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Claim Construction: The Federal Circuit Addresses the Proper Use of Dictionaries, Treatises, and Experts.

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IN THIS ISSUE

The trial court's claim construction can have a dramatic impact in a patent infringement case, often reducing the claims and defenses at issue and occasionally eliminating the need for a trial altogether. The time and effort spent analyzing the patent and prosecution history for support for a proposed claim construction is thus not surprising. But other sources of evidence are often ignored or criticized as extrinsic evidence, even though they may directly bear on the plain and ordinary meaning of a term to one of ordinary skill in the relevant art.

The Federal Circuit recently outlined the "Contours of Claim Construction" in *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002). Confirming that "the name of the game is the claim,"[1] the court stated: "In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves...."[2] This, of course, merely starts the action since, in most cases, both parties argue that they are proffering a construction compelled by the claim language, itself. Recent Federal Circuit cases have addressed some of the key questions that remain with respect to claim construction, including the proper use of dictionaries, treatises, and experts.

In *Texas Digital,* the court emphasized that claim construction focuses on the language of the claims, stating that all claim terms bear "a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by *persons skilled in the relevant art.*"[3] In addition, each claim term must be given the "full range" of its ordinary meaning, unless a different construction is compelled.

"In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves...."

But where can courts find the "full range" of the "ordinary meaning" of claim terms? According to the Federal Circuit in *Texas Digital,* publications such as dictionaries, encyclopedias, and treatises are objective and reliable resources that may provide meanings of claim terms as understood by one of ordinary skill in the art. *Texas Digital* appears to elevate these sources from the category of extrinsic evidence. To that end, the court

Claim Construction

Continued from cover

specifically stated that "categorizing [these materials] as 'extrinsic evidence' or even a 'special form of extrinsic evidence' is misplaced and does not inform the analysis."[4]

Objective sources may provide multiple possible definitions that may or may not be consistent with the understanding of persons skilled in the relevant art. The chance of incorrect definitions seems particularly high if dictionaries are used to construe technical terms, which may develop their own meaning(s) in particular field(s). As a result, courts must turn to the intrinsic record to determine which, if any, definition from the objective sources is consistent with the inventor's use of the term. The intrinsic record may rebut the presumption that a claim term has its ordinary meaning because the patentee acted as his own lexicographer. In those situations, all of the inconsistent definitions from the objective sources must be discarded.

…claim terms bear "a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art."

Recent decisions of the Federal Circuit have embraced the use of extrinsic evidence, such as expert testimony, to aid in resolving ambiguities arising from the intrinsic record. In *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116 (Fed. Cir. 2002), the Federal Circuit held that the trial court erred when it invalidated patent claims after ruling, based only on the intrinsic evidence of the specification and the prosecution history, that a particular claim term was indefinite. Because of this error, the Federal Circuit vacated the grant of summary judgment of invalidity based on indefiniteness and remanded for further proceedings in which the trial court could examine extrinsic evidence regarding the usage and meaning of the claim term at issue as understood by one of ordinary skill in the art of the field of the invention. In reaching this conclusion, the Federal Circuit emphasized judges' competency in deciding between "divergent opinions as to the meaning of a term," such as those presented by "persons experienced in a technologic field."[5]

Similarly, in *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363 (Fed. Cir. 2003), the court approved the use of extrinsic evidence and relied on expert testimony in construing the claims. The Federal Circuit specifically stated that "expert testimony serves the permissible purposes of aiding our understanding of the technology and in helping us view the patent through the eyes of the skilled artisan."[6] The court in *Altiris* then supported its claim construction by noting that the expert testimony presented at the *Markman* hearing was illustrative of the understanding of one of ordinary skill in the art.

