

Luigi Palombi*

The Impact of TRIPS on the Validity of the European Biotechnology Directive

Introduction

In July 2003, the European Commission referred Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands and Sweden to the *Court of Justice of the European Communities* (Court of Justice) for their failure to transform arts. 1 to 11 of the European Biotechnology Directive,¹ (the *Directive*) into their national patent laws by July 2002. This action by the European Commission, eight years after the European Parliament passed the *Directive* against eight out of fifteen Member States that made up the European Community (EC) at the time, demonstrates that the patentability of subject matter that comes within arts. 3.2 and 5.2 *Directive*² continues to be controversial in Europe and that the passage of the *Directive* has not yet resolved this controversy.

The fact that by the end of October, 2004 the Court of Justice confirmed that Germany had breached the *Directive*³ and that by early December 2004 Germany's Bundestag had conceded the debate by passing legislation transforming the *Directive* into German patent law does not address the complaint which is made against the European Parliament, the European Commission and those Member States that have complied with the *Directive*. They are each individually and collectively in violation of art. 27.1⁴ of the *Agreement On Trade-Related Aspects Of Intellectual Property Rights* (TRIPS) and consequently, of art. XVI.4⁵ of the *World Trade Agreement* (WTA).

The fact that these violations have been allowed to persist together with the actions of the European Commission in pursuing enforcement, is today a matter of paramount importance not only to those nations that have refused to adopt the *Directive* but to all one hundred and forty eight members of the World Trade Organisation (WTO). It must be understood that all WTO members are bound to "ensure the conformity of [their] laws, regulations and administrative procedures with [their] obligations as provided in the annexed Agreements,"⁶ with TRIPS being one of these. Relevantly, TRIPS contains a detailed set of minimum international legislative and regulatory standards that are designed to "promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual

property rights do not themselves become barriers to legitimate trade."⁷ Clearly, these standards must be uniformly adhered to if the WTO is to function fairly and efficiently and if the stated objectives of TRIPS are to be met multilaterally.

Daniel Gervais in his authoritative work⁸ on the drafting history of TRIPS described it as one of the

* LLB, BEc, is a visiting post doctoral fellow at the University of New South Wales (UNSW) and a Consultant at Minter Ellison Lawyers, Sydney. Email: luigi.palombi@minterellison.com. Luigi has practiced in intellectual property law since 1986, and has developed an emphasis on patent litigation and strategy with respect to biotechnology. His expertise in this field goes beyond Australia and includes the United States, the United Kingdom and Europe. In September 2004 Luigi completed a research thesis for the degree of Doctor of Philosophy at UNSW. His thesis topic was 'The Patenting of Biological Materials in the Context of the Agreement On Trade Related Aspects Of Intellectual Property'.

1 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions. Official Journal L 213 , 30/07/1998 P. 0013 – 0021.

2 Art. 3.2 *Directive* "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature." Art. 5.2 *Directive* "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

3 *European Commission v The Federal German Republic: Case C-5/04: Decision handed down October 28, 2004.*

4 Art. 27.1 TRIPS "...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application ... shall be available ... without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." (Emphasis added)

5 Art. XVI.4 WTA "Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements.

6 Article. XVI.4 WTA.

7 First recital to TRIPS. (Emphasis added).

8 Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 2nd Ed., London, Sweet & Maxwell, 2003. See also: Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights*, Kluwer Law International, 2002 in which the author describes

“most significant milestones in the development of intellectual property in the twentieth century,”⁹ giving “new life” to the Berne and Paris Conventions of the nineteenth century. This breath of life, he explained, came in the form of the enforcement of intellectual property rights, which “for the first time”¹⁰ enabled WTO members to seek economic redress against each other for violations of the WTA. Accordingly, if these minimum standards are violated, the WTO is able to levy economic penalties against the guilty party, but the consequences of a violation may not end with the WTO.

In *The Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission)*¹¹ the Court of Justice held that “... the legality of a Community instrument can be called in to question on grounds of breach of international agreements to which the Community is a party ... if the provisions of those agreements have direct effect.”¹² There is no question about the status of the WTA and TRIPS. They are both international agreements to which the EC, in contrast to the members of the EC, is a separate party and which have a direct effect in the EC.

The essence of the invalidity is the *Directive's* inconsistency with three key requirements of art. 27.1. Art. 27.1 provides that :

- 1) ‘patents shall be available for any inventions’. The words ‘any inventions’ establishes a condition to patentability, namely, that patents be granted only with respect to an ‘invention’.
- 2) patents shall be available ‘... provided that [the inventions are] new, involve an inventive step and are capable of industrial application’. This proviso establishes conditions of patentability that the invention must satisfy if it is to be a ‘patentable invention.’ The proviso implies that some inventions are not ‘patentable’.
- 3) that the four patentability conditions are to be applied across ‘all fields of technology ... without discrimination as to ... the field of technology ...’. This means that there must not be negative nor positive discrimination directed towards any specific technology in terms of patentability.

