

Nos. 03-1269 and 03-1286

IN THE
UNITED STATE COURT OF APPEALS FOR THE FEDERAL CIRCUIT

EDWARD H. PHILLIPS,

Plaintiff-Appellant

v.

AWH CORPORATION, HOPEMAN BROTHERS, INC. and LOFTON
CORPORATION,

Defendants-Cross Appellants

ON REHEARING *EN BANC*

**BRIEF OF AMICUS CURIAE
BIOTECHNOLOGY INDUSTRY ORGANIZATION
IN SUPPORT OF NEITHER PARTY**

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CERTIFICATE OF INTEREST

Counsel for amicus curiae Biotechnology Industry Organization hereby certify the following:

1. The full name of the amicus that we represent is:

BIOTECHNOLOGY INDUSTRY ORGANIZATION

2. The name of the real party in interest that we represent is:

BIOTECHNOLOGY INDUSTRY ORGANIZATION

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the amicus curiae that we represent are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now or are expected to appear in this court are:

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Respectfully submitted,

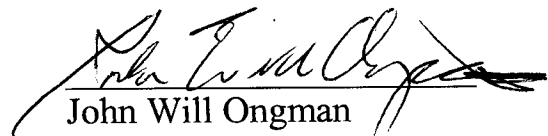

John Will Ongman

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**STATEMENT OF IDENTITY AND INTEREST OF AMICUS CURIAE
(F.R.A.P. 29(C)(3))**

The Biotechnology Industry Organization (“BIO”) is a trade association consisting of over 1,000 biotechnology companies, academic institutions, and research centers. BIO members file thousands of patent applications each year for inventions ranging from fundamental technology breakthroughs to important commercial refinements of existing technology. Patents are crucial to the biotechnology industry because often patents are the sole assets upon which our companies rely to obtain funding necessary to move a discovery to the next stage of development. Some measure of predictability of the scope of the protection conferred by these patents is critical to the biotechnology industry.

BIO is submitting this amicus brief in response to the Federal Circuit’s July 21, 2004 Order. Because BIO is a trade association, this Order authorizes BIO to file this amicus brief. In responding to seven questions posed by the Court, BIO does not support either party’s position. BIO has no interest in either of the parties or the outcome of this case.

CONSENT OF BOTH PARTIES (F.R.A.P. 29(a))

Both parties have consented to the filing of BIO’s amicus brief.

ARGUMENT

It is settled that the construction of patent claims “is an issue for the judge, not the jury.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). What is unsettled is the approach a court should take in its exclusive task to construe the meaning of claims at issue in a patent infringement suit and whether this Court’s prior conclusion that claim construction appeals from trial courts proceed under a *de novo* standard with respect to all matters before the trial court is the appropriate standard for appellate review. See *Cybor Corporation v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (*en banc*).

In its Order of July 21, 2004, this Court asked for input in seven areas. BIO submits the following responses to the Court’s questions.

I. THE PUBLIC NOTICE FUNCTION OF PATENT CLAIMS IS BETTER SERVED BY DETERMINING WHETHER THE SPECIFICATION ESTABLISHES OR LIMITS THE MEANING OF A CLAIM BEFORE CONSULTING DICTIONARIES AND OTHER SIMILAR WRITTEN SOURCES TO INTERPRET THE CLAIM.

The proper approach to claim construction is not a free-standing metaphysical inquiry but must instead emerge from the statutory scheme governing patents. See *Markman*, 517 U.S. at 373. Under the statute, the patentee controls the meaning of a claim. 35 U.S.C. § 112, ¶ 2. This permits the patentee to establish affirmatively a special construction of a term in a claim or to limit the set of meanings that would otherwise occur to a person with ordinary skill in the art.

In the absence of a special construction or limitation of a claim compelled in the specification, the focus is on the language of the claims with the view that the claim language carries the ordinary meaning to one of ordinary skill in the art. *Texas Digital Systems Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002).