The proper use of extrinsic evidence will continue to be disputed in claim construction proceedings. In both *Riverwood International Corp. v. R.A. Jones & Co.,* 324 F.3d 1346 (Fed. Cir. 2003) and *Apex Inc. v. Raritan Computer, Inc.,* 325 F.3d 1364 (Fed. Cir. 2003), the Federal Circuit reaffirmed the use of extrinsic evidence in construing claims. However, in a more recent decision, *Storage Technology Corp. v. Cisco Systems, Inc.,* 329 F.3d 823 (Fed. Cir. 2003), the Federal Circuit ruled that the district court improperly relied on an expert declaration to support its claim construction. The Federal Circuit in *Storage Technology* reasoned that "the district court did not use the extrinsic evidence to assist in defining a claim limitation, but rather used it to limit claim scope based on the purpose of the invention, which is impermissible."[7]

The types of evidence that courts examine in claim construction may have a particularly significant impact on the construction of claims to biotechnical inventions. Indeed, the relevant art may be so specialized that general sources such as dictionaries or encyclopedias may not be at all helpful in

determining what meaning one of ordinary skill in the art would ascribe to particular terms. Instead, the court may need to look to more specific, technical publications to learn how these terms are used and understood by one of skill in the art. And parties will undoubtedly continue to debate the proper use of expert testimony in determining the ordinary meaning of claim terms. While these and other questions remain, the Federal Circuit's recent decisions do provide at least some guidance on the sources of evidence for use in construing claims. ◆

The Federal Circuit Again Addresses the Requirements of Describing and Enabling a Biotech Invention: *Amgen v. Hoechst Marion Roussel*

By Terry L. Tang

The Federal Circuit has on several occasions invalidated biotech patent claims for failure either to describe or to teach the "full scope" of the claimed subject matter.[1] The issues of written description and enablement, seemingly more debated in biotech patent cases than in others, have been stalwarts of prior issues of *Biotech Update*. The Federal Circuit's decision in *Amgen Inc. v. Hoechst Marion Roussel, Inc.,* 314 F.3d 1313 (Fed. Cir. 2003) prompts us to revisit these issues again. In *Amgen*, the panel majority affirmed the district court's ruling that the asserted genus claims were adequately described and enabled, despite disclosure of only two species in the broader genus.[2] This decision clarifies what a biotech patent must disclose and teach to one of ordinary skill in the art in order to support broad genus claims, although the Court's position on these issues continues to evolve.

"…we cannot invalidate a patent for failure to describe a method of producing the claimed compositions that is not itself claimed"

Amgen asserted five patents directed to recombinant erythropoietin[4] ("rEPO") and the production of rEPO against defendants, Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc. (collectively "TKT"), who make an rEPO using amethod developed after the filing date of the application from which Amgen claimed priority. The five Amgen patents all share the same specification, which discloses the entire genomic DNA sequence of human EPO and its predicted amino acid sequence. The patents also teach how to produce an rEPO in two types of vertebrate cells. As construed by the trial court, Amgen's EPO product claims include all EPO products with certain specified characteristics, regardless of how that EPO was produced. Amgen's vertebrate cell claims were construed as including all vertebrate cells with the claimed characteristics capable of producing the specified levels of EPO protein, regardless of how those cells were created.

Prior to trial, the district court granted Amgen summary judgment of infringement on one claim. After a bench trial, the court issued an extensive opinion holding: (1) all claims enforceable, (2) the asserted claims of these patents valid and infringed, (3) the asserted process claims not infringed, and (4) one patent not infringed or, in the alternative, invalid for indefiniteness. *Amgen, Inc. v. Hoechst Marion Roussel,* Inc., 126 F. Supp. 2d 69 (D. Mass. 2001). The appeal presented many issues, including arguments by TKT that various asserted claims failed to satisfy the written description and enablement requirements.

Written Description and Enablement Revisited

Continued from page 3

Written Description

The written description requirement asks whether the patent disclosure is sufficient so one of ordinary skill in the art recognizes that the inventor invented what is claimed. On appeal, TKT argued that Amgen failed to satisfy the written description requirement by failing to: (1) describe the use of all vertebrate and mammalian cells, and (2) describe the full scope of the claims because, as construed, the claims encompassed EPO produced by TKT's method, but the patents did not describe that particular method. In essence, TKT contended that the claims were invalid because Amgen's specification failed to describe everything included within the scope of the claims, such as TKT's later-developed method.

