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Biogen Sufficiency Reconsidered

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Biogen sufficiency reconsidered

David J Brennan*

In 2009 the House of Lords reconsidered *Biogen* sufficiency – a rule in UK patent law that confers jurisdiction upon courts to revoke unduly broad patent claims. Here a quite separate reconsideration of the rule is undertaken, with a primary focus upon its provenance and its relationship to the EPC. It will be shown that *Biogen* sufficiency has a basis in the EPC and that this basis both: (i) inscribed a modest line of UK sufficiency authorities, and (ii) had a material, albeit background, influence upon the acceptance of the rule in *Biogen v Medeva*. Following this examination of its origins, a critique of the rule will be offered with a suggestion that its conceptual foundation should be reconsidered.

Introduction

Biogen v Medeva ('*Biogen*') concerned recombinant biotechnology and was the first biotechnology patent case to make its way to the House of Lords in 1996.[1] In it the patentee had isolated part of the genome of the Hepatitis B virus (the Dane particle) and, using a technique pioneered in the early 1970s by Cohen and Boyer, spliced it in a particular way into the DNA of an obliging host cell – here an *E. coli* bacteria cell.[2] As the host cell replicated, it expressed that aspect of the Hepatitis B virus which was encoded for by the spliced-in DNA. That synthetic protein – the product of recombinant gene technology – was a Hepatitis B antigen which triggered in the immune system the production of Hepatitis B antibodies in the absence of actual infection. It therefore served as the basis for a useful vaccine. In 2004 another biotechnology case involving a recombinant protein found its way to the House of Lords. In *Kirin-Amgen v Hoechst* ('*Kirin-Amgen*') the patentee had identified the human gene encoding for erythropoietin, isolated it and spliced it into another type of obliging host cell, which then expressed synthetic erythropoietin.[3] That synthetic protein could, once isolated, form the basis of a pharmaceutical to treat anaemia. In 2009 the House of Lords considered a case not involving biotechnology. In *Generics v H Lundbeck* ('*Lundbeck*') the patentee made a claim to an organic chemical molecule.[4] This was a known isomer, first isolated from a known chemical, and formed the basis of an improved anti-depressant pharmaceutical.

The respective patentees in *Biogen*, *Kiren-Amgen* and *Lundbeck* took their entitlement from being the first to produce each of those useful products and for being the first to disclose a means to produce each. The patentees made broad claims to the products *per se*. That is to say, claims which entailed all other ways of producing the product and all other

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[1] [1997] RPC 1.

[2] For general overviews of the Cohen-Boyer technology see Sally Smith Hughes, 'Making Dollars Out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980' (2001) ISIS 541 and Maryann Feldman, Alessandra Colaianni and Kang Lui, 'Commercializing Cohen-Boyer 1980-1997' DRUID Working Paper 05-21, Copenhagen Business School, 2005.

[3] [2005] RPC 9.

[4] [2009] UKHL 12.

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uses of the product.[5] In each case the primary claim was a claim in *Biogen* to a recombinant DNA molecule which will produce a Hepatitis B antigen; a claim in *Kirin-Amgen* to a DNA sequence for insertion into a host cell to express a synthetic protein structurally conforming to human erythropoietin, and a claim in *Lundbeck* to the isomer in a substantially isolated form. If the breadth of these claims were considered in an English court prior to the 1977 Patents Act, the requirement that a claim be 'fairly based on the matter described in the specification' would be relevant.[6]

In UK patent law, once claims were given the role of defining the subject matter scope of patent property, it was natural for patent law to more formally develop a way which ensured a correlation between disclosure and claims. This would ensure that the law imposed some discipline on an applicant to claim no more than the disclosed invention. Embryonic patent case law of the early 1800s had once suggested that patent titles (rather than claims) should serve the role of property definer, and had therefore required a degree of correlation between disclosure and patent title.[7] However it was not until 1932 that UK statutory patent law insisted that the specification 'sufficiently and clearly ascertain the scope of the monopoly claimed'; a prior attempt to do so in an 1883 Act had been interpreted as 'merely directory' by the House of Lords.[8] Shortly after the 1932 reform, a pair of House of Lords decisions made explicit both the property-defining role of claims and their relationship to the specification. In *Electric & Musical Industries v Lissen* Lord Russel explained the function of claims to be 'to define clearly and with precision the monopoly claimed, so that others may know the exact boundaries of the area within which they will be trespassers'.[9] In *Mullard v Philco* the House of Lords required that a claim be no more than co-extensive with the invention disclosed. There a product was claimed by reference to a desirable attribute, rather than the combination of features that went to deliver that attribute. The House of Lords found that such a claim would be revoked because it did not involve the inventive step disclosed. Lord Macmillan said: 'I do not think he is entitled to claim the article at large apart from the juxtaposition which is essential to the achievement of the result'.[10] The holding in *Mullard v Philco* was codified to become the validity ground of fair basis in the 1949 Patent Act, a requirement

[5] An overview of some of the consequences of this in the bio-medical field is provided in William Cornish, *Intellectual Property – Omnipotent, Distracting, Irrelevant?* (2004), chapter 1.

[6] Patents Act 1949, sections 4(4), 6 (examination) and 32(1)(h) (revocation). In T. A. Blanco White, *Patents for Inventions and the Protection of Industrial Designs* (1983, 5th ed) at 152 the fair basis of claims derived from naturally-occurring substances is discussed: *American Cyanamid Company v Berk Pharmaceutical* [1976] RPC 231, 247 and 257-260 where Whitford J revoked broad process claims based on a modest incremental invention and *Firestone Tire & Rubber's Application* [1966] FSR 366, 371 where the patent examiner upheld a clear chemical product claim when only one method of making the chemical was disclosed. Fair basis is also the subject of analysis in relation to a product claim in the Australian High Court decision of *Montecatini Edison v Eastman Kodak* (1971) 1B IPR 656, 662-664, also discussed (with approval) in Blanco White. There Gibbs J rejected as not fairly-based claims to a chemical product (a new polypropylene) claimed by class of features.

[7] David J Brennan, 'The Evolution of English Patent Claims as Property Definers' [2005] IPQ 361, 376-380.

[8] Ibid 387.

[9] (1939) 56 RPC 23, 39.

[10] (1936) 53 RPC 323, 347.

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that has been termed 'internal fair basis'.[11] There is scant guidance on the content of fair basis as a statutory requirement under the 1949 Act.[12] From the jurisprudence that there is it is possible to state that the issue of fair basis was limited to comparing within the specification any impugned claim against the description to ask whether the claim scope 'will cover something to which [the inventors] have really made no genuine contribution'.[13] Notwithstanding some judicial statements to the contrary, this assessment was to occur irrespective of patentee conduct or nebulous considerations of fairness.[14] Under the 1949 Act, the requirement that claims be fairly based was a ground of examination and revocation, but not a ground of opposition.[15] The European Patent Convention ('EPC') does not on its face permit lack of fair basis to be a ground of opposition or revocation.[16] There is something equivalent in the EPC to fair basis – a requirement that a claim be 'supported by the description' – but that is a matter only able to be assessed on examination.[17] The EPC does allow insufficiency as a ground of examination, opposition and revocation; this is where the patent specification fails to 'disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art'.[18] This is similar to a UK patent law requirement that has existed since eighteenth century Lord Mansfield jury charges in *Liardet v Johnson*; the requirement that a full written description of the invention should be lodged by the patentee.[19] Hence, immediately prior to the repeal of the 1949 Act, English patent law relating to claims and disclosure rested on three basic pillars of logic: (1) a claim in a specification defined the subject matter scope of property in the invention; (2) the description in the specification was required to provide sufficient disclosure of that invention; (3) the claim was required to be fairly based on the disclosed invention.[20]

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[11] Patents Act 1949, sections 4(4), 6 (examination) and 32(1)(i) (revocation). Amanda J McBratney, 'The Problem Child in Australian Patent Law: "Fair" Basing' (2001) 12 AIPJ 211 who contrasts it with 'priority fair basis' - claims deriving priority from foreign filings (under provisions implementing article 4H of the Paris Convention) and the fair basis of claims deriving priority from local provisional filings: Patents Act 1949, section 5(2). The primary authority for both varieties of fair basis was *Re Mond Nickel's Application* [1956] RPC 189 (a priority fair basis case), in particular the three-step test put forward by Lloyd-Jacob at 191-192. By the end of the 1949 Act jurisprudence, both varieties of fair basis had been judicially harmonized: *Stauffer Chemical's Application* [1977] RPC 33, 60.

[12] *American Cyanamid Company v Berk Pharmaceuticals* [1976] RPC 231, 259 (Whitford J).

[13] Ibid.

[14] *American Cyanamid Company (Damn's) Patent* [1971] RPC 425, 437 (where Lord Reid comments that the test is purely a comparison of claims against description, without involving the fairness of the patentee's conduct in a more general sense) and *Stauffer Chemical Company's Application* [1977] RPC 33, 52, 60 and 64 (where the Court of Appeal emphatically rejects Graham J's earlier suggestions that fair basis included considerations about the fairness of the applicant's conduct in a moral sense).

[15] Section 14 opposition grounds did not include lack of fair basis and as will be explained below, this omission had an indirect impact upon the *travaux préparatoires* to the EPC as it relates to sufficiency.

[16] Convention on the Grant of European Patents (European Patent Convention) done at Munich on October 5, 1973. EPC articles 100 (grounds for opposition) and 138 (grounds for revocation).

[17] EPC articles 97 (refusal or grant) and 84 (the claims).

[18] EPC articles 97 (refusal or grant), 83 (disclosure of the invention), 100(b) (ground of opposition) and 138(1)(b) (ground of revocation).

[19] Brennan above note 7, 369-372. Sufficient disclosure was a matter examined under the Patent Act 1949, and insufficiency was a ground of opposition and revocation under that Act: ss 4(3), 6 (examination); 14(g) (opposition); 32(h) (revocation).

[20] The third aspect leaves aside issues of the 'priority fair basis' discussed above in note 11.

Implementing the EPC removed the third pillar from the jurisdiction of English courts in a revocation action.

It is understandable that when a pillar of domestic law is knocked away by somewhat external forces, local patent experts see it as a problem.[21] In 1981 Cornish concluded his text book discussion on 'Claims and disclosure' under the 1977 Patents Act by offering the following opinion: 'Perhaps a patentee who has claimed more than he has invented lays himself open to the objection of lack of inventive step; or possibly that his disclosure is not sufficiently clear and complete'.[22] One prominent patent lawyer, Robin Jacob elected the second of the two possibilities nominated by Cornish. Shortly before his judicial appointment, in the *1993 Herchel Smith Lecture*, he said:

> [T]he law of insufficiency is now being called on to cover more. The trouble is that the framers of the EPC behaved very oddly: they required the EPO and consequently via the 1977 Act, the UK Office, to refuse grant of a patent for an invention which was not, in the metaphorical language of the Treaty and Act, 'supported by' the disclosure. But such lack of support -- which we used to call lack of fair basis -- is not a ground of invalidity. Why it should be all right if one could get the claim past the Patent Office when it was looking other way, but not otherwise, beats me.
>
> Of course neither the courts nor the EPO in its opposition mode are going to take this nonsense lying down. And so the law of insufficiency is being brought to bear on claims which are too wide: the notion is that a claim is regarded as insufficient if the disclosure does not provide enough instructions for the full width of the claim.[23]

Up until that time the law of insufficiency in England was generally understood to be that if a skilled addressee could, by relying upon information in the specification, make one embodiment which fell within a claim, the patentee had satisfied the sufficient disclosure requirement in relation to that claim.[24] Under the 1977 Act and prior to *Biogen*, attempts to get sufficiency to perform the role suggested by Jacob (i.e. it requiring disclosure which enabled the making of all possible embodiments across the full width of the claim) had met with mixed results. In *Chiron*, a case involving Hepatitis C diagnostics, Justice Aldous at trial rejected the proposition that sufficiency could be the vehicle for the type

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[21] The first edition of WR Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (1981) at 189 observed: 'The interrelated issues raised [by claims and disclosure] are fundamental in character. Yet patent offices may not always be in a position to consider them very effectively. If a claim is allowed through to grant in unjustifiably wide form, the courts no longer have clear power to subject it to criticism'.

