- *Novo Nordisk of North America, Inc., v. Genentech, Inc.*, 77 F.3d 1364, 37 USPQ2d 1773 (Fed. Cir. 1996);

- *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 38 USPQ2d 1321 (Fed. Cir. 1996);

- *Amgen, Inc., v. Genetics Institute, Inc.*, 98 F.3d 1328, 40 USPQ2d 1524 (Fed. Cir. 1996);

- *Genentech, Inc., v. Novo Nordisk*, 108 F.3d 1361, 42 USPQ2D (Fed Cir 1997);

- *The Regents of the University of California v. Eli Lilly and Company*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

(b) Indicate whether any judicial decisions in your country have addressed the following issues, and if so, please explain the findings and conclusions of the decision(s) :

(i) whether claims have been interpreted to cover subject matter not specifically claimed (i.e., equivalents of the specifically claimed invention, other uses of the invention), and if so, what criteria are used to determine whether a finding of infringement in such situations is justified;

A well established doctrine of U.S. patent law (i.e., the "octrine of equivalents" enables a patent owner to obtain a finding of infringement notwithstanding the fact that the allegedly infringing subject matter is not literally within the scope of protection defined by the patent claims. Many cases serve to define the conditions and limits of this doctrine, the large majority of which lie outside the technical area of biotechnology.

The key inquiry to be made in an assessment of whether an invention is infringing under the doctrine of equivalents is whether the differences between the invention as claimed and the allegedly infringing subject matter are "insubstantial." In 1997, the Supreme Court provided useful guidance to courts in applying this doctrine in *Warner Jenkinson Co., Inc. v. Hilton Davis Chemical Co*, 117 S. Ct. 1040, 41 USPQ2d 1865 (1997). In this case, the Court firmly endorsed the continued viability of the doctrine of equivalents, but provided several important clarifications in how the doctrine was to be applied.

First, the Court emphasized that the assessment of infringement under the doctrine of equivalents was to be conducted in an objective manner. It emphasized that courts were not to incorporate a subjective assessment of the intent of the alleged infringer into the analysis for equivalents (e.g., by attempting to derive a conclusion as to liability due to an intent to "teal"or by designing around the literal scope of the claims through inclusion of insignificant modifications).

Second, the Court made clear that the doctrine of equivalents assessment was to be conducted by comparing each element of the claimed invention with that of the allegedly infringing subject matter. This affirmed the "all elements" rule articulated in a number of cases by the Federal Circuit.

Third, the Court reiterated that the relief possible through use of the doctrine of equivalents can be limited by the actions of the patent owner during the prosecution of the patent application (i.e., "prosecution history estoppel") and by the prior art (i.e., one

cannot establish infringement under the doctrine of equivalents to encompass subject matter that would not have been patentable if it was originally sought by the applicant). On the former question, the Court noted that where it was unclear why an applicant during prosecution had amended the claims to exclude certain subject matter that he later tried to cover through the doctrine of equivalents, it may be presumed that he intended to forfeit any claim for protection to the excluded subject matter. The Court was careful to note that this presumption could be overcome by the patent owner.[15]

Finally, the Court indicated that there was no mandatory linguistic test for applying the doctrine of equivalents. It noted that the three part "function-way-result" test of the 1950 Supreme Court case of *Graver Tank v. Linde Air Products*, 339 U.S. 605 (1950) was still useful but not a mandatory step in the doctrine of equivalents assessment.

The question of infringement under the doctrine of equivalents in relation to patent claims directed to biotechnology inventions has been addressed in a number of decisions of the Federal Circuit. However, the question has been directly addressed as a central holding of a decision in only one case, namely, *Genentech, Inc. v. Wellcome Foundation,* 29 F.3d 1555, 31 USPQ2d 1161 (Fed. Cir. 1994).

In this case, the Federal Circuit reversed a finding by the district court on the question of infringement through the doctrine of equivalents. Genentech held claims to the naturally occurring sequence of human tissue plasminogen activator (t-PA). The defendants had produced a second generation recombinant t-PA protein that incorporated a number of significant structural modifications, including the deletion of an 81 amino acid sequence that corresponded to a fibrin binding region of the naturally occurring protein. The district court, in finding infringement, indicated that the structurally modified protein performed the same function (i.e., exerted the biological characteristic of t-PA in converting plasminogen to plasmin). It did not address in detail the question of *how* the structurally modified t-PA protein performed this function.

