claims, the court looks to three primary sources: the claims, the specification, and the prosecution history. This is referred to as the intrinsic evidence. The Federal Circuit case of *Phillips v. AWH Corp.* set forth important principles that can act as a guideline to help district courts and patent owners alike in construing claim language. Claim construction principles from *Phillips* and other cases are summarized below.

Location,  
location,  
location.



Imagine... a flow cytometer on your bench, 24/7.  
Introducing The Accuri C6 Flow Cytometer.<sup>®</sup>  
Two lasers, six detectors, starting at \$35k.

accuri  
CYTOMETERS

For more information visit [www.AccuriCytometers.com](http://www.AccuriCytometers.com) or call 1.734.994.8000 Cell analysis, within reach.<sup>™</sup>

See Claim Construction on page 13

# Claim Construction

Continued from page 10

- Claim terms are generally given their ordinary and customary meaning in context at the time of invention, i.e., as of the effective filing date of the patent application. The PHOSITA is deemed to read the claim term not only in the context of the particular claim in which the term appears, but also in the context of the entire patent, including the specification.

- Claims themselves provide substantial guidance as to the meaning of particular claim terms. However, this does not mean that the specification can be disregarded. The claims are part of a fully integrated written instrument, which includes the specification.

- The specification, including the abstract, must be considered when interpreting the claims. The claims must be read in view of the specification of which they are a part, because the specification describes the invention and, in some cases, its purposes and advantages.

- The specification must not only be considered, but must inform claim construction. The interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to cover with the claim. The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose. However, it is improper to read limitations from the specification into the claims where none had previously existed.

- The claims cannot be of broader scope than what was actually invented as described in the specification. Claim interpretation cannot be used to enlarge what is patented beyond what the inventor described as the invention. This would improperly allow the inventor to reach beyond what he told the public was his invention, and the public is entitled to take the inventor at his word and not be faced with uncertainty of claim scope.

- One cannot choose abstract constructions over constructions that reflect the context of the patent. With this, the court disfavored the use of dictionary definitions as extrinsic evidence and placed the meaning of claim terms squarely within the context of the patent and what the claim terms would mean to the PHOSITA after reading the entire patent. The court gave dictionary definitions a role subordinate to the intrinsic evidence.

- The prosecution history can play an important role in claim construction, but is generally considered less useful than the specification. The prosecution history helps to demonstrate how the inventor and the U.S. Patent and Trademark Office understood the patent and the claims and how the claims meet the statutory requirements of patentability, such as definiteness and distinguishing over the prior art. However, the prosecution history can represent the patentee's advocacy and can be less clear than the specification.

- The inventor can be her own lexicographer by providing specific definitions for claim terms. Definitions can be provided directly in the specification or can be offered during prosecution to overcome a statutory rejection. Often, such a definition limits the scope of the claims, preventing the patentee from recapturing what was previously surrendered. Although an inventor's definition

may not have a narrowing effect, it is nonetheless relevant in indicating the meaning that the inventor ascribed to the claim.