There is no point in proceeding to the dictionary meaning of a claim, therefore, until one comprehends whether the specification compels a particular construction of the claim. Thus the intrinsic evidence of the meaning of a claim should be consulted before consulting extrinsic evidence, such as dictionaries. *Vanderlande Industries Nederland BV v. International Trade Commission*, 366 F.3d 1311, 1318 (Fed. Cir. 2004); *Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1371 (Fed. Cir. 2003); *CCS Fitness Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

A patentee may act as its own lexicographer and give explicitly defined meaning to a claim term. *Mycogen Plant Science v. Monsanto Co.*, 243 F.3d 1316, 1327 (Fed. Cir. 2001); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (*en banc*). While no “magic words” are required to give such specific meaning, it must be clear that the inventor has explicitly given a particular word or phrase a special meaning throughout the patent “so as to put a reasonable

competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term.” *Elekta Instrument v. O.U.R. Scientific International Inc*, 214 F.3d 1302, 1307 (Fed. Cir. 2000); (invention must be described in “clear terms”, 35 U.S.C. § 112, ¶ 1). When the inventor has done so, the defined term should control and trump any other meaning, including the meaning which would be otherwise held by a person of ordinary skill in the art. *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 2004 U.S. App. LEXIS 16549, * 11-14 (Fed. Cir. August 11, 2004).

A patentee may also limit the construction of a claim by the context a claim term is given in the overall claim set. For example, each claim is presumed to have a distinct meaning. *Sunrace Roots Enterprise Co. Ltd v. SRAM Corp.*, 336 F.3d 1298, 1302 (Fed. Cir. 2003); *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998); (claim language must “distinctly clai[m] the subject matter which the applicant regards as his invention” 35 U.S.C. § 112, ¶ 2). In addition, the doctrine of claim differentiation states that two claims in the same patent will not have the identical scope, but instead, that there is an intended difference between the two. *Tandon Corp. v. United States Int’l Trade Comm’n*, 831 F.3d 1017, 1023 (Fed. Cir. 1987). This need for distinct meaning or other contextual or structural interrelationships among claims or words in the overall claim set may implicitly convey meaning (at least by limiting the otherwise

available set of meanings) to the particular claim term of interest. And the language and structure of a particular claim can either define or limit meanings. *ACTV v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003); *Rexnord Corporation v. Laitram Corporation*, 274 F.3d 1336, 1342 (Fed. Cir. 2001).

The patentee may also limit the claim construction in its written description. The written description may do so explicitly by language that requires the invention, as opposed to the particular embodiment of an invention, to have or not have the specified feature. *Sunrace*, 336 F.3d at 1395; *Scimed Life Systems v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1343-44 (Fed. Cir. 2001). It may also do so implicitly by distinguishing prior art on the grounds that the specified feature is present in the invention but not in the prior art. *Scimed*, 242 F.3d at 1341. Unless the written description compels the conclusion by one of ordinary skill in the art that all embodiments of the invention -- both disclosed and undisclosed -- contain those features, the features should not be read into the claim.

Patents are published so the public can be put on notice of how to make and use an invention and of what invention is exclusively reserved to the patentee. *Markman*, 517 U.S. at 390. "The public is entitled to be apprised of what is and is not protected by a particular patent and [that] is the purpose of claims." *Burke v. Bruno Independent Living Aids*, 183 F.3d 1334, 1340 (Fed. Cir. 1999).

“[C]ompetitors are entitled to review the public record [the claims, specification, and file history], apply the established rules of claim construction, ascertain the scope of the patentee’s claimed invention and, thus, design around the claimed invention.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

This public notice function is better served if claim construction proceeds first by inspecting the specification. In those instances when the specification affirmatively establishes the construction of a claim, the claim construction task is at an end.

Where the specification does not affirmatively establish the claim construction, a claim term may draw its meaning from contemporaneous dictionaries and other written sources which reflect the meaning of the relevant claim term to one of ordinary skill in the art. An appropriate written source can be a technical or general purpose dictionary, a treatise, a technical article, or other technical writing so long as it is unbiased, contemporaneous with the application, and has as its intended audience those of ordinary skill in the art. Where a specification establishes a limitation on the claim, the set of constructions otherwise understood by people with ordinary skill in the art can be reduced to a subset that satisfies the limitation.

II. DICTIONARIES AND OTHER SIMILAR WRITTEN SOURCES WHICH ARE UNBIASED, PUBLICLY AVAILABLE, CONTEMPORANEOUS WITH THE APPLICATION, AND DIRECTED TO THE AUDIENCE OF PEOPLE WITH ORDINARY SKILL IN THE ART SUFFICIENT TO PRACTICE THE INVENTION MAY BE USED WHEN THE MEANING OF THE CLAIM HAS NOT BEEN ESTABLISHED BY THE SPECIFICATION.