[22] Ibid.

[23] Robin Jacob, 'The Herchel Smith Lecture 1993', [1993] EIPR 312, 314-315.

[24] Under the 1949 Patents Act a patentee who had disclosed in its description one means to make a new product had supplied could make a valid *per se* product claim, so long as the claim was to the functional features which deliver its desirable attributes, rather than to those desirable attributes: *Nestle's Products Ltd's Application* [1970] RPC 84, 90 (Lloyd-Jacob J, adopting the hearing officer's statement that one disclosed method of making was sufficient disclosure for a broad claim to the product so made.)

of 'the judicial massage' suggested by Jacob.[25] While he applied the same approach in *Biogen* at trial, both the Court of Appeal and the House of Lords in *Biogen* was prepared to massage sufficiency in the way suggested by Jacob in 1993.[26]

Lord Hoffmann in *Biogen* found that under the EPC sufficiency required 'that the specification must enable the invention to be performed to the full extent of the monopoly claimed'.[27] The patentee had, by a deduced means disclosed in the description, been able to produce the Hepatitis-B antigen without isolating and identifying the encoding gene. The claim was to a recombinant molecule which caused the production of the antigen. Such a broad claim was held to be not fully enabled by the specification; all that could be validly claimed was production of the antigen by the particular means disclosed. In arriving at this outcome Lord Hoffmann chose to depart from the conclusion reached by an EPO Technical Board of Appeal in an earlier opposition against the same claim. There the EPO Board considered that the relevant disclosure 'directly and unambiguously implied' sufficient support for the claim.[28] Lord Hoffmann's judgment relied instead upon two EPO Technical Board decisions in an examination appeals *EXXON/Fuel Oils* and *GENENTECH I/Polypetide Expression*. In *EXXON/Fuel Oils* the patentee had, like the patentee in *Mullard v Philco*, claimed a product by reference to desirable attributes, rather than by the features disclosed in the description that delivered the attribute.[29] The claim, like the claim in *Mullard v Philco*, was considered by the EPO Board to be unduly broad because it lacked the support of what was the disclosed invention.[30] This principle – that the extent of the monopoly claimed exceeds the technical contribution to the art made by the invention as described in the specification – was found by the EPO Board to be embraced within both the EPC requirement of 'support for claims' and (more importantly) within the EPC sufficiency requirement. In *GENENTECH I/Polypetide Expression* the applicant disclosed a particular recombinant technique capable of application across a class of settings.[31] Again the EPO Board conflated the operation of the EPC article requiring a sufficiently clear and complete disclosure and that article requiring support for claims.[32] There the applicant's one disclosed means was considered by the EPO Board to support a broad claim across the class because the description had

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[25] *Chiron Corporation v Organon Teknika* [1994] FSR 202, 242. However Justice Whitford at trial in *Genentech's Patent* took a different view, which in turn was overturned (albeit in a quite ambiguous way) by the Court of Appeal: *Genentech's Patent* [1987] RPC 553, 592 (Whitford J); [1989] RPC 147, 261 (Mustill LJ), 235-237 (Dillon LJ) and 198-200 (Purchas LJ). *Genentech's Patent* is discussed further below.

[26] *Biogen v Medeva* [1995] RPC 25, 43-45 (Aldous J); 95-99 (Court of Appeal); [1997] RPC 1, 53-54 (House of Lords). In *Chiron Corporation v Murex Diagnostics* [1996] FSR 153, 178-186 the Court of Appeal, following its earlier decision in *Biogen*, also overturned Aldous's decision at trial on the construction of the sufficiency revocation ground.

[27] [1997] RPC 1, 48 and 53. There Lord Hoffmann equated the approach to ascertaining support for Paris priority to the approach to ascertaining sufficiency more generally.

[28] BIOGEN/Hepatitis B [1995] EPOR 1. The 'cavalier' dismissal of the EPO Board's approach by the Court of Appeal was described in these terms by one commentator: 'One cannot escape … from the impression that they regarded the EPO as being essentially some kind of lesser forum staffed by lesser mortals': Brian C. Reid, 'Biogen in the EPO: The Advantage of Scientific Understanding' (1995) 17 EIPR 98, 100.

[29] *EXXON/Fuel Oils T409/01* [1994] EPOR 149.

[30] [1994] EPOR 149, 155-156.

[31] *GENENTECH I/Polypeptide Expression T292/85* [1989] EPOR 1.

[32] Ibid 7.

disclosed a principle cable of such general application.[33] The invention as claimed was thus sufficiently disclosed, and conversely the claim was properly supported. Lord Hoffmann's careful reliance on these authorities led him to the conclusion that undue claim breadth was equally able to be characterised under the EPC as both a lack of support issue and an insufficiency issue.[34] In *GENENTECH I/Polypetide Expression* the Board was said by Lord Hoffmann to be doing no more than 'apply a principle of patent law which has long been established in the United Kingdom, namely that the specification must enable the invention to be performed to the full extent of the monopoly claimed'.[35] However because the inventor in *Biogen* had disclosed no general principle, merely one very specific means to make the antigen, its invention was distinguishable from that in *GENENTECH I/Polypetide Expression* and the broad claim made in *Biogen* was not fully enabled.[36] Valid jurisdiction therefore existed for the claim to be revoked for insufficiency; the requirement of *Biogen* sufficiency was born. However, it is often forgotten that *Biogen* sufficiency was obiter. The claims were found to lack an inventive step because foreign the priority document relied upon by the patentee was expressly required (by section 5 of the Patents Act 1977 and consistent with EPC article 87(1)) to provide support for the claims and failed to provide such support 'to the full extent of the monopoly claimed'.[37] *Biogen* sufficiency was defined by equating it with the requirement of support for claims from Paris Convention filings.[38]

Also by way of obiter Lord Hoffmann suggested application of the same principle in *Kirin-Amgen* where the claim was to the erythropoietin gene for recombinant use in a host cell. To the extent the claim extended beyond the disclosed means of recombination, the claim was insufficiently enabled by the description.[39] Thus, in both *Biogen* and *Kirin-Amgen* Lord Hoffmann considered that claims before the Court could not be validly enforced beyond the particular 'technical contribution' described in their specifications. If the claims had such breath, they failed to disclose the inventions claimed 'clearly enough and completely enough for them to be performed by the person skilled in the art'.[40] They were *Biogen* insufficient. Justice Neuberger, trial judge in Kirin-Amgen, sought to distinguish *Biogen* insufficiency issues from what the law was understood, prior to the 1977 Act to be insufficiency, by describing the latter as 'classic

[33] [1989] EPOR 1, 7-12.
[34] [1997] RPC 1, 54.
[35] Ibid 48.
[36] Ibid 51-52.
[37] Ibid 49-52.
[38] Ibid 53-54. Article 4H of the *Paris Convention for the Protection of Industrial Property* ('Paris Convention') provides that an earlier priority date can be derived from a foreign filing in a Paris Convention member state if the priority document as a whole 'specifically disclose' the elements of the claimed invention. In 2001 the EPO Enlarged Board of Appeal considered that the Paris Convention standard underlies EPC article 87(1), and is satisfied 'only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole': *Same Invention* G 2/98 [2001] OJ EPO 413, 433.
[39] [2005] RPC 9, [110]-[117].
[40] Section 72(1)(c) Patents Act 1977.

insufficiency'.[41] Whether *Biogen* sufficiency had indeed been 'long established' in UK law was questioned in a recent Australian patent text book by Colin Bodkin. Bodkin observed that Lord Hoffmann cited no authority supporting the 'long establishment' of the principle, 'and indeed it is not easy to locate an early enunciation of it'.[42] The Australian High Court has somewhat acerbically adopted of this characterisation of *Biogen* sufficiency: 'Since the fair basis doctrine no longer exists, it is necessary to invent it.'[43] Another commentator has wondered whether characterising lack of support for claims as insufficiency for revocation purposes is consistent with the specific removal of lack of claim support (or fair basis) as a ground of revocation in the EPC.[44] Consistency with the EPC was certainly a matter at the forefront of Aldous J's decisions when he specifically and repeatedly rejected the possibility of a revocation ground equating to what is now known as *Biogen* insufficiency.[45] Jacob considered that the drafters of the EPC had 'behaved very oddly' in causing this issue to arise in the first place, and others have called for reform of the EPC to correct this oddity.[46] The following two sections of this essay sheds light on *Biogen* sufficiency's basis, investigating both whether it sits comfortably as a ground of revocation within the EPC framework and whether it has a pedigree in 'long established' UK sufficiency law. The concluding sections offer a more normative assessment of a validity requirement directed to claim breadth, with a suggestion for its rethinking.

The EPC *travaux* and claim breadth

The 1977 Act is drafted to be consistent with the EPC, and one critical point of departure from the 1949 Act was required by EPC article 138.[47] That article enumerated five exhaustive revocation grounds, which included failure to sufficiently disclose the invention but did not include lack of clarity or lack of fair basis. Hence, the section 72 grounds of revocation in the English Patents Act 1977 mimic those five grounds and

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[41] *Kirin-Amgen v Roche Diagnostics* [2002] RPC 1, [300]. While this distinction appears completely sensible – and as will be shown is reflected in the provenance of undue claim width sufficiency within the EPC *travaux* – on appeal the Court of Appeal saw fit to criticize it: [2003] RPC 3, [71].

[42] Colin Bodkin, *Patent Law in Australia* (2008), 206-207.

[43] *Lockwood Security v Doric Products* (2004) 217 CLR 274, 300.

[44] Anthony McInerney, 'Biotechnology: Biogen v Medeva in the House of Lords', [1998] EIPR 14, 20: 'The elevation of section 14(5)(c) [support for claims] to a ground of revocation by the House of Lords represents a wolf in sheep's clothing to the internationalisation of patent laws in Europe. *Biogen* highlights the conflict between the sovereignty of national courts and the goal of Common Market integration and full harmonisation of patent laws under the EPC. *Biogen* is a well-reasoned decision which seeks to reach a just result having regard to the internal efficacy of the patent system, and implicitly rejects the fashionable winds of internationalisation which howl around it.'

[45] *Chiron Corporation v Organon Teknika* [1994] FSR 202, 242 and *Biogen v Medeva* [1995] RPC 25, 43-45. This concern too formed a large part of the puzzle which is the Court of Appeal's position in *Genentech's Patent* [1989] RPC 147, 261 (Mustill LJ), 235-237 (Dillon LJ) and 198-200 (Purchas LJ) which is discussed further below.

[46] Jacob above note 23, 314 and R Stephen Crespi, 'Recombinant DNA Patents in Litigation – A Comparative Study of Some EPO and UK National Court Decisions' (1997) 28 IIC 603 at 622. Crespi expresses the view that the EPC should be amended to correct the unacceptable position whereby national courts have fewer express grounds than the EPO to assess validity. He argues that at present courts must resort to artificial and uncertain maneuvers (in particular, *Biogen* sufficiency) to effect parity.

[47] Edward Armitage, 'The New British Patent Legislation' (1978) 9 IIC 207, 209.

thereby confer upon an English court revocation jurisdiction in respect of lack of sufficient description, but not in respect of claims lacking of claim ambiguity or undue breadth. Central to the origins of *Biogen* sufficiency lies in understanding how that jurisdictional outcome arose under article 138, which requires cognisance of the broader context of EPC formation, culminating (as it does) to the 'maximum approach'.