The majority concluded that the genus claims were sufficiently described based on the district court's findings that the patent disclosures adequately described to those of ordinary skill in the art the use of the broad class of available mammalian and vertebrate cells to produce the claimed high levels of human EPO in culture, and any minor differences between cell types could be easily figured out. In its analysis, the Court distinguished *Regents of the Univ. of Cal. v. Eli Lilly & Co.,* 119 F.3d 1559 (Fed. Cir. 1997), reasoning that, unlike the undescribed, previously unknown DNA sequences claimed in *Eli Lilly,* the claim terms at issue here "vertebrate" and "mammalian" – are not new or unknown biological materials. Instead, these terms are used in the claims to identify types of cells that can be used to produce rEPO, thereby conveying distinguishing information such that one of ordinary skill in the art could recognize the identity of the members of the genus. Furthermore, because the patent specification disclosed producing the claimed EPO in two species of vertebrate or mammalian cells, the claims covering EPO made using the genus of vertebrate or mammalian cells are adequately described.

The majority also agreed with the district court that, for a claimed composition, a patent specification need only describe the invention as claimed, and need not describe unclaimed methods of making the claimed composition, including after-filing technological developments.[5] Thus, Amgen's patents did not have to describe TKT's later-developed method. If a patentee makes no clear statements limiting the claimed invention, "we cannot invalidate a patent for failure to describe a method of producing the claimed compositions that is not itself claimed."[6]

Enablement

The enablement requirement ensures that the patentee has taught those in the art how to make and use the claimed invention without undue experimentation. On appeal, TKT argued that (1) Amgen failed to enable the use of all vertebrate and mammalian cells, and (2) Amgen failed to enable the full scope of the claims because, as construed, the claims encompassed EPO produced by TKT's method, but the patents do not teach TKT's method.

The majority affirmed the district court's conclusion that the claims satisfied the enablement requirement. As a legal matter, the Court agreed with the district court's application of *Johns Hopkins Univ. v. CellPro, Inc.,* 152 F.3d 1342 (Fed. Cir. 1998): "the law makes clear that the specification need teach only one mode of making and using a claimed composition" to satisfy the enablement requirement.[7] Similarly, the Court approved the district court's conclusion that the specification need not teach after-arising technological developments in methods by which a patented composition is made.[8] Because the district court found that Amgen's specification teaches one mode of making and using the claimed compositions, the failure of the Amgen patents to disclose TKT's after-arising technology did not invalidate the patents.[9]
The majority also focused on the "thorough and complete factual findings supporting [the district court's] holding that the claims were not proven not enabled."[10] For example, the vertebrate cell

claims encompassed genetically manipulated "vertebrate cells" with certain characteristics, including the ability to make specified levels of human EPO. The Court concluded that having disclosed one way to make the claimed EPO-producing cell, Amgen was entitled to claim the genus of all such vertebrate cells.[11] The Court based its ruling on the district court's extensive factual findings that any gaps between the disclosures and the claim breadth could be easily bridged.[12] These included findings that other types of vertebrate cells could have been used to produce human EPO, that post-filing publications demonstrated that the patent disclosure enabled those skilled in the art to produce human EPO in other vertebrate cells, and that undue experimentation was not required to use other vertebrate cells.

By contrast, in *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.,* 315 F.3d 1335 (Fed. Cir. 2003), the Federal Circuit held that broad claims to a genetically engineered cell for producing an herbicide inhibitor were not enabled. The *Plant Genetic* cell claims were construed to encompass all plant cells, including both monocotyledons ("monocots") and dicotyledons ("dicots"), with the specified characteristics. The working examples in the patent all involved stable transformation of dicots. After stating that a lower standard of enablement does not exist for "pioneer" patents, the Court examined whether the cell claims were enabled for monocots as of the 1987 filing date of the patent.