The Nature Of The Conflict

Any Invention

Art. 27.1 contains a distinction between an ‘invention’ and a ‘patentable invention.’ The proviso, ‘any inventions,’ anterior to the three conditions of patentability of novelty, inventive step and industrial applicability confirm this distinction. It is not that anything that meets the conditions of

patentability is a patentable invention. It must first be an ‘invention’.

TRIPS does not define the word ‘invention’, but the absence of an express definition does not mean that a signatory may expand patentable subject matter under its domestic patent law without limitation.

While it is true that there is no universal statutory definition of ‘invention’, it is not true that there is no commonality of understanding of what the word means.¹³ True enough that s.100 of the Patents Act, USC 35 1952 (US Act) defines invention to mean ‘invention or discovery’, however, s. 101 US Act qualifies s.100 so that to be an ‘invention’ the patentee must ‘invent or discover ... a new and useful process, machine, manufacture or composition of matter’. The definition of ‘invention’ in the US Act therefore appears to contradict the EPC because art.52(2)(a) EPC¹⁴ expressly excludes ‘discoveries’ from being ‘inventions’, however, this supposed ‘contradiction’ between US and European patent law is resolved once it is understood that firstly, under the EPC

TRIPS as “the most comprehensive international agreement on intellectual property protection ever established”, 24, 1 and he explains that TRIPS is distinguishable from both the Berne and Paris Conventions of the 19th century because first, TRIPS contains provisions which concern both copyright (Berne Convention, 1866) and industrial property (Paris Convention, 1883) and second, TRIPS contains provisions related to the enforcement of intellectual property rights, 24-25; Markus Nollf, TRIPS, PCT and Global Patent Procurement, Kluwer Law International, 2001, in which the author explains that “TRIPS is the most far-reaching intellectual property agreement yet enacted on a global level,” and that it “will for the first time set coherent standards regarding the availability, scope and duration of patent rights and their exceptions on a global scale.”, 39; and Susan K. Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights, Cambridge University Press, 2003 in which the author explains that “TRIPS is a dramatic expansion of the rights of IP owners” which is “far-reaching” with “important implications for innovation, research and development, economic development, the future location of industry, and the global division of labor”, 7-9.

9 Ibid, 3, 1.01.

10 Ibid.

11 *The Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission)* [2002] All ER (EC) 97.

12 Ibid, para 51 (Emphasis added).

13 For example the High Court of Australia held in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited* (1995) 183 CLR 65, para 5 that “what is known as an ‘invention’” is defined “under well-established traditional principles of patent law.” (Emphasis added).

14 See art. 52.2(a) EPC.

only discoveries per se fall within the exclusion and secondly, the word ‘discover’ in the definition of ‘invention’ in the US Act is to a specific form of discovery, namely the discovery of a ‘process, machine, manufacture or composition of matter’ which is ‘new and useful’. In essence, the type of discovery that is excluded from being an ‘invention’ under the EPC is exactly the same as the type of discovery which has been held by the US Supreme Court not to come within the definition of ‘invention’ under the US Act. An examination of the UK Court of Appeal decision in *Genentech Inc’s Patent*¹⁵ (*Genentech*) with the US Supreme Court decision in *Diamond, Commissioner of Patents v Chakrabarty*¹⁶ (*Chakrabarty*) demonstrates this resolution.

In the 1989 decision in *Genentech* the UK Court of Appeal explained that not all discoveries came within the exclusion in s.1(2)(a) Patents Act, 1977 (UK Act). It held,

[A] discovery ... is capable of forming the *substratum of invention* ... if it is applied in a technique or process or incorporated in a product ...¹⁷

In the 1980 decision in *Chakrabarty* the US Supreme Court explained that not all discoveries came within s.101 US Act. It held,

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. ... Such discoveries are “manifestations of ... nature, free to all men and reserved exclusively to none.” *Funk, supra*, at 130.¹⁸

This resolution is also demonstrated by the manner in which TRIPS came into being and in this regard it is important to note that both of these decisions pre-date TRIPS and both reflect patent law as it was in Europe and the United States at the time that the first draft of what became TRIPS was first circulated in 1990. Daniel Gervais dubbed this document the ‘Brussels Draft’ because it was tabled with the TRIPS Negotiating Group¹⁹ by the EC. According to him this document was “the spark which ignited the work towards the TRIPS Agreement”²⁰ He also confirmed that the US tabled its own draft in similar terms²¹ a few months after the EC and that the “common structure”²² between the ‘Brussels Draft’ and the ‘US Draft’, “subject to a few changes, ... serve[d] as the basis for the emerging Agreement.”²³

His comparison of the drafting documents revealed that the word ‘invention’ in art. 27.1 was not the subject of amendment following the tabling of the original ‘Brussels Draft’.²⁴ It was present in the ‘Brussels Draft’ and in the subsequent working document, the ‘Draft of July 23, 1990 (W/76)’²⁵. What this suggests is that the word ‘invention’ among the

drafters of the final Agreement was not controversial because it mirrored art. 52.1 EPC.