The 1962 EEC Draft and the Strasbourg Convention

With the creation of the European Economic Community ('EEC') in 1957 came, among other things, a desire to create a unified patent system which operated within the six member territories as if they were one territory.[48] The EEC proposed solution transcended harmonisation to an aspiration of truer unification. Under the proposal, a community patent applying across the entire territories of the EEC would be granted. The sensitivities involved in overriding member sovereignty were addressed by the proposal being of a 'federal patent system'; the unified system would be introduced without dismantling the existing six national patent systems. Thus under the system the grant of an EEC-wide patent and would co-exist with grants made under national patent systems in each EEC member. The originators of 1962 *Draft Convention Relating to European Patent Law* ('1962 EEC Draft') hoped that the issue of sovereignty could be side-stepped by the long-term objective that the community patent system, while operating in parallel with the national systems, would win the lion's share of the patent filing business and thereby cause the national systems to wither painlessly away.[49]

As one of the more important point of reference for the drafters of the EPC, the 1962 EEC Draft is a useful place to start considering how grounds of revocation for lack of clarity, lack of sufficient description, and lack of fair basis were proposed to be dealt with in that unified system.[50] 'Revocation' under the 1962 EEC Draft was an application, able to be initiated at any time during the life of a granted patent, to the granting body; the European Patent Office ('EPO').[51] It thereby served in effect as more of a belated opposition. The 1962 EEC Draft did not include an express ground of revocation (so understood) for lack of undue claim breadth or claim ambiguity. Rather, article 70 (titled 'contents of the specification') required:

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[48] M van Empel, *The Granting of European Patents* (1975) at 15 where van Empel observes that the impetus for the proposed creation of a 'unitary and autonomous European patent for the Common Market as such, governed by Community law proper and dealt with by Community Institutions' was not first and foremost related to patent policy. Rather, the removal of trade barriers between EEC members in so far as a patent granted in Germany covering widgets could be used to restrain the export from France of widgets made there lawfully without patent restriction. The Treaty Establishing the European Economic Community 1957 ('Treaty of Rome') in article 100 provided that: 'The Council shall … issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the common market'. (Martijn van Empel attended the EPC Inter-Governmental Conferences as an aspect of his doctorate on the EPC and he was a member of the Legal Service of the Council of the European Communities.)

[49] Van Empel above note 48, 15-16.

[50] The 1962 EEC Draft is reproduced in: G Oudemans, *The Draft European Patent Convention* (1963).

[51] Oudemans above note 50, 192 where article 130 of the 1962 EEC Draft is reproduced which sets out the revocation procedure proposed.

(1) The specification must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
(2) The specification shall conclude with one or more claims defining the protection applied for.[52]

Failure to specify the invention in accordance with article 70 was one of four grounds of revocation set out in article 127(1).[53] A commentary by Oudemans on the 1962 EEC Draft observed its internal (drafting) validity requirements were less strict than 'Anglo-Saxon patent law' and that article 70 had to be appreciated 'according to continental standards'.[54] The 1962 EEC Draft did include a provision directed to the interpretation of patent scope. Article 21 ('Extent of the protection conferred by a European patent') provided in paragraph (1) that:

> The extent of protection conferred by a European patent shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.[55]

In the year following the publication of the 1962 EEC Draft, a *Convention on the Unification of Certain Points of Substantive Law on Patents for Invention* was concluded in Strasbourg ('the Strasbourg Convention') under the auspices of the Council of Europe. The objective of the Strasbourg Convention was to define those most fundamental aspects of patent law which could be identified as forming a common denominator between signatories. It was observed that the 1962 EEC Draft and the Strasbourg Convention shared much common drafting because 'the draftsmen were to a great extent the same, and because much care has been taken to avoid discrepancies between the two instruments'.[56] Article 8 of the Strasbourg Convention essentially corresponds with articles 70 and 21(1) of the 1962 EEC Draft. Consistent with the 1962 EEC Draft, the Strasbourg Convention expressly treats neither claim ambiguity nor undue claim breadth as substantive issues of patent law.

The reorientation of the treaty progress

Stepping back from the details of patent law, the European political landscape of the 1960s provides some context to how the EPC was to emerge. Under the Treaty of Rome, six continental European countries (France, West Germany, Italy, Belgium, the Netherlands and Luxembourg) had formed the European Economic Community, having as its central feature a common market facilitated by harmonised laws to reduce trade

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[52] Oudemans above note 50, 158. It should be noted that article 71 (Requirements of the Implementing Regulations) mandated that an application must otherwise meet the conditions requirements of the Convention's Regulations, which were never drafted. Failure to meet the requirements of article 71 was not a ground of revocation under article 127(1) in the 1962 EEC Draft.
[53] Oudemans above note 50, 190-192, article 127(1)(b) proving that a final European patent will be revoked 'if the specification of the invention does not satisfy the requirements of Article 70'.
[54] Oudemans above note 50, 50.
[55] Oudemans above note 50, 126.
[56] Per von Holstein, 'International Co-Operation in the Field of Patent Law with Special Reference to the Actvities of the Council of Europe' (1967) 16 Int'l & Comp LQ 191, 202.

barriers. Under the Treaty of Stockholm seven European countries (United Kingdom, Denmark, Norway, Sweden, Austria, Switzerland and Portugal) formed the European Free Trade Association, also dedicated to free trade between members, however without the same expectation of harmonisation of laws. Throughout the 1960s the UK had made two applications to join the EEC, applications which garnered the support of five EEC members but which were vetoed on each occasion by France – in 1963 and 1967. It was into this environment that the 1962 EEC Draft emerged, and in which major stumbling blocks were the issue of Convention membership and accessibility. The first point was whether membership of the proposed Convention should be conditional upon EEC membership. The answer that the 1962 EEC Draft gave was similar to the position that pertained under EEC membership in the Treaty of Rome – membership was only possible with the consent of all six EEC (who were to be the Convention) members, with the possibility of Paris Convention members becoming 'associates' to the Convention.[57] The second, related, issue of accessibility referred to whether inventors from countries which are not Convention members (or 'associate' members, if any) should have access to the grant of a common market patent. The position on the latter point was left unclear under the 1962 EEC Draft, reflecting a conflict of views as to whether the instrument was predominately one of European economic policy or international patent policy.[58] Given a strong desire in some quarters for any European Patent Convention to be inclusive, even serving as a starting point for a world patent regime, and given the industrial importance of the UK within Europe, it seemed that no credible European Patent Convention could be concluded without UK's participation. The French vetos of the UK applications for EEC membership in 1963 and 1967 impacted negatively upon the possibility of further collaborative progress being made with the 1962 EEC Draft. Work on the European Patent Convention quietly fell into abeyance in the mid-1960s.[59]

How then did the concluded EPC emerge in 1973? Two critical developments precipitated it. The first was EFTA's devising in 1965 of a two-treaty scheme to resolve the impasse related to convention membership and accessibility to a common market patent.[60] This idea reached fruition with the EPC of 1973 and the Community Patent

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[57] Oudemans above note 50, 5-8. See also: van Empel above note 48, 18-20; Franz Froschmaier, 'Some Aspects of the Draft Convention Relating to a European Patent Law' (1963) 12 Int'l & Comp LQ 886, 891 and Fredrik Neumeyer, 'Unification of Europe Patent Legislation on the Common Market' (1961) 24 Mod LR 725, 729.

[58] Van Empel above note 48, 18-20.

[59] Van Empel above note 48, 20 observes: 'At the same time, one cannot pretend to abstract these discussions from the more general divergences of opinions between the Six as to the extent Community cooperation should be open to third States, in particular to the United Kingdom. As such, the Patent project also shared the general malaise within the EEC which followed the crisis of 1965 between France and its partners. There appeared to be no hope of reaching any agreement on the fundamentals of the plan. The discussions were simply interrupted and the project quietly shelved.' See also the comment by the same author that 'the Netherlands insisted on the United Kingdom being invited to participate in the project, a proposition firmly rejected by the French': Martijn van Empel, 'European Patent Conventions' (1972) 9 CMLR 13, 14.

[60] Dennis Thompson, 'The Draft Convention for a European Patent' (1973) 22 Int'l & Comp LQ 51, 54-55 and van Empel above note 48, 21. Dennis Thompson was a legal adviser in the Secretariat of EFTA and participated in the work of the Secretariat to the Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents.

Convention (CPC) of 1975. The second was the effect upon France of the then proposed Patent Cooperation Treaty (PCT).[61] The French patent system did not rely upon an assessment of patent applications prior to grant and the PCT's streamlined system of international patent filing was predicated on such prior examination. France could see the merit of the proposed PCT system, but needed a means to effect examination prior to grant to participate. In this environment, the creation of an EPO to undertake such examinations for France was appealing. To France an EPO servicing a dual system under the EFTA model offered a path down which the EPC could be the broad European church which all could join, while the CPC could be reserved for members of the EEC.

The 1969 Memorandum

Therefore in 1968 it was the French who restarted negotiations directed to concluding the first 'broad church' treaty. This was formally achieved by a February 1969 memorandum ('the 1969 Memorandum') issued by the EEC member countries initiating a diplomatic process which included not only the EEC member states, but other European countries important in the patent field, in particular the UK.[62] Paragraph two of the 1969 Memorandum's Introduction set out all key features of the proposed course in five points:

(i) The Member States of the E.E.C. wish to set up an international system for the grant of patents in which, in addition to the Member States of the E.E.C., other interested European States would take part.

(ii) All the rules of law and procedure required for the grant of patents would appear in a Convention (hereinafter referred to as the "Convention") to be concluded by all these States.

(iii) This international system for the grant of patents would lead, by a single act, to be performed by an international body, the European Patent Office, to the grant of a European Patent.

(iv) As from its granting, this European patent would give rise to a bundle of national patents, the effects of which would be governed by the respective national law of each of the States parties to the Convention.

(v) However, the Member States of the E.E.C. inform the other European countries that they envisage defining, by means of an act to be concluded between the Member States of the E.E.C., a uniform legal system applicable to the European patent in respect of the territory of the E.E.C.[63]

The first to fourth points foreshadowed the EPC, and fifth point foreshadowed the CPC. This memorandum sparked the 21 May 1969 Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents ('May 1969 Inter-Governmental Conference') which lay the foundation for what was to be concluded as the EPC in Munich in 1973. All EEC members and ultimately eleven other European

[61] Thomson above note 60, 55-56 and van Empel above note 48, 21-22. The PCT was concluded in 1970.
[62] Memorandum of the Council of the European Communities, Brussels, 28 February 1969. No R/360/69 (ECO 47). The 1969 Memorandum is reproduced and translated to English in: Romuald Singer, 'The European Patent Enters a New Phase' (1970) 1 IIC 19, 26-31.
[63] 1969 Memorandum above note 62 at Part I, para 2

countries states, including the UK, were represented at the Inter-Governmental Conference.

Returning to grounds of invalidity and revocation related to poor specification and claim drafting, it is important that the 1969 Memorandum diverged from the 1962 EEC Draft insofar as exhaustive grounds revocation were not flagged for the bundle of patents granted from the sole application to the EPO described in point three. Rather, what was proposed at point four set out above was the conferral of unfettered revocation jurisdiction upon national courts.[64] However, the 1969 Memorandum also made plain that a grant of a bundle of national patents from a sole application required that the rules of law concerning patentability to be made the subject of international regulation. For this purpose, the 1969 Memorandum asserted that the proposed Convention would necessarily include provisions dealing with patentability and that they would be based on the corresponding provisions of the 1962 EEC Draft and on the Strasbourg Convention.[65] As described above, the sole validity ground pertaining to drafting in both the 1962 EEC Draft and the Strasbourg Convention was sufficiency. The 1969 Memorandum thus described a hybrid system. On the one hand, it flagged uniform substantive grounds of validity for grant (those drawn from the 1962 EEC Draft and the Strasbourg Convention), yet on the other it emphasised individual national sovereignty when it came to revocation post grant - where national law applied. This was one aspect of what became known as the 'minimum approach'.