Hogan does not allow an inventor to "claim what was specifically desired but difficult to obtain at the time the application was filed, unless the patent discloses how to make and use it."

The Court first explained that under *In re Hogan,* 559 F.2d 595 (CCPA 1977), a later-existing state of the art cannot be used to invalidate a patent that was enabled for what it claimed at the time of filing. But *Hogan* does not allow an inventor to "claim what was specifically desired but difficult to obtain at the time the application was filed, unless the patent discloses how to make and use it."[13] At the time Plant Genetic filed its patent application, monocots existed, stably-transformed monocot cells were highly desirable but difficult to produce, and the patent specification did not teach such transformation. The Court focused on the district court's finding that in 1987 no reliable transformation method for use with monocots existed that could be used without undue experimentation.[14] The Court also noted that the district court properly used post-filing publications to confirm that monocot cells were not readily transformable as of 1987.[15]

Although the claims in both *Amgen* and *Plant Genetic* encompassed cells other than those exemplified in their respective patent specifications, the Court reached opposite enablement conclusions. The two factors apparently responsible for this difference are: (1) whether the patentee's teachings were applicable for the full scope of the claims; and (2) the state of the art at the time of filing. In *Amgen*, the patents' specification taught a method of practicing the claimed inventions that was generally applicable to all types of vertebrate cells without requiring undue experimentation. On the other hand, the claims at issue in *Plant Genetic* encompassed both monocot and dicot cells, but that patent failed to teach transformation of monocots, which would have required undue experimentation.

Conclusion

Under *Amgen*, a patent need not describe or enable an unclaimed method of making a claimed product, such as an after-arising, unclaimed method of production. Moreover, a genus claim for a biotech invention can be described and enabled by as few as two species examples, provided the factual record establishes that the gap between what is disclosed in the patent and what is covered by the claims can be bridged by one of ordinary skill in the art without undue experimentation. ◆

WTO Negotiations Fail to Resolve Access by Developing Countries to Patented Drugs

By Monica Bhattacharyya

WTO members continue to disagree on how to reconcile public health concerns with patent rights. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) already permits any WTO member country, under limited conditions, to override patent rights through a compulsory license for manufacture and use *in that member country*. At issue now: compulsory licenses authorizing someone other than the patentee to produce and export patented pharmaceuticals from a member country where there is applicable patent protection to another member country facing public health problems but lacking the capacity to manufacture the pharmaceuticals. WTO negotiations on this issue have stalled. Although all members agree that such compulsory licenses should be allowed under some conditions, they disagree over the diseases that should be covered, the countries that should benefit, and the appropriate safeguards against the diversion of pharmaceuticals manufactured under such a compulsory license from low-income countries to wealthier markets.

The Doha Declaration, adopted in November 2001 by the Fourth WTO Ministerial Conference, called for "an expeditious solution" to this problem within the TRIPS framework. Subsequent negotiations have produced numerous proposed solutions, and unilateral interim solutions from the United States and European Union, but still no consensus. This issue will become increasingly important as TRIPS transitional periods expire and the pharmaceutical patent provisions apply to more developing and least-developed countries.

The Doha Declaration And Its Paragraph 6 Directive

The Fourth WTO Ministerial Conference in Doha, Qatar initiated the WTO's current round of trade talks in November 2001. A key condition for developing countries was clarification of TRIPS provisions affecting access to patented pharmaceuticals.[1] The TRIPS Agreement, which went into effect in 1995, was designed to guarantee certain minimum standards of intellectual property protection in all WTO member countries, including protection for pharmaceutical product patents. The TRIPS Agreement also incorporates measures intended to provide flexibility, such as a staggered compliance schedule.[2] Article 31 of TRIPS further authorizes compulsory licensing of patents under certain circumstances and conditions.[3] For example, in cases of "national emergency or other circumstances of extreme urgency," a member country may use a patented invention under a compulsory license without seeking permission from the patent holder. A compulsory license is conditioned on "adequate remuneration" to the patent holder and is authorized "predominantly for the supply of the [member country's] domestic market."