Like art. 52.1 EPC, art 27.1 TRIPS provides a two step test of patentability:

Step One: Is the patent application directed to an invention? If no, it is not eligible for patentability consideration. If yes, then go to Step Two.

Step Two: Is the invention:

(a) industrially applicable?²⁶ and

(b) new?²⁷ and

(c) inventive?²⁸

If no to any of these questions, it is not a patentable invention. If yes to all three questions it is a ‘patentable invention’.

This two step test was confirmed in terms of s.1(1) UK Act and art. 52.1 EPC, which undoubtedly was the lingual genesis of art. 27.1, by the UK Court of Appeal in *Genentech*. There Mustill LJ explained that the word ‘invention’ in s.1(1) UK Act and art. 52(1) EPC was one of the “four conditions” that “turns an invention into a patentable invention”.²⁹ This interpretation, he held, was “fortified”³⁰ by the *Guidelines for Examination in the EPO* which stated:

15 *Genentech Inc’s Patent* [1989] RPC 149 (UK Court of Appeal).

16 *Diamond, Commissioner of Patents v Chakrabarty* 447 U.S. 303 (US Supreme Court).

17 *Genentech Inc’s Patent* [1989] RPC 149 per Purchas LJ para 12.09 (Emphasis added).

18 447 U.S. 303, 309

19 The TRIPS Negotiating Group was formed as part of the Uruguay Round of GATT. The chairman was Ambassador Lars E.R. Anell of Sweden. For a detailed history see D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 2nd Ed., London, Sweet & Maxwell, 2003, 3-26.

20 *Ibid.*

21 Daniel Gervais speculates that the similarity in structure and language between the ‘Brussels Draft’ and the ‘US Draft’ suggested that there had been “transatlantic consultations” before the tabling of the two documents. *Ibid.*, 16, 1.18.

22 *Ibid.*

23 *Ibid.*

24 This is the terminology of Daniel Gervais.

25 This is the terminology of Daniel Gervais.

26 Art 57 EPC states “An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.”

27 Art 54.1 EPC states “An invention shall be considered to be new if it does not form part of the state of the art.”

28 Art 56 EPC states “ ... having regard to the state of the art, [the invention] is not obvious to a person skilled in the art”.

29 *Genentech Inc’s Patent* [1989] RPC 149 per Mustill LJ, 262, line 45 (UK Court of Appeal).

30 *Ibid.*, 262, line 4.

First, in paragraph 1.1 of Chapter IV [of the Guidelines] that:

1. There must be an 'invention'.
2. The invention must be 'susceptible of industrial application'.
3. The invention must be 'new'.
4. The invention must involve an 'inventive step'.

Secondly, in paragraph 2.2 of Chapter IV [of the Guidelines] that:

It must also be borne in mind that the basic test of whether there is an invention within the meaning of Article 52(1) is separate and distinct from the questions whether the subject-matter is susceptible of industrial application, is new and involves an inventive step.³¹

The reasoning of Mustill LJ on this issue was undoubtedly correct. Not only was his reasoning consistent with the distinction between 'invention' and 'patentable invention' contained within art. 52(1) EPC and s.1(1) UK Act, but it was also consistent with the same distinction contained in s.101 US Act³² and s.18(1) Patents Act, 1990 (Australian).³³

The Directive, however, renders the first step superfluous because it uses the isolation of biological material or their production by technical processes as the criteria upon which to distinguish these biological materials from their natural counterparts and presumes them to be 'inventions' within art. 52.1 EPC. It therefore removes step one from the scrutiny of the EPO in the grant of European patents and from national courts in revocation proceedings. Therefore, under the Directive any isolated or technically produced biological material is presumed to be an 'invention' and only the conditions of 'industrial applicability', 'novelty' and 'inventive step' have to be satisfied for the patentability threshold to be met.

The question which this article poses is this: Given that the EPC came into effect in 1973 and TRIPS came into effect in 1995, and that art. 52.1 EPC and art. 27.1 TRIPS mirror each other, how can the Directive which came into effect in 2000 legitimately presume 'isolated' or 'technically produced' biological materials to be 'inventions' within the meaning of art. 27.1? Or, if isolated or technically produced biological materials were always 'inventions' within art. 52.1 EPC what was the point of the Directive?

In short, the answer to the first question is that the Directive cannot legitimately create this presumption because it is, for the reasons that Mustill LJ gave in *Genentech*, inconsistent with both the EPC and TRIPS. In this regard it is necessary to take a closer look at *Genentech*.

Genentech (UK Court of Appeal)

The subject matter of the *Genentech* patent was the recombinant production of human tissue plas-

minogen activator (t-PA), a protein used by the human body in the process of dissolving blood clots. The patent taught that by using recombinant DNA technology, t-PA could be produced in large quantities. However, before production of t-PA by this means could be effected, it was first necessary to identify the whole genetic sequence of this protein. It was generally known that all proteins consisted of amino acids, but the amino acid sequence of t-PA was not known. The patent taught the amino acid sequence of t-PA.