The minimum approach

The May 1969 Inter-Governmental Conference authorised the drafting (through a working group) of a First Preliminary Draft of a Convention Establishing a European system for the grant of Patents ('First EPC Draft').[66] Also published at this time were the Reports on the First Preliminary Draft Convention for a European System for the Grant of Patents ('Reports on the First EPC Draft').[67] The reason for their publication was to 'receive the comments of organisations representing the interested circles in the States in question'.[68]

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[64] 1969 Memorandum above note 62 at Part II, para 5(b) explained further that: 'as regards the validity of a European patent when granted, this could only be contested before the national authorities competent to decide on the validity of national patents granted by the national authorities'.

[65] 1969 Memorandum above note 62, Part II, para 1: 'The grant of a European patent by the European Patent Office, following an international procedure, would seem to be possible only if the rules of law concerning patentability are also made the subject of international regulation. Consequently, the proposed Convention must of necessity include provisions of this nature. They would be based on the corresponding provisions of the Brussels Draft and on the Council of Europe's Convention on the unification of certain points of substantive law on Patents for Invention, of 27 November, 1963.'

[66] Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents, *First Preliminary Draft Convention for a European System for the Grant of Patents* (Office for official publications of the European Communities - Luxembourg, 1970). Also reproduced at: (1970) 1 IIC 80.

[67] Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents, *Reports on the First Preliminary Draft Convention for a European System for the Grant of Patents* (Office for official publications of the European Communities - Luxembourg, 1970).

[68] First EPC Draft above note 66, 12 (Introduction). This was similarly noted in Reports on the First EPC Draft, above note 67, 3 (Foreword).

Deliberately absent in the First EPC Draft was any equivalent to article 127(1) of the 1962 EEC Draft which had set out four exhaustive grounds of revocation. Consistent with the 1969 Memorandum the First EPC Draft consigned revocation grounds (together with the term of the patent and exclusive rights attached to the patent) to the national law of Contracting States.[69] This reflected a desire to express a so-called 'minimum approach' in the proposed EPC system, which left national patent laws (and national sovereignty) as unaffected as possible.[70] The First EPC Draft described the scope of the EPC as pertaining to a system of law for the 'grant of patents' effective in the Contracting States.[71] The General Report on the EPC Draft from the Intergovernmental Conference explained that the grant of a European patent is equivalent to the grant of a bundle of national patents.[72] While a bundle, they were to be subjected to uniform grant and opposition procedures before the EPO, however once past that stage, the grants would operate as individual national patents and subject 'only to the jurisdiction of the competent authorities of the respective State and to the law of that State'.[73] The First EPC Draft contained a note which amplified what was intended at that stage in consigning revocation to national law:

> The validity of a European patent subsequent to grant is to be decided exclusively under national law. Such a patent could therefore, although meeting the conditions for patentability (Articles 9 – 14), be revoked in certain States if it did not at the same time meet the national conditions of patentability.[74]

As will be described, those articles were to be nominated as providing possible exhaustive revocation grounds. They dealt with: what was meant by and excluded from the concept of a patentable invention (article 9); policy-based exceptions to patentability (article 10); novelty (article 11); non-prejudicial disclosures (article 12); inventive step (article 13), and industrial application (article 14). None related expressly to sufficiency, claim clarity or claim scope.

The note to the First EPC Draft then went on to explain that the Conference would consider whether a provision (or protocol) should oblige Contracting States to limit the grounds of revocation to the criteria laid down in the articles 9 to 14, with the possibility of States being able to make reservations enabling them to continue to apply national provisions.[75] This was expanded upon in part of the Conference Report compiled by the

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[69] First EPC Draft above note 66, 16: 'Subject to the provisions of this Convention the European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State. This shall apply in particular to the term of the patent, the grounds of revocation and the exercise of rights attached to the patent.' (article 2(2))

[70] This approach is well explained by Thompson above note 60, 56-58.

[71] First EPC Draft above note 66, 16 (article 1).

[72] Reports on the First EPC Draft, above note 67, 6 (General Report by Mr JB van Benthem, President of the Netherlands Patent Office).

[73] First EPC Draft above note 66, 16 (article 2).

[74] First EPC Draft above note 66, 17 (note to article 2(2)).

[75] Ibid. The note flagged article 12 of the Strasbourg Convention as providing a model in this regard. The note also flagged the possibility of a uniform 20 year patent term – again with the possibility of Contracting States under conditions retaining a different term.

UK Delegation on the First EPC Draft, which asked whether the EPC 'should go further and provide in addition a common law for judging the validity of the patents when granted' – an aspect of what was described there as the 'maximum' approach.[76] It was suggested that this might occur if there was 'strong pressure' from the interested circles being consulted.[77] In the course of industry consultations and treaty negotiations the maximum approach indeed prevailed, and this was reflected in changes to the three most critical post-grant matters of revocation grounds, term of patent and scope of exclusive rights (especially for processes) which all became subject to prescribed uniform standards within subsequent drafts and the concluded EPC.

Opposition proceedings before the EPO were only partially provided for in the First EPC Draft insofar the grounds of opposition were not specified.[78] A note explained that 'the grounds on which an opposition may be lodged, mainly those based on Articles 9 to 14, will need to be specified later'.[79] The Conference Report on the opposition provisions (also prepared by the UK delegation) suggested additional opposition grounds including 'lack of clarity in the claims'.[80] This appears as the first suggestion in EPC treaty history that claim drafting should be specifically tied to validity. The First EPC Draft did include in article 71 a provision which corresponded to article 70(1) of the 1962 EEC Draft: an obligation that the application discloses the invention in a manner 'sufficiently clear and complete for it to be carried out by a person skilled in the art'.[81] However whereas failure to meet the sufficiency requirement was one of the four exclusive grounds of revocation (which in substance was belated opposition) under the 1962 EEC Draft, in the First EPC Draft sufficiency was a matter to be assessed solely on examination.[82]

Finally, an article of the First EPC Draft was a provision which copied article 21(1) of the 1962 EEC Draft.[83] It set out that the extent of protection was to be determined by the claims, but that the accompanying description and drawings were to be used to interpret those claims.[84] The Conference Report on article 21 (again prepared by the British delegation) noted that 'some members of the Working Party were anxious to ensure that there would be uniform interpretation of the claims in all member States, but no agreement could be reached on any more precise formulation than that of the Strasbourg text'.[85] That position evolved also over the course of the treaty process.

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[76] Reports on the First EPC Draft, above note 67, 11 (Report by the British Delegation on Articles 1 to 20).
[77] Ibid.
[78] First EPC Draft above note 66, 82 (article 101).
[79] First EPC Draft above note 66, 83 (notes to article 101, point 1). As described above, those nominated articles dealt with: what was meant by and excluded from the concept of a patentable invention, policy-based exceptions to patentability, novelty, non-prejudicial disclosures, inventive step, and industrial application. They did not deal with claim or specification drafting matters *per se*.
[80] Reports on the First EPC Draft above note 67, 23.
[81] First EPC Draft above note 66, 58 (article 71).
[82] First EPC Draft above note 66, 64 and 78 (articles 77and 96).
[83] First EPC Draft above note 66, 30 (article 20(1)), which also corresponded to article 8(3) of the Strasbourg Convention.
[84] The First EPC Draft had as a formal required that an application for a European patent contain 'one or more claims defining the protection applied for': First EPC Draft above note 66, 54 (article 66(c)).
[85] Reports on the First EPC Draft above note 67, 13.

The 'maximum approach'

The publication of the First EPC Draft was to facilitate input from 'interested circles', comprising those in innovative European industries who were prospective customers of the patent system being proposed and the professionals (lawyers and patent attorneys) likely to be engaged by them.[86] The reason such consultations were critical was that the 'sole application, bundle of patents' model proposed for the EPC was conceived on the same basis as the system proposed by the 1962 EEC Draft – it would exist in parallel with national patent systems. Therefore, and like the earlier EEC model, for it to succeed it needed to attract business.[87] From those consultations came a surprising result. Rather than express a 'minimum approach' which emphasised the preservation of national sovereignty in the face of the grant of European patents, interested circles considered that a 'maximum' approach was required to ensure that the new system would be used to the extent necessary for it to be a success.[88] This resolved to the insertion of provisions which offered patentees greater grant and enforcement security in the system by setting uniform Treaty standards in three critical matters: (1) specifying exhaustive and finite grounds of opposition and revocation; (2) fixing a minimum 20 year patent term; and (3) stipulating the scope of exclusive rights, including broad rights in method patents. All three were intended to bolster certainty and remove scope for national law to cater to parochial interests.[89] The strength of this view caused a change of direction, accepted at the Inter-Governmental Conference in 1970 midway through the treaty-making process.

Revisions in the Second Preliminary Draft of a Convention Establishing a European system for the grant of Patents, ('Second EPC Draft') most relevant to this essay included:

(i) A new article 71a which, for the first time, required that claims define the matter for which protection is sought, be clear and concise, and be fully supported by the description, a matter to be assessed on examination.[90]

(ii) Three exhaustive grounds of opposition and four exhaustive grounds of revocation, each set out grounds which included (apart from failure to satisfy the criteria contained in articles 9 to 14) failure to satisfy the sufficiency requirement of article 71.[91] (The text of article 71 remained unaltered from the

[86] First EPC Draft above note 67, 12 (Introduction) and van Empel above note 48, 23.
[87] Van Empel above note 48, 23-24 and Thomson above note 60, 63-65.
[88] An example of the effect of the maximum approach is found in expansion of exclusive rights in method patents to products resulting from the patented methods: Minutes of the Munich Diplomatic Conference for the Setting Up of a European System for the Grant of Patents, Munich 10 September to 5 October 1973 (Federal Republic of Germany, 1977), 32-3.
[89] Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents, *Reports on the Second Preliminary Draft Convention for a European System for the Grant of Patents* (Office for official publications of the European Communities - Luxembourg, 1971), 56 and Thomson above note 60, 64-65.
[90] Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents, *The Second Preliminary Draft Convention for a European System for the Grant of Patents* (Office for official publications of the European Communities - Luxembourg, 1971), 88 and 92 (articles 71a and 77).
[91] Second EPC Draft above note 90, 116 and 138 (articles 101a and 133).

