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Biogen v Medeva (1996)

LUKE McDONAGH

A. INTRODUCTION

The decision in *Biogen v Medeva*¹ was handed down by the House of Lords on the night of Halloween 1996, more than 20 years ago.² The case is a landmark one because it was the first time the House of Lords considered genetic engineering in the context of patent law. Every student of UK patent law still studies the case, often in great detail. Consequently, in exams it is not uncommon for students to be asked to discuss the legacy of Lord Hoffmann's statement on 'Biogen insufficiency' in the context of earlier cases like *Genentech* (1989) and later cases such as *Generics v Lundbeck* (2009).³ Ambitious students take their time in writing their essays, trying to

¹ *Biogen Inc v Medeva plc* [1997] RPC 1, [1996] UKHL 18, (1997) 38 BMLR 149, on appeal from the Court of Appeal - *Biogen Inc v Medeva Plc* [1995] FSR 4; [1995] RPC 25, and the Patents Court - *Biogen Inc v Medeva Plc* (Unreported, November 4, 1993). See also Patents Act 1977 1(1), 3, 5(2)(a), 14(3) & (5), & 72(1) and the Text of the European Patent Convention, of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991, and the Act revising the EPC of 29 November 2000, available at <https://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma1.html>. The House of Lords judicial panel was made up of Lord Goff of Chieveley, Lord Browne-Wilkinson, Lord Mustill, Lord Slynn of Hadley and Lord Hoffmann.

² The Committee of the House of Lords heard the case on 29 and 30 April and on 1, 2, 7, 9, 13, 14, 15, 16, 20, 21, 22 and 23 May 1996.

³ *Genentech Inc.'s Patent* [1989] RPC 147, 272. *H Lundbeck A/S v Generics (UK) Ltd.* [2008] EWCA Civ 311, [2008] RPC 19 as affirmed by the House of Lords in [2009] UKHL 12, [2009] 2 All ER 955. See also D. Brennan, 'Biogen Sufficiency Reconsidered,' *Intellectual Property Quarterly* 4 (2009), 476; J Pila, 'Chemical

craft an argument as sly as Lord Hoffmann's brilliant judgment. For the intellectual property scholar, reading the case again is undoubtedly a nostalgic experience. Moreover, despite later rulings that have narrowed the scope of its effect, the judgment should still be viewed as a seminal one in UK patent law.⁴ It still has things to teach us, even after all this time, not least about how dissimilar the areas of law and science are from a methodological point of view, with each field possessing its own rational processes and own standards of acceptable proof.⁵ On this, one can say that *Biogen v Medeva* provides firm evidence – to scholars of science and law alike – that it is precisely this dissonance that makes patent law both a fascinating area and a hugely challenging one.

In this regard, over the course of this chapter I will first assess the reasoning behind the judgments at the High Court, the Court of Appeal, and finally, the House of Lords, exploring each ruling in detail. Following that I will consider what makes the case a landmark today from the perspective of its judicial legacy, also taking into account the views of the case participants twenty years on.

To understand the whole story of the litigation – from the Patents Court to the House of Lords, as well as the European Patent Office (EPO) opposition hearings, one must first go back to 1978, when four molecular biologists met in Geneva to make what would prove to be a prescient decision: to found a new company – Biogen Inc. – in order to commercialise their ongoing research in the then-new and blossoming field of biotechnology.⁶ The four scientists were: Walter Gilbert (a US citizen and Harvard University Professor), Kenneth Murray (a British

Products and Proportionate Patents Before and After Generics v Lundbeck,' *King's Law Journal* 20 (2009), 489 and C. Helmers and L. McDonagh, 'Patent litigation in the UK: an empirical survey 2000-2008,' *JIPLP* 8 (2013), 846.

⁴ The case is heavily featured in the latest edition of the leading practitioner textbook on patents – The Hon Mr Justice Colin Birss, Andrew Waugh, QC, Tom Mitcheson, QC, Douglas Campbell, QC, Justin Turner, QC, Tom Hinchliffe, QC, *Terrell on the Law of Patents* (18th edition: London: Sweet & Maxwell, 2017), including at Chapter 2, section 2: 'What is an Invention?' and Chapter 13, section 3: 'Biogen Insufficiency' (last accessed via Westlaw, 13 December 2016).

⁵ A. Pottage and B. Sherman, *Figures of Invention: A History of Modern Patent Law* (New York: Oxford University Press, 2010), 1-29.