Claim 1, the primary claim, defined the scope of the monopoly as '*recombinant human tissue plasminogen activator essentially free of other protein of human origin.*' Claim 3 defined the scope of the monopoly as '*human tissue plasminogen activator as produced by recombinant DNA technology.*'

One issue was whether the product defined in claims 1 to 6 of the patent were 'inventions' within the meaning of the word in s.1(1) UK Act.

Purchas LJ held that while claims 1 to 6 were product claims, the products were t-PA per se, a human protein, "in one form or another and prepared by one method or another"³⁴ and as such were discoveries within s.1(2)(a) UK Act and not inventions within s.1(1) UK Act. He considered that while the other claims did incorporate the use of a method, such as the use of recombinant DNA technology, that particular method of production had to be "clearly identified and defined"³⁵ so as to "exclude any speculative element".³⁶

Mustill LJ was of the view that a protein produced by recombinant means did not make that protein per se new and in assessing whether the protein was an invention it was the protein itself and its genetic construction which was relevant, rather

³¹ Ibid.

³² P.C. Ducor, *Patenting the Recombinant Products of Biotechnology and Other Molecules*, Kluwer Law International, 1998, 6 confirms that "[f]irst, the invention must constitute patentable subject matter, as defined by s.101 of the Patent Act. This requirement can be considered as a 'precondition' for patentability, anterior to any other legal evaluation."

³³ The High Court of Australia in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited* (1995) 183 CLR 65, para 9 held that whether something is an 'invention' is not based upon a consideration of the conditions of patentability of 'novelty' or 'inventive step' in s.18(1)(b) AU Act because the "more specific requirements of novelty and inventive step" are only to be considered after the condition of 'invention' is first satisfied.

³⁴ Ibid, para 14.13, 229 lines 1-2.

³⁵ Ibid, para 14.13, 228 lines 50-51.

³⁶ Ibid, para 14.13, 228 line 52.

than its method of production or its stasis. His Lordship held,

We are here concerned with a process for synthesising a substance *identical to that which occurs in nature*. The t-PA produced by the process is not “artificial” t-PA or “synthetic” t-PA, in the sense of artificial silk or synthetic rubber; ie in the sense of something which resembles the natural substance, or can perform a similar function, or act as a substitute. It is not ersatz. The t-PA which Genentech made is neither more nor less than t-PA.³⁷

His Lordship compared the product defined in the primary claim by reference to naturally produced t-PA. The fact that it was isolated did not alter his opinion of what it was.

He held that s. 1(1) UK Act contained a “fundamental requirement”³⁸ of invention which must be satisfied prior to and independently of “the three conditions precedent to the grant of a patent set out in paragraphs (a) to (c) of section 1(1)”.³⁹ This conclusion was underlined when he held that s.1(2) UK Act “then goes on to exclude certain matters from the scope of ‘invention’”.⁴⁰

He concluded that claims 2⁴¹ and 4⁴² were not inventions and that “they should fall at the very first hurdle”.⁴³ Similarly, he concluded that the inventions defined in claims 1⁴⁴ and 3⁴⁵ were equally invalid because “there is no difference between recombinant t-PA and any other kind of t-PA.”⁴⁶

So, in 1989 the UK Court of Appeal held in *Genentech* that the claims to isolated and purified t-PA were not ‘inventions’ under s.1(1) UK Act. It followed that they were not under art. 52.1 EPC.

Then in 1996 came the decision of the House of Lords in *Biogen Inc. v Medeva plc (Biogen)*.⁴⁷

Biogen – House of Lords (1996)

The *Biogen* patent concerned the application of recombinant DNA technology, with respect to the production of hepatitis B virus (HBV) antigens.

The House of Lords referred to the issue of invention even though it was not an issue argued in the appeal. Both Lord Hoffmann, who wrote the leading speech and Lord Mustill who delivered the only other speech, confirmed that the word ‘invention’ in s.1(1) UK Act does not mean that anything that satisfies the patentability conditions is a patentable invention and that in an appropriate case the word ‘invention’ in s.1(1) UK Act can be assessed separately to the patentability conditions in s.1(1)(a)-(d).⁴⁸

Lord Hoffmann commenced his analysis of the issue by reference to the absence of a specific definition of the word ‘invention’ in the UK Act and the EPC implying that the “various conditions, both positive (in paragraphs (a) to (c)) and negative (in paragraph (d)) which an invention must satisfy in order to be a ‘patentable invention’ ... probably ...

contain every element of the concept of an invention in ordinary speech.”⁴⁹ But, he then qualified his analysis by suggesting that the word ‘invention’ in s.1(1) UK Act may mean more “because in the absence of a definition one cannot say with certainty that one might not come across something which satisfied all the conditions but could not be described as an invention.”⁵⁰

The thrust of this part of Lord Hoffmann’s speech was that in most cases whether something was an ‘invention’ would either not be in issue or could be answered by reference to the conditions contained within the s.1(1)(a)-(d). If the subject of the patent in question was a mechanical technology this would generally be the case.