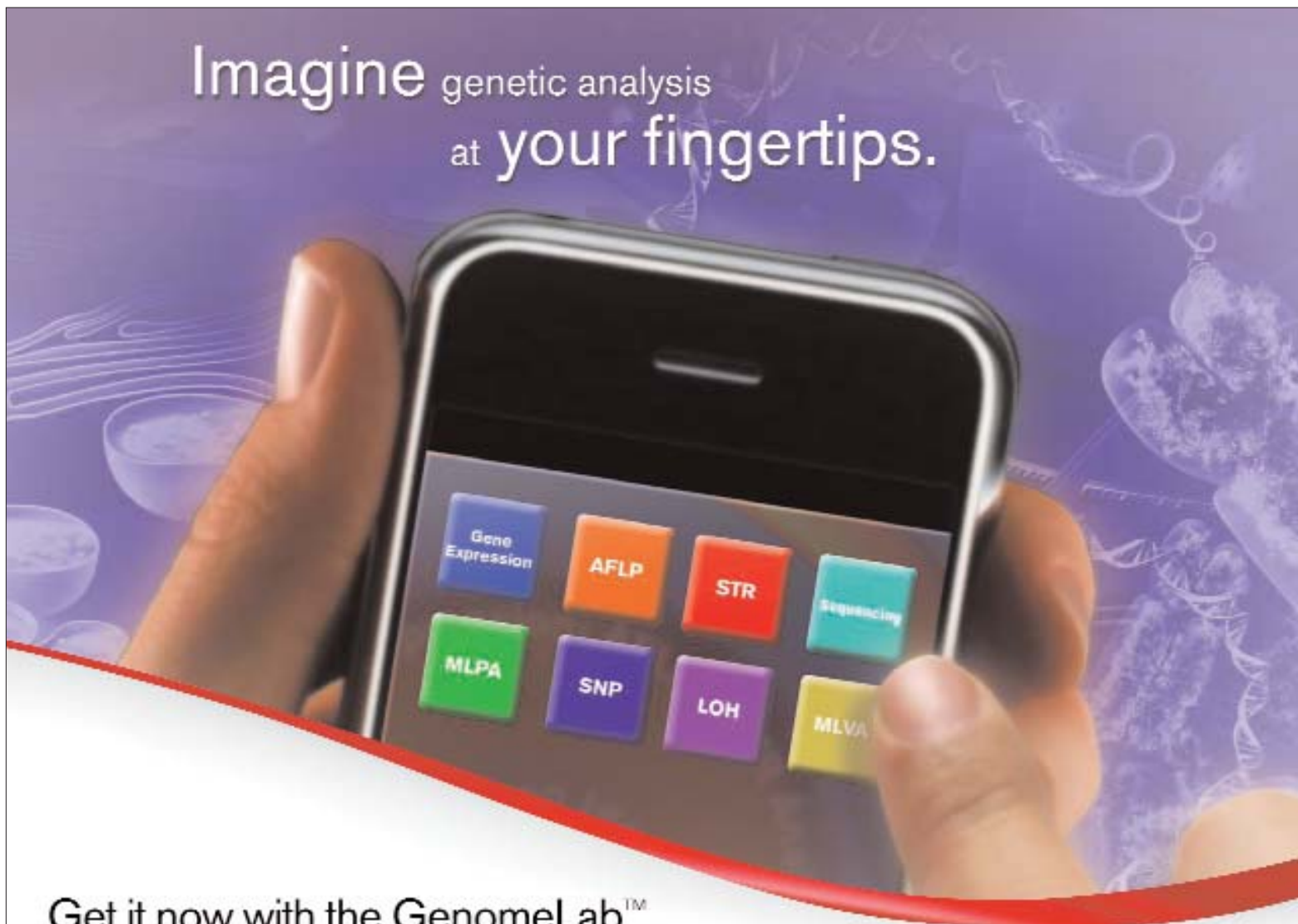
- The maxim that claims are to be interpreted in a manner to preserve their validity was retained by *Phillips*, but was described as being of limited use. If a claim is not ambiguous in view of the intrinsic evidence, yet is invalid, so be it. If a claim remains ambiguous after application of all of the claim construction canons, the maxim may be useful so as to err on the side of validity in an ambiguous situation.

The court is allowed to refer to extrinsic

evidence, such as dictionary definitions and expert testimony, but extrinsic evidence is disfavored, inter alia, because it is not generally contemporaneous with an understanding of the claims at the time of the filing of the patent application, and so may not accurately reflect the understanding of the PHOSITA. In addition, expert witnesses in some circumstances may be viewed by a judge as being a strong advocate, which may not result in a claim interpretation that meets the public notice function of claims.

The canons of claim construction should

be used by companies to understand the meaning of claims as accurately as possible to help guide patent strategy. The goal is to create a measure of certainty in the interpretation of the claims, so that legal risks and benefits can be assessed before resorting to court action. Although the reversal rate of patent cases on appeal based on issues of claim construction is considered high, assessing the objective scope of claims using the canons of construction can only improve the odds of a proper claim construction at the outset. **GEN**



Imagine genetic analysis  
at your fingertips.

## Get it now with the GenomeLab™ GeXP Genetic Analysis System.

Now you can perform multiple applications on one platform.

- Multiplex your most important genetic assays on robust, field-proven technology.
- Increase sensitivity and reproducibility for more accurate results.
- Deliver results with low sample requirements.

To learn more about performing your ideal genetic assays on one platform, visit [www.ceLeader.com/GeXP](http://www.ceLeader.com/GeXP).



Get the results you need all on one platform—using one gel, one capillary array and one software package!

For research use only; not for use in diagnostic procedures.

Genomics Protomics Cell Analysis Centrifugation Lab Tools Particle Characterization Bioprocessing Lab Automation

© 2008 Beckman Coulter, Inc.



Simplify · Automate · Innovate