⁶ 'Harvard keeps its hands clean' *New Scientist*, 20 November 1980, 497; 'Harvard, Biogen in Patent Deal' *The New York Times*, 29 November 1983; S. Yanchiski, 'Chemical Giants Turn to Biotechnology' *New Scientist*, 6 November 1980, 349.

citizen and Professor at the University of Edinburgh, who later became Professor Sir Kenneth Murray), Phillip Allen Sharp (a US citizen and Professor at MIT), and Charles Weissmann (a Hungarian-born Swiss citizen and Professor at the University of Zurich).⁷ All were undoubtedly world-leading experts, and two of them, Gilbert and Sharp, later became Nobel Laureates, with Gilbert receiving the Nobel Prize in Physiology or Medicine, and Sharp receiving the Nobel Prize in Chemistry.⁸

Biogen was the first Europe-based Biotechnology firm – albeit one with close links with Harvard University - and the company went on to become one of the world's largest and most important biotech companies. In fact, Biogen Inc. continues to thrive commercially today: in 2015 its revenues amounted to more than \$ 10 billion.⁹ For the purposes of this chapter, what is particularly significant is that Biogen was one of the first companies to use genetic engineering to develop pharmaceutical products – a business model heavily reliant on patent law.

Although Prof. Kenneth Murray, unlike two of his business partners, was never honoured by the Nobel Committee, he was a remarkable and innovative researcher in the field of DNA recombination; indeed, he was held in such high regard at the Department of Molecular Biology at the University of Edinburgh that on his passing in 2013 the event was marked by obituaries in several UK national newspapers, including *The Guardian* and *The Times*.¹⁰ One seminal achievement derived from his experimental work in the late 1970s was the successful isolation of part of the genome of the virus Hepatitis B - the Dane particle – and the splicing of it into the

⁷ See, generally, P. Goujon, *From Biotechnology to Genomes: The Meaning of the Double Helix* (London, World Scientific Publishing, 2001) 225; ‘Harvard wins key Biotech Patent’ *New Scientist*, 8 December 1983, 741. See also A.D. Chandler, *Shaping the Industrial Century: The Remarkable Story of the Evolution of the Modern Chemical and Pharmaceutical Companies* (Harvard: Harvard University Press, 2005), 275-276.

⁸ See S. Müller-Wille, H-Jörg Rheinberger, *A Cultural History of Heredity* (The University of Chicago Press, 2012), 190.

⁹ Biogen Inc.’s annual revenue can be seen in its 2015 10-K submission to the US Securities and Exchange Commission - <https://www.sec.gov/Archives/edgar/data/875045/000087504516000042/biib-20151231x10k.htm> - See also J. Silverlight, ‘Cashing on DNA’ *The Guardian*, 10 Feb 1980, 34.

¹⁰ T. Dalyell ‘Obituary: Professor Sir Kenneth Murray, the scientist who developed the vaccine against Hepatitis B’ *The Independent*, 15 April 2013; D. Finnegan, ‘Obituary: Sir Kenneth Murray’ *The Guardian*, 21 April 2013; ‘Obituary: Professor Sir Kenneth Murray; Molecular biologist who helped to create a life-saving machine’ *The Times*, 26 April 2013; W.J. Brammar and W.B. Gratzer ‘Sir Kenneth Murray: 30 December 1930-7 April 2013’ *Biogr. Mem. Fell. R. Soc.* 60 (2014), 331-348.

DNA of a host cell.¹¹ When the host cell replicated, the part of the Hepatitis B genome encoded for in the spliced-in DNA was expressed. This expression was a Hepatitis B antigen capable of triggering the production of Hepatitis B antibodies in the immune system. What Prof. Murray's experiments produced, therefore, was the basis for a useful - and lucrative - Hepatitis B vaccine.¹²

The result of this experimentation led to the filing of a patent application by the newly formed Biogen Inc. on 22 December 1978 in the UK (the Biogen 1 application). On 21 December 1979 Biogen made a filing at the EPO - claiming the earlier priority date - for a patent (the Biogen patent) for a claimed invention comprising:

'A recombinant DNA molecule characterized by a DNA sequence coding for a polypeptide or a fragment thereof displaying HBV antigen specificity, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule and being expressed to produce a polypeptide displaying HBV antigen specificity when a suitable host cell transformed with said recombinant DNA molecule is cultured, the transformed host cell not producing any human serum proteins and any primate serum proteins other than the polypeptide displaying HBV antigen specificity.'¹³

Claim 1 of the Biogen patent thus concerned a product defined 'partly by the way it had been made ("recombinant DNA") and partly by what it did (the words followed by "characterised by")'.¹⁴ Meanwhile, Claims 2 to 7 described specific embodiments of the recombinant DNA molecule according to Claim 1.