For example, it is difficult to imagine a scenario where a patent concerning a mechanical apparatus could be challenged on the basis that it is not an ‘invention’ separately to the other conditions of patentability that it be industrially capable, new and inventive. The point which his Lordship made is that there are technologies where these conditions of patentability are insufficient to assess patentability and that it would be wrong to ignore the invention condition in every case.

Lord Mustill, referred to *Genentech* reinforcing the reservations that he first raised in the circumstances of that case.

37 Ibid, 262 lines 1- 6 (emphasis added).

38 Ibid, 262 line 35.

39 Ibid, 262 lines 33-34.

40 Ibid, 262 lines 48-49.

41 Human tissue plasminogen activator unaccompanied by associated native glycosylation.

42 Biologically active human tissue plasminogen activator in essentially pure form, unaccompanied by protein with which it is ordinarily associated.

43 Genentech Inc’s Patent [1989] RPC 149 per Mustill LJ 264 line 33 (UK Court of Appeal).

44 Recombinant human tissue plasminogen activator essentially free of other protein of human origin.

45 Human tissue plasminogen activator as produced by recombinant DNA technology.

46 Genentech Inc’s Patent [1989] RPC 149 per Mustill LJ 270 lines 25-28 (UK Court of Appeal).

47 *Biogen Inc. v Medeva plc* [1997] RPC 1 (House of Lords).

48 s.1(1) UK Act, “A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say- (a) the invention is new; (b) it involves an inventive step; (c) it is capable of industrial application; (d) the grant of a patent for it is not excluded by subsections (2) and (3) below;”

49 *Biogen Inc v Medeva plc* [1997] RPC 1 per Lord Hoffmann 41 lines 33-39, 41-52 (House of Lords).

50 Ibid, 41 line 52 – p. 42 line 2.

Then came the *Kirin-Amgen* appeal to the House of Lords in 2004.

Kirin-Amgen – House of Lords (2004).

Although the appeal came after the Directive amendments were made to the UK Act in July 2000, the pre-Directive law applied.

Erythropoietin (Epo) is a protein that is produced by humans in the kidneys and facilitates the production of red blood cells. Its existence and function had been known since the 1950's and it was first extracted from human urine (uEpo) in the late 1970's. In the early 1980's Dr. Lin, an Amgen scientist became the first person to produce recombinant Epo (rEpo). The biological and genetic differences between uEpo and rEpo were immeasurable. The invention was shown to have industrial application through the use of recombinant technology, which at the time of the invention, was known to the skilled person.

The primary claim was the broadest of all the claims, however, Amgen did not allege infringement of claim 1, rather it alleged infringement of claims 19,⁵¹ 20, 22 and 26⁵² which were all dependant on it.

The House of Lords agreed with the Court of Appeal on the issue of infringement holding that neither claims 19 nor 26 were infringed by TKT's process, but disagreed with it on the issue of validity holding the patent to be invalid in its entirety.

In their Lordships opinions, the proper construction of claim 1, the primary claim, was to be decided by "what the person skilled in the art would have understood the patentee to be using the language of the claim to mean"⁵³ and confirmed that Lord Diplock's decision in *Catnic Components Ltd v Hill & Smith Ltd*⁵⁴ continued to be good law even though the now applicable patent statute, the Patents Act, 1977 (UK) ushered in provisions which were consistent the EPC. In particular, their Lordships made it clear that Article 69 EPC, which provides that "[t]he extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims" and the *Protocol on the Interpretation of Article 69*, did not necessarily extend the scope of the claim to be at one with the scope of the specification. Lord Hoffmann explained,

The purpose of a patent specification, as I have said, is no more nor less than to communicate the idea of an invention. An appreciation of that purpose is part of the material which one uses to ascertain the meaning. But purpose and meaning are different. If, when speaking of the widest purpose, Jacob LJ [in *Rockwater Ltd v Technip France SA* (unreported) [2004] EWCA Civ 381, at paragraph 41, ... says ... that to be 'fair to the patentee' one must use 'the widest purpose consistent with his teaching'] meant the widest meaning, I would respect-

fully disagree. There is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables.⁵⁵

On the facts of the appeal before them, their Lordships were unpersuaded by Amgen's construction of claim 1 because the notional skilled person would have understood that the claim required the use of exogenous Epo DNA in a host cell and that this specific limitation in the scope of the claim was a matter for the patentee. In this regard, 'purposive construction' could not be applied so as to bring the process used by TKT to manufacture rEpo within the scope of claim 1.