> First EPC Draft.) Notably failure to meet the requirements of newly included article 71a was neither a ground of opposition nor revocation.[92]

The precise impetus which led to article 71a emerging in the Second EPC Draft as an examination ground, but only as an examination ground, is not easy to locate in the Reports on the Second Preliminary Draft Convention for a European System for the Grant of Patents ('Reports on the Second EPC Draft').[93] The reasons for the omission of article 71a matters as grounds of opposition were explained this way in the Reports on the Second EPC Draft:

> Some delegations believed that obscurity of the claims should be made a ground of opposition. This belief was based on the view that it was most important for third parties to be able to identify clearly the precise area in which the patentee has a monopoly and in which they must not trespass. … However, other delegations took the different view that this ground of opposition was unnecessary since the Examiner during the application procedure, would have considered the clarity of the claims. They also felt that such a ground of opposition would lead to undue delay in prosecution and possibly involve further search and re-examination of the description. For the time being therefore this ground has not been included [as an opposition ground] but this matter may be re-examined later.[94]

Van Empel provides this account of the reasons behind the decision in 1971 to omit 'the more formal requirements' of claim drafting as opposition grounds:

> Ex parte examination by the Examining Division should suffice here. Third parties, in fact can not add anything but partisan argument here. … [I]t might be argued that obscurity of the claims should have been so included amongst the opposition-grounds. At the time, however, a proposal to this effect was rejected on the ground that it would unnecessarily complicate proceedings and would open the door to dilatory oppositions. … [E]xaminers of the EPO should be in a position to give due attention to these points by themselves without the assistance of third parties.[95]

This reflects a division between the UK on the one hand, and countries rooted more strongly in civil law tradition. Common law patent tradition focussed more heavily on matters of specification linguistics, whereas civil law patent traditional was concerned that textual matters did not get in the way of affording protection to substantive inventive contribution.[96] This appeared to lead to the UK side pushing for ambiguity and lack of

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[92] Second EPC Draft above note 90, 92 and 116 (articles 77 and 101a).
[93] Reports on the Second EPC Draft above note 89 where there is a failure to mention article 71a when discussing filing requirements (at page 68) and examination (at page 69).
[94] Reports on the Second EPC Draft above note 90, 72 (from the Report by the United Kingdom Delegation on Opposition Procedure).
[95] Van Empel above note 48, 218 (notes omitted).
[96] Hence the respective conceptions of claims as 'fence posts' on the Anglo side, and as 'sign posts' on the Continental side: Brennan above note 7, 383-384.

fair basis as revocation grounds (to deal *inter alia* with the vague or unduly broad claim), and to the Continental side to reject those grounds on the basis that they were matters best left only to examination, and would invite parties seeking to avoid a patent to engage in time-wasting word games. The Continental side, while conceding ambiguity and lack of support as examination matters, appeared to largely win the debate, and so these did not appear as matters included in the opposition or revocation grounds. This omission was intended to have substantive effect; the 'exhaustive character' of the revocation grounds was intended to be a central plank of the maximum approach.[97]

Following further consultations on the Second EPC Draft, a third and final EPC draft was prepared for the 1973 Munich Diplomatic Conference for the Setting Up of a European System for the Grant of Patents ('Final EPC Draft').[98] Both articles 71 (sufficient disclosure of the invention) and 71a (clear and supported claims) of the Second EPC Draft were carried forward into the Final EPC Draft without substantive modification.[99] These became in the concluded EPC articles 83 and 84 respectively.[100] In the Final Draft, and similar to the position under the Second EPC Draft, the article 84 requirement that claims be 'clear and concise and be supported by the description' was able to be assessed only on examination prior to grant; failure of the requirement was neither a ground of opposition nor revocation.[101] Indeed at no point did the requirement that claims be clear, concise and fully supported ever feature as a ground of opposition or a ground of revocation in the drafting history. The Final EPC Draft carried forward the three opposition grounds from the Second EPC Draft.[102] The four revocation grounds of the Second EPC Draft had added to them the ground of lack of entitlement.[103] These exhaustive opposition and revocation grounds remained in the concluded EPC as articles 100 and 138 respectively. Both sets of grounds included substantive failure to meet the requirement set out in article 83; sufficient disclosure.[104] Thus, within the EPC's regime, the sole internal drafting matter that was to be assessed equally on grant, and as grounds of opposition and revocation, was that the description disclosed 'the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art'.[105] Article 84 matters were deliberately confined to be assessed on examination. This

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[97] Van Empel above note 48, 299.
[98] Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents, *Munich Diplomatic Conference for the Setting up of a European System for the Grant of Patents 1973 - Preparatory Documents* (Office for official publications of the European Communities - Luxembourg, 1972).
[99] Final EPC Draft above note 98, 86 (articles 81 and 82 respectively).
[100] In the light-handed revision to the EPC in 2000 these provisions remained substantively unaltered.
[101] Final EPC Draft above note 98, 102, 106, 144-6 (articles 96, 99 and 138). Article 96 of the Final EPC Draft mandated refusal where an application 'does not meet the requirements of this Convention', thus taking account of article 84 – unlike article 99 (opposition grounds) and article 138 (revocation grounds). In the concluded EPC this because article 97. It has remained substantively unaltered in the 2000 revision to the EPC.
[102] Final EPC Draft above note 98, 106 (article 99).
[103] Final EPC Draft above note 98, 144 (article 138).
[104] EPC articles 100(b) & 138(1)(b). In the revision to the EPC in 2000 these provisions remained substantively unaltered.
[105] EPC article 97(1) (which requires that account be taken of article 83), article 100(b) and article 138(1)(b).

is a decision that may well be contestable, but the logic supporting the decision is certainly intelligible especially in the context of the maximum approach.

The inscription of UK 'speculative claiming' jurisprudence within EPC insufficiency

However, it was in reporting on the insufficiency ground in the Reports on the Second EPC Draft that the UK side arguably got its revenge for the omission of opposition and revocation grounds dealing with article 84 concerns; vague or unduly broad claims. It was left once more to the UK delegation to write the Conference Report on the work of the conference in relation to opposition procedure. That Report explained that the insufficiency ground entailed two 'fundamental questions which are interrelated'.[106] The first is what has been aptly referred to by Justice Neuberger as 'classic' insufficiency; that the specification fails to enable a person skilled in the art to perform, without having to exercise further inventive ingenuity, one embodiment of the invention falling within the relevant claim. The second aspect was described in the Conference Report in the following terms:

> [a person asserting insufficiency] may also argue that, although the description is clear and gives enough detail to enable the embodiment described to be carried out, the claims are so widely drawn that they must be regarded as "speculative".[107]

As will be explained below this passage in the *travaux* was an influential (albeit never-cited) EPC foundation for *Biogen* sufficiency.[108] With the word speculative heavily adorned in quotation marks, it assimilated a line of UK authority which regarded speculative claims within insufficiency, and thereby provided the 'long established' principle that Lord Hoffmann asserted in *Biogen* 25 years later.

In the year just prior to the UK Delegation's report a judgment in *Eastman Kodak* delivered by Justice Whitford applied a line of three authorities which treated 'speculative claiming' as a species of insufficiency.[109] The first of those cases, *Re Esau and C Lorenz Aktiengesellschaft* pre-dated *Mullard v Philco* by five years, and was a decision in which Solicitor-General Stafford Cripps relied upon insufficiency to disallow a broad claim.[110] There the patentee had disclosed a method of using electrical energy to aggregate fine particles from gasses and liquids to effect their removal. Claim one was a

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[106] Reports on the Second EPC Draft above note 89, 71 (Report of the UK Delegation on Opposition Procedure).
[107] Ibid. Later in the *travaux*, insufficiency as an EPC opposition ground was equated with insufficiency as an EPC revocation ground: Reports on the Second EPC Draft above note 89, 76 (Report of the UK Delegation on Revocation of the European Patent) stating that '[g]rounds (a) to (c) are in fact the same grounds on which a European patent may be opposed'.
[108] Discussed in the section headed '*Biogen* sufficiency and the hidden role of the EPC travaux'.
[109] *Eastman Kodak Company's Application* [1970] RPC 548, 563-564 in which Whitford J applied *Re Shell Development* (1947) 64 RPC 151 and *Re A Patent by Abraham Esau and C Lorenz Aktiengesellschaft* (1931) 49 RPC 85. A further decision, decided at about the same time as *Esau*, stands for the same proposition: *Re British Celanese* (1934) 51 RPC 192.
[110] *Re A Patent by Abraham Esau and C Lorenz Aktiengesellschaft* (1931) 49 RPC 85.

claim to the use of electrical energy in any way upon any substance that may give a useful result. The claim was successfully opposed for lack of 'a sufficiently detailed and full description' to support it. The Solicitor-General reasoned that there must be 'some relationship between that which is disclosed and that which is claimed' and that 'broad and indeterminate claims of a speculative character' would rarely be sufficiently described in the specification.[111] The term 'speculative' as applied to claims, thus entered into English patent law lexicon. The 1970 Whitford J decision in *Eastman Kodak* upheld a 'speculative claiming' insufficiency opposition under the 1949 Act, notwithstanding that lack of fair basis was not a statutory ground of opposition.[112] In reasoning that was a foretaste of the means of statutory (and treaty) construction that would come to sustain *Biogen* sufficiency, Justice Whitford considered that the inclusion of fair basis as an examination matter and lack of fair basis as a ground of revocation in the Patents Act 1949 did not alter, in opposition proceedings, the applicability of the approach to insufficiency taken in *Re Esau and C Lorenz Aktiengesellschaft*.[113] Before Whitford J the patent application was successfully opposed on the ground of insufficiency when the claims were to a polypropylene with features defined by ranges (such as 'a tensile strength of at least 5,500 pounds per square inch') which gave the claims a scope which dwarfed what was considered a modest inventive step.[114] It seems that the rule against speculative claiming applied by Whitford J was in effect a twin of the rule against lack of fair basis, a matter acknowledged in substantively identical litigation conducted the following year in the Australian High Court where lack of fair basis was found.[115] And so that while lack of fair basis was expressly not let in the front door of the EPC as opposition or revocation grounds, its twin was seemingly able to sneak into those grounds through the back door of *travaux*-inscription.

An epilogue to this line of authority can be found in Justice Whitford's 1987 decision at trial in *Genentech's Patent*.[116] The invention related to the synthetic production of a human protein which dissolves blood clots. Justice Whitford, in revoking a product claim for reasons which included insufficiency, observed that 'indeed under the old Act there was very often an overlap between the grounds of insufficiency and lack of fair basis'.[117] It was perhaps unfortunate that Whitford J did not cite his earlier *Eastman Kodak* decision for that proposition. Perhaps if he had so provided that authority for his

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[111] Ibid 87.
[112] In the Patents Act 1949 section 14 setting out opposition grounds which included insufficiency at (g) but omitted lack of fair basis, whereas section 32 included both insufficiency at (h) and lack of fair basis at (i) as revocation grounds.
[113] *Eastman Kodak Company's Application* [1970] RPC 548, 563-564.
[114] Ibid.
[115] In the Australian High Court decision of *Montecatini Edison v Eastman Kodak* (1971) 1B IPR 656, Gibbs J at 661 observed in relation to Justice Whitford's decision that 'it is very difficult to separate [the question of fair basing] from insufficiency'. For the same reasons that led Whitford J to characterise the claims as speculative, Gibbs J held that the claims lacked fair basis: ibid 663-664. In the Chartered Institute of Patent Agents, Patent Law in the United Kingdom (1975) at 90 it is stated (immediately following a summary of the principle in *Eastman Kodak Company's Application* [1970] RPC 548) that 'an allegation that a claim is not "fairly based" on the complete specification is not a ground of opposition, but in practice fair basis can usually be argued if [insufficiency] is pleaded'.
[116] [1987] RPC 553.
[117] Ibid 592.

statement, '*Genentech* sufficiency' might have been received without much controversy into UK patent law and we would never have heard of '*Biogen* sufficiency'. However, it was with obvious regret (and, as will be explained below, much confused judgment writing) that the *Genentech* Court of Appeal over-turned Justice Whitford's approach.[118] Lord Justice Mustill gave as his reason for so doing the emphatic nature of the statutory words which provided a closed list of revocation grounds.[119] Such drafting, required by the EPC, was 'simply too strong to enable the court, as guardian of the public interest, to assert an inherent power to revoke a patent on grounds not expressly conferred by the statute'.[120] It seems clear enough that the *Genentech* Court of Appeal did not fully appreciate that insufficiency had been a vehicle to revoke unduly broad claims in UK law since 1931. By its reference to 'speculative' claims, the Conference Report inscribed that expanded concept of insufficiency into its EPC-meaning. In *Biogen* Lord Hoffmann made reference to neither the 'speculative claiming' authorities nor the EPC *travaux*, although for reasons that will be discussed below, they played a behind-the-scenes role in sparking *Biogen* sufficiency to life. More importantly, Lord Hoffmann's 'long established principle' statement has a foundation in UK law and *Biogen* sufficiency has a foundation in the EPC.