Written extrinsic evidence can be dictionaries, treatises, technical papers, or other writings which can be demonstrated to reflect or inform the meaning of terms as used by persons of ordinary skill in the art. Typically, district judges use publicly available and contemporaneous dictionaries (technical ones if available or, if not, general purpose ones) to reflect the meaning given to a particular term by a person of ordinary skill in the art at the time of the application. Dictionaries are preferred by courts because they are asserted to be general purpose documents that do not take a point of view or otherwise have an advocate's agenda as a treatise or a technical paper might have. *Telegenix*, 308 F.3d at 1203.

Written extrinsic evidence can never be used, however, if it is inconsistent with the intrinsic record. Stated another way, the universe of relevant definitions must be those that are consistent with the intrinsic evidence. *Telegenix*, 308 F.3d at 1213; *ACTV*, 346 F.3d at 1090; *Sunrace*, 336 F.3d at 1307. BIO agrees with this line of this Court's precedent. The statutory scheme and the public notice function of patent claims requires that the claims, written description, and prosecution history of a patent supersede any inconsistent extrinsic evidence.

Current Federal Circuit precedent, however, also allows judges to employ dictionaries whether or not they are in the record and subject to scrutiny by the parties. *Telegenix*, 308 F.3d at 1202-03. BIO disagrees with this aspect of the Court's precedent. In fast-changing fields such as biotechnology, dictionaries often do not reflect the meanings used by persons of ordinary skill in the art but may reflect a more limited meaning. An early step in patent infringement litigation is to perform an extensive search to identify a dictionary most aligned with a particular position. Dictionary definitions often are not consistent. Nor are they subject to peer review; in fact the compilers of the dictionaries are often not experts in the range of technologies they list.

Thus dictionaries often do not address terms in their full scope or with nuance. They can, therefore, be ill-suited to establish the meaning which would be held by a person with ordinary skill in the art, particularly in a newly evolving, rather than an established, field. As a result, BIO suggests that dictionaries should only be employed by judges when they are part of the trial court record so that the parties may test the reliability of any particular dictionary.

This vetting process has several elements. First, the dictionaries should be tested for bias. It may be that a particular dictionary was issued or compiled by an organization or individual with an interest in the subject matter of the litigation.

Second, the dictionary should be contemporaneous with the application. *Brookhill-Wilk 1 LLC v. Intuitive Surgical Inc.*, 334 F. 3d 1294, 1299 (Fed. Cir. 2003). The written description in the application must enable the invention by reference to a person with ordinary skill in the art measured as of the point in time the application is filed. Third, the dictionary must be directed to an appropriate audience. For example, some biotechnology inventions may require the skills of a Ph.D. in biochemistry to practice, while others may require only the skills of a laboratory technician with a B.S. in a natural science such as biology, chemistry or physics. Still others may involve treatment protocols where the appropriate skill level is that of a physician. Yet others may involve treatment delivery systems where the appropriate skill level is that of an MBA or a lawyer. The appropriate dictionaries to consider are those that are directed to persons with ordinary skill in the art. *Vanderlande*, 366 F.3d at 1318.

Treatises, technical papers and other writings may also be employed to develop the meaning a term would have to a person of ordinary skill in the art. Even more than for dictionaries, however, these other technical writings can have an agenda. In order to fully appreciate their context, a judge should permit such written extrinsic evidence to be placed in the record and made subject to the same vetting process employed for dictionaries.

Even after this screening function is done, there may be more than one written evidentiary source that gives a definition that is unbiased, contemporaneous with the application, and targeted to allow persons of ordinary skill in the art to practice the invention. When this occurs, the claim terms may be construed to encompass the definition conferred by each written source that passes this screen. *Brookhill-Wilk*, 334 F.3d at 1300; *Telegenix*, 308 F.3d at 1203. In this circumstance, the trial court should read the terms as embracing all surviving definitions. This is because, unless the inventor has expressly defined or limited the claim language, words should be presumed to have the broadest set of meanings consistent with the intrinsic record.