Therefore, their Lordships explained that application of 'purposive construction' was constrained by the manner in which the patentee chose to define the scope of the claim and did not permit "extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims."⁵⁶ If the scope of protection defined by the claims, as understood by the notional skilled person, was narrower than the description of the invention in the specification, it was an error to construe the claim 'purposively' for the aim of providing "fair protection for the patentee".⁵⁷

51 A recombinant polypeptide having part or all of the primary structural conformation of human or monkey erythropoietin as set forth in Table VI or Table V or any allelic variant or derivative thereof possessing the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells to increase hemoglobin synthesis or iron uptake and characterized by being the product of eukaryotic expression of an exogenous DNA sequence and which has higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources.

52 A polypeptide product of the expression in a eukaryotic host cell of a DNA sequence according to any of Claims 1, 2, 3, 5, 6 and 7.

53 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286, para 34 (House of Lords).

54 *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, particularly per Lord Diplock, 243, "A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge."

55 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286, para 33.

56 *Ibid*, para 34.

57 See 'The Protocol on the Interpretation of Article 69'. Also per Lord Hoffmann: "The Catnic principle of construction is therefore in my opinion precisely in accordance with the Protocol. It is intended to give the patentee the full extent, but not more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim."

So while Neuberger J, the trial judge, held that “the whole thrust of the specification, and, indeed with commercial common sense, indicates that the patentee is getting at the production of EPO”,⁵⁸ according to their Lordships, claim 1 was not the isolated DNA sequence of the Epo gene. Their Lordships, criticised the trial judge’s claim construction and agreed with the Court of Appeal, that the invention of claim 1 was to a specific process for the recombinant manufacture of rEpo not to the recombinant manufacture of rEpo generally. In their Lordships opinions, while the specification was cast in broad terms, the primary claim was not because a claim to the production of rEpo howsoever made was tantamount to a claim to the isolated DNA sequence of the Epo gene, and this could never be an ‘invention’ within s.1(1) UK Act.⁵⁹

In their opinions, even though the primary claim was to “a perfectly good and ground-breaking process for making [Epo] and its analogues, [Amgen] were determined to try to patent the protein itself, notwithstanding that, *even when isolated*, it was not *new*”.⁶⁰

Their Lordships emphasised the word ‘new’ with respect to rEpo, the physical substance. The fact that the DNA sequence of the Epo gene, which was an essential feature of the primary claim, was (a) isolated and (b) unknown at the priority date did not save the patent. This meant that as Epo per se, that is, the end product, was not itself ‘new’, any claim to any process for its production was invalid even though the gene that coded for Epo and the genetic sequences of both the Epo gene and Epo were unknown at the priority date.

It is important to understand that the patentability of the process of the primary claim was considered, by both the Court of Appeal and the House of Lords, to be a technology that was *prima facie* an ‘invention’ within s.1(1) UK Act. Moreover, their Lordships considered that it was a “ground-breaking” process. In this context their Lordships implied that they considered the Amgen process to meet the novelty and inventive step conditions of s.1(1)(a) and (b) UK Act. Furthermore, the evidence at trial conclusively proved that the Amgen process enabled the production of Epo in quantities that were otherwise unavailable at the priority date and that rEpo had demonstrated therapeutic effects on humans which uEpo had not experimentally replicated. This evidence supported the argument that the industrially applicable criterion of s.1(1)(c) UK Act was also satisfied.

Despite this, their Lordships held the patent invalid. Why?

Firstly, their Lordships did not distinguish between Epo as it occurred in nature and isolated Epo. In their opinions, as supported by the overwhelming trial evidence, uEpo and rEpo were indistinguishable either physically, biologically or genetically. The existence of natural Epo as a substance was known before the priority date.

Secondly, their Lordships did not distinguish between the physical substance, Epo and the DNA sequence of the Epo gene that coded for it. The fact that the complete genetic sequence of the Epo gene was unknown at the priority date was irrelevant because the end result of the claimed process was merely the physical form of the substance produced by the gene that corresponded to the isolated DNA sequence of the Epo gene. In other words, while the isolated DNA sequence of the Epo gene was new at the priority date, that information was analogous to the physical substance which was the end result of the claimed process and this was not ‘new’. So new information about an old substance does not make the old substance new.

Thirdly, the isolated DNA sequence of the Epo gene was a ‘discovery’ within s.1(2)(a) UK Act and, by implication, art. 52.2a EPC. Therefore, it could not be an ‘invention’ within s.1(1) UK Act and, by implication, art.52.1 EPC, even though it had been held in a series of cases starting with the Court of Appeal’s decision in *Merrill Lynch’s Application*⁶¹ (*Merrill Lynch*) that a technology that fell within the express exclusion of ‘invention’ in s.1(2) UK Act could, if it made a technical contribution that had a practical application, be an invention. For example, Aldous J relied on *Merrill Lynch* in his decision in *Chiron Corporation v Murex Diagnostics Ltd and Others (No 3) (Chiron)* to hold

58 *Kirin-Amgen Inc v Roche Diagnostics GmbH and others* [2002] RPC 1 per Neuberger J, para 624 (UK Patents Court).