The Swedish ambiguous claim concern

The issue of ambiguous claims did feature more prominently in a different context in the EPC *travaux*. The Second EPC Draft had preserved the stipulation derived from the 1962 EEC Draft and the Strasbourg Convention concerning the extent of protection being determined by the claim, interpreted in light of the description and drawings.[121] In the Final EPC Draft this became article 67(1), and ultimately comprised article 69(1) of the concluded EPC. In the Final EPC Draft it was, for the first time in the drafting history, accompanied by a note which 'suggested that the Diplomatic Conference should adopt the following declaration in respect of Article 67'; a declaration which became the Protocol on the Interpretation of Article 69.[122] When first proposed it sparked some disquiet in the Swedish Government at the Munich Conference. While recognising that the competence of the proposed EPO provided 'sufficient security against the grant of patents which are not justified', there was a concern that the patentee should not be able to profit from obscure claims.[123] The Swedish delegation suggested a rule of construction that conferred upon the description and drawings a merely a limiting role whenever resort to them was required to interpret a claim.[124] Under such a rule, it was argued that the general public and competitors would be able to conduct their affairs with greater

[118] [1989] RPC 147.
[119] Patents Act 1977, section 72(1)(a)-(e).
[120] [1989] RPC 147, 261. Reasons (and regrets) to like effect were delivered by the other members of the Court of Appeal: Dillon LJ at 235-237 and Purchas LJ at 198-200.
[121] Strasbourg Convention article 20(1).
[122] Final EPC Draft above note 98, 74-5 (article 67 and note to article 67).
[123] Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents, *Munich Diplomatic Conference for the Setting up of a European System for the Grant of Patents 1973, Comments on the Preparatory Documents* (Office for official publications of the European Communities - Luxembourg, 1973) 82-4 (Comments by the Swedish Government).
[124] Ibid.

certainty.[125] The Swedish suggestion – seconded by Finland – generated discussion on the floor of the Main Committee of the Munich Conference.[126] The Dutch delegation supported the existing text (including the declaration) on the basis that 'it had been very carefully drafted after lengthy discussions'.[127] The German delegation likewise supported the existing text on the basis it was 'very well-balanced'.[128] The English delegation supported the Dutch and German positions, adding that the:

> Swedish proposal might be well suitable for most cases of obscure claims but not for all. It was therefore not advisable to become committed to an interpretation of obscure claims in the way proposed.[129]

All industry delegates spoke against the Swedish proposal, which was defeated in a vote of the Main Committee.[130] The Main Committee then recommended that the declaration be annexed to the Convention 'perhaps as a Protocol', which it was.[131]

The interesting thing about the suggestion by the Swedish government and the ensuing debate was the failure to integrate into either a discussion of what became article 84 – the examination requirement that the claims be clear, concise and well-supported. One obvious solution to the problem of ambiguously broad claiming in granted patents was to make failure to satisfy that requirement an express ground of opposition and revocation. Perhaps the idea of introducing such a ground of invalidity, and stirring up the Civil Law - Common Law linguistic debate, was considered too difficult in light of the entrenched maximum approach, that it simply was not uttered by the Swedes. In any case, the omission of article 84 matters from the grounds of opposition and revocation notwithstanding the spotlight being put on claim ambiguity in granted patents can only be understood to be a deliberate choice by the drafters of the EPC. It was a choice explicable by two factors: (1) that the EPC was drafted more in the Continental European patent tradition which is less strict in matters of drafting linguistics, and (2) that the EPC was setting up a new pan-European system seen to be in competition with existing national offices where the maximum approach was intended to offer maximum appeal to prospective patentees to use the system. However, and as has been suggested above, this deliberate decision tied to the maximum approach had already been somewhat circumvented by the *travaux*-insertion of speculative claiming within the EPC conception of insufficiency.

Biogen* sufficiency and the hidden role of the EPC *travaux

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[125] Ibid.
[126] *Minutes of the Munich Diplomatic Conference for the Setting Up of a European System for the Grant of Patents*, Munich 10 September to 5 October 1973 (Federal Republic of Germany, 1977), 31-2.
[127] Ibid.
[128] Ibid.
[129] Ibid.
[130] The International Federation of Intellectual Property Attorneys ('FICPI') observation was that the Swedish proposal was 'likely to detract to a large extent from the European patent's appeal': ibid.
[131] Ibid.

Thus, the EPC obliged the UK to revise its patent law in one clear respect: grounds of revocation were to be confined to the five exhaustive grounds set out in article 138.[132] These grounds are found in section 72 of the 1977 UK Patents Act. The EPC required that certain grounds of revocation in the Patents Act 1949 could not be in section 72; that the claims lack clarity or lack a fair basis in the description.[133] However, article 138 did permit in section 72 as an ongoing revocation ground that the patent 'does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art'.[134] In other words, ambiguity and lack of fair basis were out as revocation grounds, but sufficiency could remain as such a ground.

As has been flagged above, prior to the House of Lords decision in *Biogen* there was a period of uncertainty where different judges offered different views on whether the revocation ground of sufficiency could do the work that fair basis once did. For reasons expressed in the above section Justice Whitford at trial in *Genentech's Patent* was in favour of sufficiency being able to perform the role that fair basis once did.[135] As noted in the Introduction, Aldous LJ, at trial in both *Chiron* and *Biogen*, took the opposite view.[136] His view was on the basis of the sheer drafting logic of both the EPC and the corresponding statutory text of the 1977 UK Act. All members of the *Genentech's Patent* Court of Appeal – the first Court of Appeal to consider the issue – sided with the Aldous LJ construction.[137] However they did two things which made the position far from clear. First, each appellate judge expressed regret that was the outcome foistered upon the court by the paramountcy of the statutory text within its EPC context.[138] Second, after unanimously rejecting Justice Whitford's proposition that sufficiency could do the job that fair basis once did, each member of the Court of Appeal then provided differing bases to revoke claims on the basis that they were unduly broad. Paradoxically, each one of those views appeared to be essentially a rehash of the very view just rejected. Purchas LJ considered that a 'claim which extends beyond the invention achieved is, to that extent, not an invention at all for the purposes of the Act'.[139] Mustill LJ rejected an approach tied to absence of invention, but felt instead that a broad claim could be revoked for insufficiency because the specification 'does not disclose the [claimed] invention clearly enough and completely enough for it to be performed by a person skilled in the art'.[140] This, Mustill LJ asserted (without reasons) 'differs from an allegation that the claim is

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[132] Edward Armitage, 'The New British Patent Legislation' (1978) 9 IIC 207, 209 who observed that the requirements of the EPC could have been met by the 1977 Act without changing the conditions for granting domestic patents or the rights attaching to them. However a decision was made that UK patent law should be identical for patents granted domestically or by the EPO.

[133] In the 1949 Act section 32(1)(i) gave revocation jurisdiction to a court on the ground 'that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification.'

[134] See Patents Act 1977 section 72(1)(c). Compare Patents Act 1949 section 32(1)(h).

[135] [1987] RPC 553, 592.

[136] *Chiron Corporation v Organon Teknika* [1994] FSR 202, 242 and *Biogen v Medeva* [1995] RPC 25, 43-45.

[137] [1989] RPC 147, 198-200 (Purchas LJ), 235-237 (Dillon LJ) and 261 (Mustill LJ).

[138] Ibid.

[139] [1989] RPC 147, 226.

[140] [1989] RPC 147, 272.

not supported by the description'.[141] Dillon LJ, similar to Mustill LJ, accepted by *obiter* that a broad claim could be revoked under section 72(1)(c) 'on the ground that there is no disclosure or teaching in the patent to enable the person skilled in the art to perform the invention the subject of these claims'.[142] There was no attempt at reconciliation by Dillon LJ of this statement with his earlier holding that lack of support emphatically could not be a ground of revocation under the logic of the EPC and 1977 Act.[143] The description 'fairly unintelligible' of this aspect of the judgments of the Court of Appeal in *Genentech* (coming from counsel for the successful party) is perhaps understatement.[144]

Notwithstanding the difficulties with the *Genentech's Patent* Court of Appeal decision, the difference in approach between the *Genentech's Patent* and *Biogen* Courts of Appeal in construing of the revocation ground is puzzling given that a Court of Appeal is, in general, bound by prior Court of Appeal decisions.[145] Whereas all three members of *Genentech's Patent* rejected Whitford J's approach, the subsequent *Biogen* Court of Appeal clearly sided with Whitford J's view on construction and first instituted what is now known as *Biogen* sufficiency.[146] The answer to this precedential puzzle seems to be found in the way in which the *Biogen* litigation was conducted. The *Biogen* trial was before Justice Aldous, who as the trial judge in *Chiron* had fully expressed himself this way:

> The defendants' complaint is that the claims are so widely drawn as to cover polypeptides which the plaintiffs have not discovered and did not know how to manufacture. In essence, the complaint is that claims of the width of claim 1 are not properly supported by the description. Unfortunately, such a submission is not available under section 72. Therefore the defendants attempted to persuade the court that the claims relate to more than one invention and the specification is insufficient. Despite the attractive way that those submissions were advanced before me, I do not believe that section 72(1)(c) can be the suggested vehicle for the judicial massage that the defendants would wish. The equivalent of that section is being applied in many European countries, some of which have in the past had a different attitude to the effect and ambit of claims. It is therefore important that the effect of the law is, in so far as possible, the same in those countries as in this.[147]

Given the above, this passage in Aldous J's trial judgment (delivered a year after his *Chiron* decision) in *Biogen* is understandable:

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[141] Ibid.
[142] [1989] RPC 147, 248.
[143] [1989] RPC 147, 235-237.
[144] Jacob above note 23, 315.
[145] *Young v Bristol Aeroplane* [1944] KB 718. The principle, with some additional patent-specific riders, is discussed in *Symbian v Comptroller General of Patents* [2008] EWCA Civ 1066, [33]-[36].
[146] *Biogen v Medeva* [1995] RPC 25, 95-99 and followed shortly after by a differently-constituted Court of Appeal in *Chiron v Murex Diagnostics* [1996] FSR 153, 184-185.
[147] *Chiron Corporation v Organon Teknika* [1994] FSR 202, 242.

> I believe that what I said in the *Chiron* case is applicable to this case and counsel for the parties did not submit to the contrary, although they reserved their positions to make different submissions in a higher court.[148]

Despite the apparent consistency of the Aldous J view with the Court of Appeal in *Genentech's Patent*, before the Court of Appeal in *Biogen* there seemed to have been no real contest between the parties that the view expressed by Aldous J at trial and in *Chiron* should be overturned. Mr Hugh Laddie QC, counsel for the patentee (Biogen), appeared to concede that sufficiency could now also do the work that fair basis once did, and simply argued about how the expanded sufficiency rule should be applied in the circumstances of the present case:

> Before us Mr. Laddie for the plaintiff modified the submission. He in effect argued that, where the patent related to the invention of a principle, the enablement of a single embodiment of that principle would suffice. He thus went some way towards accepting what we have held to be the correct view of the law. But this does not advance the plaintiff's case unless he can show that the claims in the patent in suit have that character and are so limited. This he cannot do.[149]

In the *Biogen* litigation, why did Mr Laddie for the patentee concede before the Court of Appeal that sufficiency could have such an expanded role? Doing so was plainly at odds with the interests of the patentee, and seemed contrary to what might have been argued to be an emerging 'Aldous' orthodoxy in UK patent law in the mid-1990s. The answer to that was provided by Mr Martin Howe QC, one of the counsel for the respondent in the *Biogen* litigation and an attendee at a 2009 seminar when (in outline form) the above research on the EPC *travaux* and the speculative claiming cases was delivered.[150] Mr Howe explained both in the seminar room and by subsequent email the reason for Mr Laddie's concession. The relevant section of the email reads:

> I attach copy of the relevant section of Medeva's skeleton argument in the Court of Appeal. As you see, we relied on the very passage in the *travaux preparatoires* which you referred to this evening, and also the UK 'speculative claims' line of cases. Hugh Laddie QC, counsel for Biogen, cunningly conceded the question of law on sufficiency and for this reason the EPC *travaux* and the speculative claiming cases were not dealt with in the judgments in the Court of Appeal or in Lord Hoffmann's speech in the House of Lords. It is not incumbent on a court to deal *in extenso* with points which are conceded. However, as and when you publish on this issue I hope that the attached will enable you to enlighten posterity about the basis on which the case was in fact argued by Medeva in the Court of Appeal and the [House of Lords].[151]

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[148] *Biogen v Medeva* [1995] RPC 25, 45.
[149] *Biogen v Medeva* [1995] RPC 25, 98.
[150] David Brennan, '*Biogen* Sufficiency Reconsidered', Public Seminar 12 March 2009, Queen Mary Intellectual Property Research Institute, London.
[151] Email from Martin Howe to the author, dated 12 March 2009 attaching a draft written submission titled 'Insufficient Description'. Copies of both the email and its attachment are on file with the author. One of the cases in the speculative claiming line (the headnote to Whitford J's decision in *Eastman Kodak*

Given the debates about *Biogen* sufficiency, including its 2009 reconsideration by the House of Lords in *Lundbeck*, it is surprising that an EPC foundation for *Biogen* sufficiency, rooted in UK law, had been identified during the course of the *Biogen* litigation and has remained unpublished until now. If this information had been made public (or available to the courts in *Biogen*) some uncertainty surrounding *Biogen* sufficiency might have been long-ago answered.[152] As it was, *Biogen* sufficiency was arrived at by a Court of Appeal and House of Lords unaided by some quite pertinent of material regarding the EPC *travaux* and the inscription therein of the speculative claiming authorities. At the same time that material seemingly had an instrumental background role in changing Biogen's litigation posture so that it conceded into existence *Biogen* sufficiency.