Nevertheless, only those definitions that are relevant to the art and consistent with the disclosures should be relied upon. Without compelling evidentiary support to the contrary, a claim should not be construed to exclude the only embodiments disclosed in the specification. *Elekta*, 214 F.3d at 1308; *Vitronics*, 90 F.3d at 1583. One way to implement this principle is to apply a definition that survives the above-described screening process to the disclosed embodiment(s). If that definition describes those embodiments (even if it may also describe many more embodiments), that definition is correct unless the patentee has limited the scope of the claims.

III. UNLESS THE SPECIFICATION MAKES PLAIN THAT THE INVENTION MUST CONTAIN A FEATURE, THE CLAIM SHOULD NOT BE LIMITED TO A CONSTRUCTION CONTAINING THAT FEATURE EVEN IF ALL EMBODIMENTS DISCLOSED IN THE SPECIFICATION POSSESS THAT FEATURE.

The specification need not list every embodiment of the invention that the inventor wishes to protect through the claims of the patent. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004), *Mars Inc. v. H.J. Heinz Company L.P.*, 377 F.3d 1369 (Fed. Cir. 2004). Biotechnology companies often are crucially dependent on venture capital funding or early stage alliances with large pharmaceutical companies. Those companies have relied on the premise that “an applicant is not required to describe in the specification every conceivable embodiment of his invention.” *Rexnord*, 274 F.3d at 1344. Unless a biotechnology firm can rely on an invention measured by the full scope of its claims, the settled expectation of the industry would be disrupted and it would be much harder for such companies to secure the capital required to succeed. Thus patent claims should not be limited to the features in the disclosed embodiment(s) unless one of ordinary skill in the art at the time of filing the application would have necessarily concluded that the invention must include those features.

IV. THE CLAIM CONSTRUCTION METHODOLOGIES IN THE MAJORITY AND DISSENTING OPINIONS OF THE PANEL DECISION ARE NOT COMPLEMENTARY BUT ARE RATHER CONFLICTING.

The majority and dissenting opinions in the panel decision reflect the two schools of thought in this Court's precedent. The majority opinion seeks to find meaning entirely within the intrinsic record, limiting the scope of the invention to what is actually disclosed in the specification. The dissenting opinion seeks to broadly define the invention according to how claim terms are generally understood, unless that broad meaning is inconsistent with the disclosure or the patentee expressly disclaimed subject matter. In effect, this view assumes that the inventor had in mind the invention as set forth in the claims and the fact that the disclosed embodiments may be narrow is irrelevant. These views are different and not complementary.

If the methodologies in the panel decision were understood as consulting intrinsic evidence in the majority opinion and relying on extrinsic evidence in the dissenting opinion, the methodologies would have been complementary where extrinsic evidence is understood to be consulted only if intrinsic evidence does not resolve the claim construction. The majority opinion in the panel decision, however, limits the claim construction to the embodiments disclosed in the specification whereas the dissenting opinion approached claim construction by defining terms based on their plain meaning. This makes the methodologies

conflicting since the narrower meaning conveyed in the disclosed embodiments would conflict with, and control, the broader meaning contained in dictionaries or other extrinsic sources.

V. CLAIMS SHOULD NEVER BE NARROWLY CONSTRUED FOR THE SOLE PURPOSE OF AVOIDING INVALIDITY.

Under the statutory scheme, infringement exists if for a given construction of a particular claim all the features of the construed claim are present in the assailed product or process. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997). An affirmative defense to infringement exists, however, when the claim is invalid for anticipation, obviousness or otherwise because an inventor may only “obtain” a patent “subject to the conditions and requirements of this title.” 35 U.S.C. § 101.

Patents are presumed valid and can be shown to be invalid only by clear and convincing evidence. 35 U.S.C. § 282. Consequently, if the prior art is ignored in determining claim meaning and if the meaning determined covers the accused product or process, the plaintiff will win the infringement suit unless the defendant can show, as a matter of clear and convincing evidence before the finder of fact, that the patent is invalid. On the other hand, if the validity issue is considered in determining the meaning of the claim, there is no such burden of proof. More importantly, the decision is not made by the finder of fact, which is the jury under

the Seventh Amendment if the plaintiff so chooses, but the judge. Under the statute, therefore, the validity determination is both irrelevant to, and independent of, the task of claim construction.