59 First, I think that the judge’s construction pays no attention to the claims. It does not even use them as ‘guidelines’ but goes straight to Table VI and declares that to be the invention. Secondly, I think that the Court of Appeal was right in saying that Table VI could not have been the invention. Standing alone, it was a ‘discovery...as such’ within the meaning of section 1(2) of the Act: see *Genentech Inc’s Patent* [1989] RPC 147, per Purchas LJ at p 204 and per Dillon LJ at p 237. ... In such a case, while it may be true to say, as the Court of Appeal did ([2003] RPC 31, 62) that Table VI lay ‘at the heart of the invention’, it was not the invention. *Ibid*, per Lord Hoffmann, paras 76-77.

60 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286 per Lord Hoffmann, para 132.

61 *Merrill Lynch’s Application* [1989] RPC 561 (UK Court of Appeal).

that a claim to an isolated hepatitis C virus protein was an ‘invention’.⁶²

So their Lordships ruled that the isolated DNA sequence of the Epo gene could not make a technical contribution within the principle explained by *Merrill Lynch*. Although they did not cite *Merrill Lynch* it is worth noting that, Fox LJ who wrote the lead judgment for the Court of Appeal in that case held that:

Something further is necessary. The nature of that addition is, I think, to be found in the *Vicom* Case where it is stated: ‘Decisive is what technical contribution the invention makes to the known art.’ There must, I think, be some *technical advance* on the prior art *in the form of a new result* (eg a substantial increase in process speed as in *Vicom*).⁶³

Therefore, to accord with *Merrill Lynch* it was essential for a technical contribution to produce “some technical advance on the prior art *in the form of a new result*”. On the evidence their Lordships concluded that no new result was producible. The rEpo produced as a result of the process defined by the primary claim was indistinguishable from natural Epo. Therefore, the isolated DNA sequence of the Epo gene was not a technical contribution. They held, “a difference in the method of manufacturing an identical product [to one that is known at the priority date] does not make [the product produced by that method] new”.⁶⁴

Clearly, the House of Lords confirmed that under pre-Directive s.1(1) UK Act and, by implication under art. 52.1 EPC, an isolated DNA sequence and the protein for which it codes for (a) could never be an ‘invention’ and (b) could not be claimed as part of a ‘patentable invention’ unless the invention produced something that was ‘new’ so as to be physically, biologically and genetically distinguishable from existing biological materials. Moreover, while technical processes for the production of biological materials were *prima facie* ‘inventions’ within art. 52.1 EPC, they were not ‘patentable inventions’ unless the biological materials produced by those processes were physically, biologically and genetically distinguishable from existing biological materials.

Without Discrimination

Before their Lordships in *Kirin-Amgen*, senior counsel for Amgen, Andrew Waugh QC used the language of art. 5 Directive to argue that the production of a ‘natural element’ by means of a technical process was patentable subject matter under the EPC and UK Act because the Directive “is understood to be clarificatory of the law”.⁶⁵

Clearly, their Lordships rejected this argument. Unlike the Court of Appeal in *Kirin-Amgen*, which drew “comfort from the Directive”⁶⁶ in upholding the validity of the patent, the House of Lords applied pre-Directive patent law and invalidated it. This means that the Directive, rather than clarifying pre-existing patent law, amended it so that “claims to biological elements ‘isolated ... or otherwise produced by means of a technical process even if the structure of that element is identical to that of a natural element’”⁶⁷ are presumed to be ‘inventions’ under the post-Directive patent law.

Furthermore, the Court of Appeal held in *Kirin-Amgen* that “the Directive envisages that claims can be validly directed to polypeptides produced by a process”, a result which is inconsistent with their Lordships ruling that the product of the process must be ‘new’ for the process to be a ‘patentable invention’. Arguably, if something is identical to a pre-existing natural protein it can hardly be ‘new’. Yet this is precisely the distinction that the language of articles 3 and 5 Directive ignores.

Arguably, the Directive was never a clarifying law but put into effect the policy announced in 1988 by the EPO, USPTO and JPO in their joint communiqué.⁶⁸ This was in fact confirmed by Dr. Ulrich Schatz, Principal Director, International Affairs, EPO to the *Organisation for Economic Co-operation and*

62 “In the present case, the claims are concerned with a technical aspect of the discovery. They are limited to products, kits, methods of testing, vaccines and cell cultures. The submission that the claims are concerned with discoveries as such is untenable.” Per Aldous J, *Chiron Corporation v Murex Diagnostics Limited* (No 3) [1996] RPC 535.

63 *Merrill Lynch’s Application* [1989] RPC 561, 569. (UK Court of Appeal).

64 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286, per Lord Hoffmann, para 98 (House of Lords).

65 Transcript from the House of Lords hearing in *Kirin Amgen Inc v Transkaryotic Therapies Inc*, [July 2004] 677 line 14.