The *Lundbeck* reappraisal

In *Lundbeck* both Lord Hoffmann and Lord Justice Jacob sat together on the Court of Appeal. It was a case which provided an opportunity for them to reassess their views on sufficiency.[153] This was because it involved an appeal from a judge who had found as *Biogen* insufficient a claim to an organic chemical.[154] In the case the hapless trial judge, Justice Kitchin, found that a claim to a known enantiomer, escitalopram, first isolated from a known racemate, citalopram, could give no rights in escitalopram *per se*.[155] This was because the disclosed technical contribution was merely to invent one particular means of isolation. To the extent the patentee (Lundbeck) claimed escitalopram itself, isolated by whatever means, it claimed beyond the disclosed technical contribution and the claim was therefore *Biogen* insufficient. On any reading, Justice Kitchin was merely making a fair fist of applying *Biogen* sufficiency as he was required to do under the doctrine of precedent.

Confronted with the consequence of *Biogen* sufficiency in respect of *per se* claims for a novel and useful chemical substance supported by one disclosed means of production, both Lord Hoffmann and Lord Justice Jacob seem to come awfully close to recanting. Lord Hoffmann stated, supported by the Court, that where a product is the invention, 'it is sufficiently enabled if the specification and common general knowledge enables the skilled person to make it. One method is enough.'[156] This conclusion was buttressed in his judgment by reference to a series of EPO Technical Board of Appeal decisions in

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Company's Application [1970] RPC 548) was in fact referred to in passing by the Court of Appeal in *Biogen v Medeva* [1995] RPC 25, 96.

[152] See for example Phillip W Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (4th edition, 2004) 260 who perceptively identified both the tension with 'the normal law for chemical inventions, where a novel compound may be validly claimed *per se* if one method of making it is given' and how the claim in *Biogen* might be distinguished 'the claim was to a recombinant DNA, which imports into the claim the way in which the product is made'; Bodkin above note 42, 206-207; McInerney above note 44, 20; *Lockwood Security v Doric Products* (2004) 217 CLR 274, 300.

[153] *H Lundbeck v Generics* [2008] EWCA Civ 311.

[154] *Generics v H Lundbeck* [2007] RPC 32 (Kitchen J).

[155] Ibid [250]-[265].

[156] [2008] EWCA Civ 311, [27].

which one disclosed means of production was presumed to provide full support for broad *per se* product claims. In not one of these cases was the issue of insufficiency raised by an opponent.[157] Jacob LJ restated the consequences in patent law of conceiving escitalopram as *the* invention:

> [A]ny product claim is apt to give the patentee "more than he has invented" – and in two ways. Firstly such a claim will have the effect of covering all ways of making the product including ways which may be inventive and quite different from the patentee's route. Secondly it will give him a monopoly over all uses of the patented compound, including uses he has never thought of.[158]

The conclusion of the Court of Appeal was endorsed unanimously by the House of Lords.[159] In both appellate courts the earlier decision in *Biogen* and the obiter dicta in *Kirin-Amgen* were not distinguished on the ground that they had biotechnology as their subject matter and *Lundbeck* had organic chemistry as its. To say so, however candid that might be, would provide evidence of a type of discrimination against a field of technology that might be considered offensive to TRIPS-defined international patent norms.[160] Instead, the earlier cases were distinguished on the ground that biotechnology products there were claimed by being the result of recombinant technology (such as the claim in *Biogen*), or for use in recombinant technology (such as the claim in *Kirin-Amgen*). Once any element of a product was defined by a process, it was accepted that for the claim to be *Biogen* sufficient that the product claim must be limited to the disclosed process. This was a special rule applicable only for claims to a 'product-by-process', a type of claim Lord Hoffmann considered to be largely a relic from the period before process claims had conferred upon them exclusive rights extending to products made from the process.[161] (There is, however, another good explanation for such claims in modern patent practice; they provide a means by which a patentee may describe products which defy any alternative description.[162]) The product claim in *Lundbeck* was manifestly not a product-by-process claim, and therefore seemingly escaped the logic of *Biogen* altogether.[163]

This position is an awkward one for patent law to take, begging questions which strain at the coherence and credibility of the legal rule. The categorisation as Biogen's claim as a product-by-process claim is a dubious one; the term 'recombinant' does not so much distinguish any specific process as denote a broad field of genetic engineering. If a claim in *Biogen* was expressed as a claim to a 'synthetic micro-organism' which expressed part of a Hepatitis-B antigen, would the one method disclosed by the patentee (involving the

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[157] Ibid [34]-[40].
[158] Ibid [54].
[159] *Generics v H Lundbeck* [2009] UKHL 12.
[160] TRIPS article 27(1).
[161] [2005] RPC 9, [88]-[90].
[162] See the recent discussion by Newman J in *Abbott Laboratories v Sandoz*, 566 F 3d 1282, 1300-1321 (2009) explaining this so-called 'rule of necessity'. See also Lord Hoffmann's discussion of EPO practice at [2005] RPC 9, [91].
[163] [2008] EWCA Civ 311, [42] (Lord Hoffmann) and [2009] UKHL 12, [24]-[27] (Lord Walker); [49]-[52] (Lord Mance); [99] (Lord Neuberger).

Dane particle) have been enough? It seems quite likely that the term 'synthetic' in such a claim would be interpreted to import something of the recombinant process by which the micro-organism was made, and thereby be as susceptible to a *Biogen* sufficiency analysis as any claim which expressly implicated a process aspect. However, the claim to escitalopram in *Lundbeck* was not anticipated by citalopram because it was interpreted to mean escitalopram 'isolated' from citalopram.[164] Such an interpretation means that the claimed product is to some extent defined by a process; the process of isolating the product in substantially pure form. Why should a claim to an 'isolated chemical' escape the logic of *Biogen* sufficiency if a claim to a 'synthetic micro-organism' does not? Warren nicely captures the consequence of this differential treatment:

> most instances of patents to chemical compounds are deemed to be product claims and so will not fall under [the requirement of *Biogen* sufficiency] … therefore … what discharges the burden of 'sufficiency' can be seen to be unduly restrictive and discriminatory in the specific cases of biotechnology.[165]

As alluded to above, it is perhaps easier to explain another, less doctrinal, way. *Biogen* and *Kirin-Amgen* involved genetic inventions. The citing by Lord Hoffmann in *Biogen* of the Robert Merges and Richard Nelson *Columbia Law Review* article 'On the Complex Economics of Patent Scope' gives a hint of a principled concern to confine claim scope especially narrowly for gene patents.[166] But by so doing precedents are generated which must apply without discrimination to all fields of technology where (arguably) the same principled concerns are not seen to be present – such as the organic chemical claim in *Lundbeck*. In such a case *Biogen* sufficiency arguably reveals itself to be bad patent policy which requires confinement. Although confinement occurs on a basis more confected than connected to the underlying concern that generated *Biogen* sufficiency in the first place. To be connected to reality would have required more candid

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[164] [2008] EWCA Civ 311, [12] (Lord Hoffmann); [50] (Jacob LJ).

[165] Amanda Warren, 'Discrimination by Redefinition: the Judicial Approach to Patenting Biotechnology in the United Kingdom' [1997] JBL 575, 584.

[166] *Biogen v Medeva* [1997] RPC 1, 52. The article's full citation is Robert P. Merges and Richard R. Nelson, 'On the Complex Economics of Patent Scope' (1990) 90 *Columbia Law Review* 896. Sparked by Lord Hoffmann's reference to it in *Biogen*, in *Lundbeck* Lord Mance undertook his own excursion into the article to distinguish certain examples there given from Lundbeck's claim to escitalopram: *Generics v H Lundbeck* [2009] UKHL 12, [47]-[48]. A passage from Merges and Nelson (at page 914-915) selected by Lord Mance dealt with a *per se* product claim to purified human adrenalin which was considered valid by US courts in 1911. Merges and Nelson state: 'In such cases protection consistent with the actual achievement of the inventor would have been provided if the initial patent had been for a process, or at most a "product-by-process", rather than for a product. And inventive efforts to come up with a significantly better process to make the product would not be blocked. These concerns seem to have animated a recent British case denying broad claims for Genentech's t-PA drug [Genentech Inc's Patent [1989] RPC 147]. One perhaps controversial way to achieve this would be to recognise a reverse equivalents defence [*that is, an American law defence available to an alleged infringer who has so far changed in principle a product described in a patent claim that it performs in a substantially different way*] when a recombinant product is accused of infringing a prior purification patent.' (Notes in the quotation were omitted and Lord Mance made the explanatory insertions in square parenthesis.) The reverse equivalents defence is rarely applied in US patent law and as at July 2008 the specialist Patent law appellate court, the United States Court of Appeals for the Federal Circuit had never affirmed a finding of non-infringement under the doctrine: *Roche Palo Alto v Apotex,* 531 F 3d 1372, 1377-8 (2008).

acknowledgement of what seems to be the true distinction between *Biogen* and *Lundbeck*; the differing fields of technology. That would, however, admit to a type of discrimination which is prohibited under article 27 of the TRIPS agreement.

Is *Biogen* sufficiency good law?

Any coherent patent system should have a comprehensible legal means to deal with an otherwise valid yet unduly broad claim in a granted patent. No matter how admirable the objectives were in first planting a foundation for, and then crafting *Biogen* sufficiency within the confines of the EPC, it has been a doctrine not always well-applied.