Moreover, the public notice function of patent claims requires that they have a definite meaning. The meaning of a claim cannot be allowed to flex like a “nose of wax” based on whatever prior art is provided to a court in a given case. *White v. Dunbar*, 119 U.S. 47, 51-52 (1886).

VI. PROSECUTION HISTORY SHOULD BE USED ONLY TO DETERMINE WHETHER THE PATENTEE ADOPTED A LIMITATION TO THE CLAIM AND EXPERT TESTIMONY SHOULD BE USED ONLY TO EDUCATE THE TRIAL JUDGE IN THE ART OR TO ESTABLISH WHETHER A DICTIONARY OR SIMILAR WRITTEN SOURCE IS UNBIASED AND DIRECTED TO THE APPROPRIATE AUDIENCE.

A. Patent Prosecution History Should Be Employed in Claim Construction When It Demonstrates that the Patentee Disclaimed or Disavowed a Relevant Reading of the Claim.

The inventor has total control over the language used in both a patent’s claim set and in its written description. This is not the case with prosecution history. A patentee does not control the language entered into the prosecution history by the examiner. In addition, oral interviews are reflected in a brief interview summary and are rarely fully transcribed or recorded. The prosecution history, therefore, is often incomplete and can sometimes be misleading.

“[C]laims do indeed serve both a definitional and notice function.” *Warner-Jenkinson*, 520 U.S. at 33. But the “focus in construing disputed terms in claim language is not the subjective intent of the parties to the patent contract when they use a particular term. Rather, the focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean.” *Markman*, 52 F.3d at 986.

For these reasons, use of the prosecution history in claim construction must occur with due care. “Although the prosecution history can and should be used to understand the language used in the claims, it too cannot ‘enlarge, diminish, or vary’ the limitations in the claims.” *Markman*, 52 F.3d at 980. Unless the prosecution history is unambiguous, it should not be used as a tool to advance the claim construction process. *Omega Engineering Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003); *Gart v. Logitech Inc.*, 254 F.3d 1334, 1342 (Fed. Cir. 2001); *DeMarini Sports Inc. v. Worth Inc.*, 239 F.3d 1314, 1326 (Fed. Cir. 2001). Where it is unambiguous, prosecution history may legitimately show an inventor disclaimed or disavowed subject matter, narrowed the scope of the claims, or otherwise manifested a limitation from the ordinary meaning of the claims. *ACTV*, 346 F.3d at 1091; *Vitronics*, 90 F.3d at 1582-83; *Prima Tek II LLC v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1149 (Fed. Cir. 2003).

B. Expert Witnesses May Only Educate the Trial Judge in the Art or Establish the Appropriateness of Using a Particular Extrinsic Written Evidentiary Source.

Oral extrinsic evidence may be used to educate a trial judge in the field covered by an invention. Oral extrinsic evidence also may be used as direct evidence of the appropriateness of using a particular written extrinsic evidentiary source. *Vanderlande*, 366 F.3d at 1321. In either case, oral testimony by expert witnesses can be biased or otherwise unsound. The trial judge should permit such oral extrinsic evidence to be forensically tested by the usual discovery techniques and by cross examination of the person providing the oral extrinsic evidence.

“Where the patent documents are unambiguous, expert testimony regarding the meaning of a claim is entitled to no weight. Any other rule would be unfair to competitors who must be able to rely on the patent documents themselves, without consideration of expert opinion that then does not even exist in ascertaining the scope of a patentee’s right to exclude (citations omitted).” *Telegenix*, 308 F.3d at 1212. Moreover, expert testimony on the meaning of a claim is inherently unreliable because it may be influenced by “events subsequent to the fixing of the intrinsic record by the grant of a patent, ... colored by the motives of the parties, and ... inspired by litigation.” *Id.* at 1203.

VII. ALTHOUGH THE ULTIMATE CLAIM CONSTRUCTION ESTABLISHED BY THE TRIAL COURT SHOULD BE SUBJECT TO *DE NOVO* REVIEW IN THE REVIEWING COURT, THE TRIAL COURT'S CONCLUSIONS REGARDING ORAL EXTRINSIC EVIDENCE SHOULD NOT BE DISTURBED UNLESS THEY ARE CLEARLY ERRONEOUS.