The Doha Declaration…called for "an expeditious solution" to this problem within the TRIPS framework.

Article 31 thus establishes a mechanism for countries to authorize manufacture of generic pharmaceutical products under certain conditions. Because of Article 31's "domestic market" requirement, however, this provision may not authorize exports of generic pharmaceuticals, such that countries without the capacity to produce the drugs domestically may still face access problems.

The Doha Declaration, adopted by the WTO Ministerial Conference in November 2001, sought to address this issue. The Declaration recognized "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." Paragraph 6

of the Declaration directed the TRIPS Council[4] to "find an expeditious solution" to the difficulties that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face... in making effective use of compulsory licensing under the TRIPS Agreement."

Paragraph 6 Negotiations

The Doha Declaration directed the TRIPS Council to find a Paragraph 6 solution "before the end of 2002." But negotiations to date have failed. The United States and the developing countries represent two poles of this debate, while the European Union, Switzerland, and Japan (among others) have taken intermediate positions.

The U.S. approach has focused on the diseases named in the Doha Declaration, and on the needs of low-income countries. Under this approach countries could export generic drugs, under a compulsory license, into least-developed countries and low-income developing countries for certain eligible diseases.[5] Eligible diseases would be limited to those specifically referenced in the Doha Declaration – HIV/AIDS, tuberculosis and malaria – and other infectious epidemics "of comparable gravity and scale." The U.S. has also supported substantial safeguards (for example, clear identification of exported generic products) to prevent diversion of product from low-income countries to wealthier markets.

The developing countries disagree with the U.S. both on the proper scope of eligible diseases and on eligible countries.[6] The developing countries have argued that the solution should extend to any disease that threatens public health, and to any country (whether or not low-income) that lacks domestic capacity to address a particular public health problem. The developing countries have also objected to administrative safeguards against diversion that might place too great a burden on countries seeking to address public health crises.

Negotiations over Paragraph 6 remain stalled, reflecting continued disagreement over how the TRIPS framework should reconcile intellectual property rights and member countries' rights to protect public health.

Although compromise proposals were considered, negotiations stalled in December 2002 primarily over the scope of eligible diseases. Shortly afterwards, the U.S. adopted a unilateral interim Paragraph 6 solution. The interim pledge reflects the U.S. negotiating position, and states that the U.S. will not challenge any WTO member that exports generic drugs to a country lacking domestic production capacity when needed to treat HIV/AIDS, malaria, tuberculosis, and other infectious epidemics "of comparable gravity and scale."[7] The European Union made a similar unilateral pledge, applicable to aid countries without pharmaceutical manufacturing capacities, which includes a broader definition of eligible diseases.[8]

Conclusion

Negotiations over Paragraph 6 remain stalled, reflecting continued disagreement over how the TRIPS framework should reconcile intellectual property rights and member countries' rights to protect public health. The U.S. and European Union interim solutions indicate agreement on access issues for certain public health crises, such as HIV/AIDS, in low-income countries. But member countries otherwise diverge in how they assess risks posed to intellectual property rights, including risks of diversion to other markets, and potential benefits to public health. Failure to reach agreement before the WTO Fifth Ministerial Conference in September 2003 could threaten other aspects of current WTO trade talks. ◆

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NOTES

From Page 1
Claim Construction

1 Giles S. Rich, *Extent of Protection and Interpretation of Claims — American Perspectives,* 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990) (emphasis omitted).
2 *Texas Digital,* 308 F.3d at 1201 (quoting *Interactive Gift Express, Inc. v. Compuserve, Inc.,* 256 F.3d 1323, 1331 (Fed. Cir. 2001)).
3 *Id.* at 1202 (citing, *inter alia, CCS Fitness, Inc. v. Brunswick Corp.,* 288 F.3d 1359, 1366 (Fed. Cir. 2002)) (emphasis added).
4 *Id.* at 1203.
5 *Verve,* 311 F.3d at 1120.
6 *Altiris,* 318 F.3d at 1371.
7 *Storage Tech.,* 329 F.3d at 832.