The Federal Circuit reversed the district court's finding of infringement under the doctrine of equivalents. The court focused on the "same function" element of the three step test for equivalents. It held that the defendant's structurally altered t-PA did not perform substantially the same function as that of patented full length t-PA protein.

[15] As the Court held in discussing the process of assessing the rationale offered by the patent owner for his actions in amending a claim during prosecution of the patent application:

> The court then would decide whether that reason is sufficient to overcome prosecution history estoppel as a bar to application of the doctrine of equivalents to the element added by that amendment. Where no explanation is established, however, the court should presume that the PTO had a substantial reason related to patentability for including the limiting element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine equivalents as to that element. The presumption we have described, one subject to rebuttal if an appropriate reason for a required amendment is established, gives proper deference to the role of claims in defining an invention and providing public notice, and to the primacy of the PTO in ensuring that the claims allowed cover only subject matter that is properly patentable in a proffered patent application. Applied in this fashion, prosecution history estoppel places reasonable limits on the doctrine of equivalents, and further insulates the doctrine from any feared conflict with the Patent Act.

Specifically, it held that the function performed by the full sequence t-PA was not simply the conversion of plasminogen to plasmin but included fibrin binding. On this basis, the court concluded that no reasonable jury could have found that the structurally altered recombinant t-PA had the substantially the same function as the patented full sequence t-PA, and as such, no finding of infringement through equivalents could be supported.

For other cases which address the doctrine in the context of patents claiming biotechnological inventions, see *Hormone Research Foundation, Inc. et al., v. Genentech, Inc.*, 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990); *American Hospital Supply Corporation et al., v. Travenol Laboratories, Inc., et al.*, 745 F.2d 1, 223 USPQ 577 (Fed. Cir. 1984); *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 38 USPQ2d 1321 (Fed. Cir. 1996); *The Regents of the University of California v. Eli Lilly and Company*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

(ii) whether claims can be interpreted to cover a scope that is less than that literally defined by the terms of the claim;

The scenario referred to in the question has been termed the "reverse doctrine of equivalents" within the United States. While it has been recognized as a theoretical defense to a claim of infringement, no U.S. court has held that literal infringement was avoided on the basis of the doctrine. One reason for this situation was summarized by the Court of Appeals for the Federal Circuit in the case of SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1124, n19, 227 USPQ 577, 587, n19 (Fed. Cir. 1985), where it noted that "[b]ecause products on which patent claims are readable word for word often are in fact the same, perform the same function in the same way and achieve the same result, as the claimed invention, a defense on the reverse doctrine of equivalents is rarely offered." Although several cases have raised the issue of the reverse doctrine of equivalents in relation to claims defining biotechnology or pharmaceutical products, in no reported case has a party successfully used the theory to avoid liability for literal infringement. See, e.g., *Scripps Clinic & Research Foundation et. al., v. Genentech, Inc., et al.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); *Zenith Laboratories, Inc., v. Bristol-Myers Squibb Company*, 19 F.3d 1418, 30 USPQ2d 285(Fed. Cir. 1994).

(iii) whether claim language specifying physiological, biological or other functional characteristics of a product specified in question A.a) has been interpreted in the

Claim language relating to physiological or biological activity has been issue in the interpretation of claims in a number of cases decided by the Federal Circuit. The most significant examples can be found in the case of *Amgen, Inc., v. Chugai Pharmaceutical Co., Ltd., et. al.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). This dispute focused on the enforcement of two patents concerning erythropoeitin, one being held by each party. Each patent relied to a certain extent on the use of functional terms in claims to define claim scope. For example, claim 7 of the Amgen patent covered any nucleotide sequence encoding a "polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake." The court first noted that while the scope of the claim could be identified through reliance on the functional language, it literally encompassed millions of potential sequences. It then upheld a finding of invalidity for the claim on the basis of lack of enablement, noting that the specification failed to

provide support for the very broad scope of the claim. The court also found that claims in the Genetics Institute patent that defined an erythropoeitin composition having a particular specified activity were invalid on the basis of lack of enablement. The court noted that the disclosure of the GI patent was not capable, when practiced, of yielding compositions having the specified levels of biological activity. Again, the court was able to rely on the functional limitation (i.e., the specified biological activity) to define the scope of the claims; the basis for invalidation was lack of enablement.