In its *en banc* decision in *Markman*, the Federal Circuit ruled that “[b]ecause claim construction is a matter of law, the construction given the claims is reviewed *de novo* on appeal.” *Markman*, 52 F.3d at 979 & 981. After the Supreme Court’s decision in *Markman*, the Federal Circuit issued panel decisions on the appropriate standard of review on appeal for the claim construction determination of a trial court. Most panels held that because “claim construction is purely a matter of law, this court reviews the district court’s claim construction *de novo* on appeal.” *Cybor*, 138 F.3d at 1454. In other panel decisions, “a clearly erroneous standard [was] applied to findings considered to be factual in nature that are incident to the judge’s construction of the patent claims.” *Id.* In *Cybor*, the Federal Circuit, acting *en banc*, concluded that the *de novo* standard of review remained good law. *Id.* at 1455.

In *Cybor*, the Federal Circuit implicitly assumed that trial court conclusions on oral extrinsic evidence in claim construction cases had to be pure questions of law subject to *de novo* review or else the conclusions would have had to have been made by the jury under the Seventh Amendment. But this assumption is inconsistent with the Supreme Court’s *Markman* decision in two respects. First,

the Supreme Court characterized “construing a term of art following receipt of evidence” as a “mongrel practice” – where the “sounder course” is not to assert the relevant demarcation “line as one between issues of fact and law.” *Markman*, 517 U.S. at 378. Second, the Supreme Court noted that when an issue “falls somewhere between a pristine legal standard and a simple historical fact, the fact/law distinction at times has turned on a determination that, as a matter of the sound administration of justice, one judicial actor is better positioned than another to decide the issue in question.” *Id.* at 388.

Granting a measure of deference to a trial court in its conclusions as to oral extrinsic evidence on appeal would not raise Seventh Amendment questions. The Supreme Court in *Markman* squarely and unanimously held that the “construction of a patent, including terms of art within its claim, is exclusively within the province of the court,” even in a “case in which a simple credibility judgment would suffice to choose between experts whose testimony was equally consistent with a patent’s internal logic” -- i.e., the intrinsic evidence. 517 U.S. at 389. This is because the Supreme Court “expect[ed] any credibility determinations [to be] subsumed within the necessarily sophisticated analysis of the whole document, required by the standard construction rule that a term can be defined only in a way that comports with the instrument as a whole.” *Id.*

Determinations regarding oral extrinsic evidence where credibility considerations may loom large “are the province of the trial court.” (See Order, Chief Judge Mayer, concurring). The trial court can, of course, make mistakes and should be reversed when its conclusions on oral extrinsic evidence are clearly erroneous. For the reviewing court to substitute its judgment on a cold record *de novo*, however, will continue unnecessarily to consume judicial resources and impede the rational settlement of patent infringement suits. By contrast, the trial court does not have a similar advantage with respect to analyzing the intrinsic evidence or the written extrinsic evidence or in making the ultimate claim construction determination. Accordingly, while a trial court’s ultimate claim construction determination and its conclusions as to intrinsic evidence and written extrinsic evidence are properly subject to *de novo* review, the trial court’s conclusions on the meaning and reliability of oral extrinsic evidence before it should stand unless they are clearly erroneous.

CONCLUSION

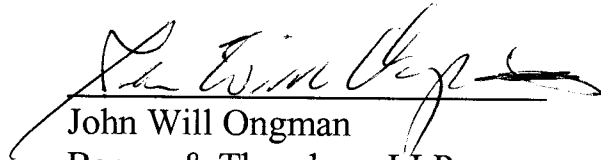
For the foregoing reasons, the Court should adopt the methodology for patent claim construction set forth herein.

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CERTIFICATE OF SERVICE

I hereby certify that I caused two copies of the foregoing BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INDUSTRY ORGANIZATION to be served on this 20th day of September, 2004, via express courier service on the following counsel of record:

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CERTIFICATE OF COMPLIANCE

Amicus curiae Biotechnology Industry Organization submits its brief under Rules 32(a)(5)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure. As required by Rule 32(a)(7)(C), I hereby certify that amicus curiae Biotechnology Industry Organization's brief complies with the type-volume limitation therein provided and with the Court's order limiting amicus briefs to 5,000 words. I further certify that the foregoing BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INDUSTRY ORGANIZATION contains 4,372 words. In preparing this certificate, I have relied on the word count of the word processing system used to prepare this brief, including headings, footnotes, and quotations.

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Dated: September 20, 2004