From Page 3
Written Description and Enablement Revisited

1 *See, e.g., Regents of the Univ. of Cal. v. Eli Lilly & Co.,* 119 F.3d 1559 (Fed. Cir. 1997) (written description); *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362 (Fed. Cir. 1999) (enablement).
2 Judge Clevenger dissented with respect to the enablement and written description because the district court failed to consider "whether Amgen's disclosure of *one* means of producing synthetic EPO in mammalian cells… entitles it to claim all EPO produced by mammalian cells in culture, or *all* cultured vertebrate cells that produce EPO." 314 F.3d at 1359 (Clevenger, J. dissenting).
3 314 F.3d at 1331.
4 EPO is a naturally occurring protein that initiates and controls the production of red blood cells in bone marrow.
5 *Id.* at 1331, 1333 (citing *U.S. Steel Corp. v. Phillips Petroleum Co.,* 865 F.2d 1247 (Fed. Cir. 1989); *In re Koller,* 613 F.2d 819 (CCPA 1977)).
6 *Id.* at 1334. The majority also distinguished *Gentry Gallery, Inc. v. Berkline Corp.,* 134 F.3d 1473 (Fed. Cir. 1998), reiterating that *Gentry Gallery* did not create a new "essential element" test. *Id.* at 1333 (citing *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.,* 291 F.3d 1317, 1323 (Fed. Cir. 2002)). TKT argued that following *Gentry Gallery* Amgen's product claims were invalid because the claims did not contain an exogenous DNA limitation even though the specification only provided examples using exogenous DNA. The Court rejected TKT's argument, explaining that Amgen's specification did not clearly indicate that "exogenous expression is the *only* possible mode of the invention or that other methods were outside the stated purpose of the invention." 314 F.3d at 1334.
7 *Id.* at 1335.
8 *Id.* (citing *U.S. Steel Corp. v. Phillips Petroleum Co.,* 865 F.2d 1247 (Fed. Cir. 1989); *In re Koller,* 613 F.2d 819 (CCPA 1977); *In re Hogan,* 559 F.2d 606 (CCPA 1977)).
9 *Id.* at 1335.
10 *Id.* at 1334-35.
11 *Id.* at 1337.
12 *Id.* at 1336.
13 315 F.3d at 1340.
14 *Id.* at 1343-44.
15 *Id.* at 1344.

From Page 6
WTO Talks on Compulsory Licensing

1 *See* "Tough Talkers: Poor Nations Win Gains In Global Trade Deal, As U.S. Compromises," THE WALL STREET JOURNAL, November 15, 2001.
2 *See, e.g.,* TRIPS Agreement, Articles 30, 65 and 66.
3 A "compulsory license" is authorization by a member country to use a patented invention without the patent holder's consent. *See id.,* Article 31.
4 The TRIPS Council, open to all members of the WTO, administers the TRIPS Agreement.
5 "U.S. Announces Interim Plan to Help Poor Countries Fight HIV/AIDS and Other Health Crises in Absence of WTO Consensus," Press Release from the Office of the U.S. Trade Representative dated Dec. 20, 2002; "Moratorium to Address Needs of Developing and Least-Developed Members With No or Insufficient Manufacturing Capacities in the Pharmaceutical Sector," Communication from the United States to the WTO dated January 13, 2003.
6 *See* "Elements Of A Paragraph 6 Solution," Communication from Kenya, Coordinator of the African Group, to the WTO dated November 14, 2002; "Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health," Communication from Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela to the WTO dated June 21, 2002.
7 *See* n.5, above.
8 Letter dated January 7, 2003 from Pascal Lamy to WTO members; Main Elements of The Chair's 16 December 2002 Draft Compromise Decision, *available at* http://europa.eu.int/comm/trade/csc/memo090103_en.htm.