(iv) whether a claim to a biotechnological process has been found to cover a product obtained directly from the practice of the process, even of the product per se cannot be patented;

Under U.S. law, the holder of a patent covering a process can enforce those rights in respect of the product that is produced through the practice of the patented process. See, 35 U.S.C. 271(g). This issue was addressed in the case of *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 38 USPQ2d 1321 (Fed. Cir. 1996). The Federal Circuit has also addressed the meaning of "process" under 271(g) in the context of claims to living organisms. See, *Amgen Inc., v. United States International Trade Commission, et al.*, 902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990) (holding that a claim to a microorganism cannot serve as basis for invoking 271(g), as the claim does not define a process).

(v) whether a claim to a process or a product that covers a self-replicating organism extends to successive identical generations of organisms derived from the original organism.

Yes, provided the successive generations retain those characteristics or properties necessary to place the successive generation within the scope of the patent claim.

Use for Non-Commercial Research

(c) Indicate whether the standard governing liability for unauthorised use of a patented invention for research or experimentation purposes differs for inventions in the field of biotechnology, as compared to inventions in other fields of technology. List any judicial decisions that have issued in your country where a third party has been found liable for the unauthorised use of a patented invention where such use was for research or experimental purposes.

The legal standards governing liability for unauthorized use of a patented invention are the same for biotechnological inventions as for inventions in any field of technology.

No judicial decisions have issued in the United States in which a third party has been found liable for patent infringement where the infringing activity was shown to be for non-commercial experimental or "research" purposes.

Patent Enforcement Issues in Respect of Plant Varieties

(d) Indicate whether any judicial decisions in your country have addressed the following issues, and if so, please explain the findings and conclusions of the decision(s) :

(i) an action by a patent holder in response to the use of a patented gene manipulation procedure to produce a new plant or plant variety without the prior authorisation of the patent holder ;

No reported judicial decisions in the United States have addressed this fact pattern.

(ii) an action by a patent holder in response to the use of a plant subject to a patent to produce a new plant variety without the prior authorisation of the patent holder ;

No reported judicial decisions in the United States have addressed this fact pattern.

(iii) an action by a patent holder in response to the use or sale of products harvested from a specific plant variety that has been produced using a patented plant or plant that has incorporated a patented gene.

No reported judicial decisions in the United States have addressed this fact pattern.

Use without Authorisation of the Patent Holder

(e) Indicate whether and explain the circumstances under which a party can obtain the right to use a patented biotechnological invention specified in questions A.a) and b) without the authorisation of the patent holder. If so, please indicate how frequently such rights to use are granted and whether any such right to use has been granted with respect to patented biotechnological inventions specified in questions A.a) or b).

No basis exists in U.S. law to grant a compulsory license under a patent directed to any of the inventions specified in question A.(a) or (b).

C. PLANT VARIETY PROTECTION ISSUES RELEVANT TO PLANT INVENTIONS

Availability of Plant Variety Protection

(a) Indicate:

(i) whether plant varieties are protected under a sui generis system in your country;

Sexually produced plant varieties are protected through the Plant Variety Protection Act (7 U.S.C. 2321 et seq.). The PVPA is administered by the Plant Variety Protection Office of the United States Department of Agriculture.

Asexually produced plant varieties are protected through the Plant Patent Act (35 U.S.C. §§ 161-164). The Plant Patent Act is administered by the Patent and Trademark Office.

(ii) the Act of the UPOV Convention which your country has acceded to or ratified (i.e., 1991, 1978, 1972 or 1961), if any; and

The United States has acceded to the 1978 Act of the UPOV.

(iii) whether your country has implemented changes to conform to the 1991 Act of UPOV.