66 *Kirin Amgen Inc v Transkaryotic Therapies Inc* [2003] RPC 31, 57, 34 (UK Court of Appeal).

67 *Ibid.*

68 “Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.” 1988 Joint Statement of USPTO, EPO and JPO. See footnote 9, Nuffield Council of Bioethics Discussion Paper *The Ethics of Patenting DNA*, 26, para 3.14.

Development in 2002.⁶⁹ Indeed one of the principle architects of the *Directive*, Dominique Vandergheynst,⁷⁰ has explained that the *Directive* was a “true revolution”⁷¹ and the fact that it took ten years and two attempts for the European Parliament to pass it into law tends to suggest that if it were merely ‘clarificatory’, the *Directive* would have been a straightforward initiative. Finally, even today the *Directive* remains surrounded in controversy, some seven years later, with seven of the originating fifteen EC member states still steadfastly refusing to comply with it.⁷²

Therefore, if the *Directive* was not a clarification of pre-*Directive* European patent law and was an amendment, the issue under art. 27.1 TRIPS is this: Does the *Directive* and post-*Directive* European patent law violate art. 27.1 TRIPS?

TRIPS requires that the patentability criteria in art. 27.1 be applied across “all fields of technology ... without discrimination as to ... the field of technology ...”.

Given this requirement, the *Directive* violates TRIPS because by requiring EC to amend the EPC and member countries to enact amendments to their patent laws so that technologies that come within arts. 3 and 5 *Directive* are presumed to be ‘inventions’, it positively discriminates against all other technologies which do not benefit from such a presumption.

The 2004 Danish Council of Ethics Report

In its 2004 Report entitled *Patenting Human Genes and Stem Cells* the Danish Council of Ethics described the language of art. 5 *Directive* as “a creatively worded ploy to avoid the criticism leveled at patents on human material”⁷³ because even though art. 5.1 *Directive* confirms that human biological materials, such as genes cannot be patented, art. 5.2 *Directive* confirms that *isolated* human biological materials can be patented.

The Council explained that its “principal objection to the wording of the directive was precisely that in reality it *rubber-stamps* the practice that has gradually evolved in the USA, Japan and Europe whereby, under certain conditions—which it turns out to be very hard to get a grasp on in practice—parts of the human body can nevertheless be patented⁷⁴.”

The Council’s criticism was directed at the 1988 joint communiqué of the EPO, USPTO and JPO⁷⁵ which stated that “purified natural products are not regarded under any of the three [patent] laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form.”

The notion that the ‘isolation’ of natural biological material or the production of identical biological

material by the use of a technical process is sufficient to avoid the universally recognised ban on the patenting of technologies or things that are not ‘inventions’ is fundamentally flawed and fallacious. Support for this criticism is not only found in the *Kirin-Amgen* decision but also by the Danish Council of Ethics which stated in its Report:

In the members’ view, it cannot be said with any reasonableness that a sequence or partial sequence of a gene ceases to be part of the human body merely because an identical copy of the sequence is isolated from or produced outside of the human body.⁷⁶

Conclusion

January 1, 1995 marked the start of a new era in international intellectual property law. Today, TRIPS is the most important multi-lateral intellectual property agreement and unless its terms are uniformly adopted into the laws by all members the principal rationale for its existence will be undermined. Accordingly, it must be recognised once and for all that isolated biological materials that are indistinguishable from natural biological materials and the processes and methods for their production cannot be the subject of a patent monopoly.

69 In his presentation to the OECD he stated, that the “background against which EPO [biotechnology patent] practice has developed since the Office opened its doors in 1978 ... has been codified in the 1998 EU-Directive on the legal protection of biotechnological inventions.” Dr. Ulrich Schatz, Principal Director, International Affairs, EPO, Berlin, January 24-25 2002, Workshop on Genetic Inventions, IPRs in his presentation entitled, The patentability of genetic inventions in EPO practice.

70 Former Responsible Official at the European Commission from 1990 to 1999 for the proposed *Directive* – see G. Kamstra et al, *Patents on Biotechnological Inventions: The E.C. Directive*, London, Sweet & Maxwell, 2002.

71 *Ibid.*

72 In July 2003, the European Commission referred Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands and Sweden to the Court of Justice of the European Communities for their failure to transform arts. 1 to 11 of the *Directive* into their national patent laws by July 2002. In March, 2004, however, Germany introduced amending legislation consistent with the *Directive* for debate in its Bundestag and in December 2004 it was passed into law.

73 Danish Council of Ethics Report, *Patenting Human Genes and Stem Cells*, 2004, 13, (Emphasis added)

74 *Ibid.*

75 1988 Joint Statement of USPTO, EPO and JPO. See footnote 9, Nuffield Council of Bioethics Discussion Paper *The Ethics of Patenting DNA*, 26, para 3.14.

76 Danish Council of Ethics Report, *Patenting Human Genes and Stem Cells*, 2004, 98.