The *Biogen* sufficiency of claims should be assessed internally by reference to the priority date.[167] It should not be undertaken by asking whether the specification enables the alleged infringement, or by some process of reasoning whereby a court says: 'if these claims cover this particular infringement they can not be properly supported'.[168] However the methodology in *Biogen* itself and obiter to the same effect in *Kirin-Amgen* tests for insufficiency by reference to the alleged infringements. In *Biogen* Lord Hoffmann observed: 'The respondents … owe nothing to [the patentee's] invention.'[169] This was because the defendant, Medeva, had sequenced the Hepatitis-B virus genome and did not need to rely upon any technique unique to the Dane particle. To the extent that this suggests patent liability, like copyright liability, is predicated upon derivation from the patented invention, it is a suggestion that can not be correct.[170] In *Kirin-Amgen* Lord Hoffmann said by way of obiter that because the claims were construed by the appellate courts in a way narrower than that contended for by the patentee 'they do not cover [the defendant's] process and the specification need not enable it'.[171] But if the patentee's construction had been accepted, 'the specification does not disclose a way of making it in sufficiently general terms to include the [the alleged infringement]'.[172] Therefore, to the extent it was said that the process did infringe the Kirin-Amgen claim, the claimed invention could not have been clearly and completely enough disclosed in the specification. 'It is a classic patent law squeeze', Lord Hoffmann observed.[173] Where the alleged infringement is a subsequent invention (as was the case in *Kirin-Amgen* with the defendants' gene activation technology) *Biogen* sufficiency creates the requirement that a patentee's specification must comprise an enabling disclosure (and thus an anticipation)

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[167] *Biogen v Medeva* [1997] RPC 1, 99-102.
[168] In *Durel Corporation v Osram Sylvania* the US Court of Appeals for the Federal Circuit has expressed the analogous principle in US law as '[t]he dispositive question of enablement does not turn on whether the accused product is enabled': 256 F 3d 1298, 1306 (2001).
[169] [1997] RPC 1, 52.
[170] While innocent infringers are given remedial relief, patent property is a far stricter form of property than copyright in that derivation (or 'causal connection') is not required to be established: Patents Act 1977, section 62 and *Kewanee Oil Co v Bicron Corp*, 416 US 470 (1974) where the US Supreme Court observed (at 478) that the nature of patent protection 'goes not only to copying the subject matter, which is forbidden under the Copyright Act … but also to independent creation'.
[171] [2005] RPC 9, [110].
[172] Ibid [114].
[173] Ibid [105].

of the defendant's subsequent invention, for the defendant to infringe a valid claim.[174] Warren identifies the absurdity of this outcome from *Biogen*: 'the impossibility of ever being able to satisfy such a nonsensical level of disclosure did not appear to be any inhibition in reaching this decision'.[175]

Biogen sufficiency causes courts to collapse claims into the description, and puts any patentee on an insufficiency tightrope whenever an attempt was made to stretch claiming language for infringement purposes. For example, the Court of Appeal in *American Home Products v Novartis* reasoned (applying *Biogen*) that if a claim to a use of a chemical included within its scope the use of the defendant's improved derivative, then the claim could not be *Biogen* sufficient.[176] The patentee had not disclosed the defendant's improvement. The Court stated that it 'did not believe that the patent system should be used to enable a person to monopolise more than that which he has described in sufficient detail to amount to an enabling disclosure.'[177] This statement by the Court of Appeal seems not to do justice to the respective roles given to the specification and the claim in English legal patent tradition, and the body of claim construction jurisprudence that has arisen around that. It suggests a yearning for a time when there were no claims, and courts could determine liability by comparing the description against the defendant's alleged infringement.[178] Sufficiency and infringement are distinct. Assessing sufficiency by reference to the alleged infringement runs together two separate questions, can operate very harshly against patentees, and makes patent specification drafting an even more fraught task.

These problems in application shed light on a more fundamental problem: the coupling of unduly broad claims with sufficiency is inherently flawed. What is really at the heart of a rule against 'speculative claiming', or requiring 'internal fair basis' or indeed *Biogen* sufficiency? Arguably it is the nature of the relationship of the claim to the disclosed inventive step; the first of the two suggestions made by Cornish in 1981 to deal with the removal of lack of fair basis as a revocation ground. It is instructive to think about the four types of cases discussed above in which nature of the claims have offended one or other of these doctrines.

(i) The simplest of those is the claim at such a high level of abstraction that it levitates far above the inventive step – such as the claim in *Re Esau and C*

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[174] The Court of Appeal in *Kirin-Amgen* pointed out that '[t]he law contemplates that patents will not lack sufficiency even though the claims cover inventive improvements': [2003] RPC 3, [69]. This comment was met by Lord Hoffmann with this statement: 'As for the point made by the Court of Appeal, it is of course correct so far as it goes. The choice of a particular form of an integer falling within the terms of the claim may improve the way the invention works and be in itself an inventive step. The specification is not insufficient merely because it does not enable the person skilled in the art to make such an invention. The use of the improvement is still a way of working the original invention': [2005] RPC 9, [117]. This suggests – contrary to several other indications offered by Lord Hoffmann in *Biogen* and *Kirin-Amgen* – that *Biogen* sufficiency does not require full claim-scope enablement.

[175] Warren above note 165, 578.

[176] [2001] RPC 8, [46]-[47].

[177] Ibid [46].

[178] See generally Brennan above note 7.

Lorenz Aktiengesellschaft to any method of using electricity to achieve a useful result.[179]

(ii) Then there is a claim like that in the *Eastman Kodak* cases in which functional product features are claimed by such a broad range or class, that the scope of the claim dwarfs any inventive step involved in that claim.[180]

(iii) Then, there is the type of claim in *Mullard v Philco* and *EXXON/Fuel Oils*, which claim not the functional features but rather the end desirable consequences of those features.[181] The claim does not so much levitate above the inventive step or dwarf it, but claims the downstream desirable consequences created by the inventive step.

(iv) Then there is a claim such as the one in *Kirin-Amgen* where claim 1, at least on the construction contended for it by the patentee, is to something (arguably) quite a long way upstream from the inventive step.[182] Whatever the inventive step was in *Kirin-Amgen* it could not be the mere discovery of the EPO gene, and unlike *Lundbeck* it was not suggested to be the means of its physical isolation.

If a patentee's claim is to an abstraction levitating far above the inventive step, or is to something the scope of which dwarfs the inventive step, or is to the downstream desiderata achieved by the inventive step, or is to basic research situated a very long way upstream from the inventive step, then in all cases the claim might be considered to be too remote from the inventive step, so as to not properly 'involve' the inventive step. This is not to say that claims should be to be to the inventive step. Manifestly, a claim is to the novel features of the invention. However the degree of involvement of the disclosed inventive step in any claim should be close, or at least not remote.

If claim scope was treated as an issue of the proximity of the inventive step's involvement in the claim, it would lead patent law away from discourse about disclosure sufficient to enable performance across the full width of the claim and would require instead satisfaction that any claim in issue involves the inventive step in a reasonably direct way. It would also not have recourse to the subjective and impressionistic 'technical contribution to the art', which reached a confusing nadir at one point in *Lundbeck*.[183] It would bring UK patent law relating to claim scope back to a doctrinal position closer to that adopted in *Mullard v Philco* by requiring that the question to be focused upon the relationship between any claim and the disclosed inventive step.[184] Finally, it would return sufficiency to its more comprehensible classic form.

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[179] (1931) 49 RPC 85.

[180] In *Montecatini Edison v Eastman Kodak* (1971) 1B IPR 656 and *Eastman Kodak Company's Application* [1970] RPC 548, Gibbs J (at 662-664 in the former) rejected as not fairly based and Whitford J (at 563-564 in the latter) rejected as speculative and thereby insufficient claims to a chemical product (a new polypropylene) because they were claims to a class of features the scope of which towered over the modest and incremental nature of the inventive step.

[181] (1936) 53 RPC 323 and [1994] EPOR 149.

[182] [2005] RPC 9.

[183] [2009] UKHL 12, [29]-[30] (Lord Walker) and [101] (Lord Neuberger).

[184] While not going so far as the extreme Australian position represented by *Lockwood Security v Doric Products* (2004) 217 CLR 274. In *Lockwood Security*, the Australian High Court held that a claim will be

Applied in *Biogen* and *Lundbeck*, it would probably lead to a different outcome in the former and the same outcome in the latter. The claim in *Biogen* was in effect to a 'synthetic antigen factory', a product proximate to the inventive step (the particular use of the Dane particle to make such a factory) even if that step was more serendipitous than systematic. In *Lundbeck*, the product claim to escitalopram (the isolated isomer) can be seen to involve a similarly proximate relationship to the inventive step (the means of isolation), and this would lead to the same outcome as that arrived at by the Court of Appeal and the House of Lords. Biogen's and Lundbeck's claims equally involved their respective inventive steps because the inventive steps in both cases were of the same essential nature; overcoming the problem of how to first make the product so claimed. Moreover, in both *Biogen* and *Lundbeck* the claims were to products described specifically, not by a 'range' or 'class' of features, but by the products' actual features.[185] They were not claims to abstractions, mere desiderata, or basic knowledge. Each product claim was equally proximate to the disclosed inventive step.

Conclusion

The problem of undue claim scope is difficult because at it brings together inventive step and claim construction – each which in and of itself is complex. The UK statutory ground of revocation of lack of fair basis was a 1949 codification of the holding in *Mullard v Philco*.[186] Whitford J observed in the mid-1970s that there was by then 'really no authority' on lack of fair basis.[187] Another judge at around that time had repeatedly suggested that the ground had something to do with a normative characterisation of the patentee's conduct.[188] Reservations about its uncertain nature in UK law might have fuelled fears that the ground represented an invitation to UK judges to apply idiosyncratic notions of 'fairness' camouflaged in high-brow linguistics. If so, it seems understandable why under a harmonized 'maximum' approach that the EPC drafters expressly denied

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fairly based if the other matter in the specification shows that the invention there disclosed is not narrower than what is claimed in the claim. In so holding, the High Court described *Mullard v Philco* as being of 'very limited assistance', and somehow chose to imagine that fair basis in modern Australian patent law is autochthonous. The approach renders the current Australian fair basis doctrine at the polar opposite end of the spectrum from the *Biogen* sufficiency requirement of full claim scope enablement, to a point where it is a textually circular and toothless validity requirement. (An even more acerbic view on the Australian High Court's *Lockwood Security* decision is offered by David Catterns, 'Lockwood v Doric – Fair Basis and the High Court' (2006) 65 IP Forum 34.)

[185] In *Firestone Tire & Rubber's Application* [1966] FSR 366, 371 the patent examiner drew a critical distinction: 'I find it quite impossible, having regard to the practice which has obtained over many years, to hold that an unrestricted claim to a clearly defined chemical is not a proper claim when only one method of making the chemical is described. This, however, is not to say that difficulty may not arise if a claim is made to a class of substance which is much wider in scope than the particular instance of the class whose manufacture is described, but no allegation of this kind is made here.'

[186] Separate lines of authority had developed in respect of 'lack of fair basis' as it related to disconformity between claims and an earlier filing from which the claims derived priority: McBratney above note 11, 214-222.

[187] *American Cyanamid Company v Berk Pharmaceuticals* [1976] RPC 231, 259.

[188] Mr Justice Graham in *Letraset v Rexel* [1974] RPC 175, 196-197; *Farbenfabriken Bayer AG's Application* [1973] RPC 698, 703-704, and *Stauffer Chemical's Application* [1977] RPC 33, 42.

lack of fair basis to national courts as a revocation ground. However it should not be forgotten that central to *Mullard v Philco* was inventive step. The House of Lords did not adopt the then nascent invalidity ground of 'speculative claiming' rooted in sufficiency. Instead it chose to deploy the concept most central to patent merit. *Biogen* sufficiency was derived from that alternative, 'speculative claiming' line of authority grounded in sufficiency because of EPC constraints. *Biogen* sufficiency has not been overruled in *Lundbeck*, but it has been exposed as a flawed vehicle to achieve its stated aims. It has been confined by *Lundbeck* to product claims which are defined by a process element and (presumably) to process claims. The coherence of this confinement is dubious. It is suggested that some of its flaws in application were apparent prior to *Lundbeck*, and indeed while the principle of revoking unduly broad claims is eminently sound, it is here argued that *Biogen* itself was a poor application of that principle. It is suggested that what lay at the heart of *Mullard v Philco* (decided when clear claims were mandated but no express ground of revocation for undue claim breadth was then in existence) offers a key to reconsidering this area of law. This can be undertaken well within EPC article 138 which provides that lack of involvement with an inventive step as a ground of revocation. A test along the lines of 'whether the claim involves the disclosed inventive step in a proximate enough way' may offer a helpful avenue to reconsider *Biogen* sufficiency.