After a lengthy examination procedure, the patent was granted by the EPO in 1990 as European patent No. 0 182 442.¹⁵ Oppositions to the patent were filed at the EPO shortly thereafter. The

¹¹ D. Brennan, 'Biogen Sufficiency Reconsidered,' *Intellectual Property Quarterly* 4 (2009), 476, 476-479.

¹² C. Marwick, 'Genetic engineers in the sin-bin...and making vaccine against hepatitis' *New Scientist*, 11 September 1980, 764; M. Walters, 'Prof. Murray's Biogen mint' *The Daily Mail*, 22 February 1983, 29. See also J. Watts and T. Alkin, 'A Road to Unification: Patent Litigation in the United Kingdom 1990-2012,' *Fordham Intell. Prop. Media & Ent. L.J.* 23 (2013), 571, 581.

¹³ BIOGEN/Hepatitis B [1995] EPOR 1.

¹⁴ European Patent specification available at <https://register.epo.org/application?number=EP85201908>.

¹⁵ *Ibid.*

Opposition Division of the EPO revoked the patent on 21 January 1993.¹⁶ On appeal, the EPO Board of Appeals overturned that decision on 28 July 1994, which meant that the patent remained valid.¹⁷ Of course, due to the fragmentary nature of enforcement within the European Patent Convention system, national litigation could still proceed over the same patent on the issues of infringement and validity. Furthermore, while the UK's courts must take the EPO's validity decisions into account, there nonetheless tends to be some leeway for divergent judicial decisions at the EPO and national levels.¹⁸ This kind of divergence did indeed occur in *Biogen v Medeva*.¹⁹

B. OBSERVING THE CASE THROUGH THE COURTS

(1) At the Patents Court

UK national litigation over the patent was initiated in July 1992 when Biogen Inc. filed a patent infringement case against Medeva plc at the Patents Court - part of the High Court of England and Wales - in London.²⁰ The rationale behind the case being filed was that a pharmaceutical group called Medeva planned to market a third-generation hepatitis B vaccine manufactured via recombinant DNA technology.²¹ Biogen argued that this was an infringement of the patent granted to them by the EPO in 1990 (EP 0 182 442), as well as another of their European

¹⁶ See Text of the European Patent Convention, of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991, and the Act revising the EPC of 29 November 2000, available at <https://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma1.html>

¹⁷ <https://www.epo.org/law-practice/case-law-appeals/recent/t930296ex1.html>

¹⁸ L. McDonagh, *European Patent Litigation in the Shadow of the Unified Patent Court* (Cheltenham: Edward Elgar, 2016), 1-11.

¹⁹ Y. Cripps 'Recombinant DNA Technology. A Patent Case in the House of Lords' *The Cambridge Law Journal*, 56 (1997), 262-267 and J. Straus, 'Patent Litigation in Europe—A Glimmer of Hope? Present Status and Future Perspectives,' *Wash. U. J. L. & Pol'y* 2 (2000), 403, 407.

²⁰ *Biogen Inc v Medeva Plc* (Unreported, November 4, 1993). See also *Chiron Corp. v Organon Teknika Ltd. (No. 3)* [1994] FSR 202. The Patents Court was created in 1980 by section 96 of the Patents Act 1977 (subsequently repealed and replaced by section 60 of the Senior Courts Act 1981). For a comment, see J. Rimmer 'The UK patents court decisions in Chiron and Biogen: a review of the issues' *Patent World*, March 1994, 22-28; see also I. Judge, S. Cooke, M. Burdon, T. Powell, P. Gilbert and C. Hore, 'Chiron v Organon and Biogen v Medeva: A Boost for the Biotech Industry' *Patent World*, December/January 1994, 20-26.

²¹ 'Medeva's fate could hinge on patent case' *The Times*, 30 September 1993, 30 and G. Counsell, 'Medeva faces court action over patent' *The Independent*, 25 August 1993, 40.

patents (EP 0 013 828) though infringement proceedings over this other patent were not pursued through to trial.²² Medeva made a counter-claim for revocation.

Interestingly, Biogen had licensed EP 0182 442 - the Biogen patent - to Smith Kline Beecham and Merck, both of whom went on to market successful vaccines based on the patent;²³ and early on during the proceedings Medeva attempted (unsuccessfully) to join Smith Kline Beecham as a defendant to their revocation counter-claim.²⁴ What is crucial for our purposes is analysis of the precise grounds of Medeva's counter-claim for revocation of the Biogen patent.²⁵ The fundamental ones can be summarised as follows:

(i) that the claimed invention was *obvious* in accordance with sections 1(l)(b) and 3 of the Patents Act 1977, both at the date of application for the Biogen patent filed in December 1979 and at the claimed priority date of the Biogen 1 application in December 1978. (During the trial Biogen conceded that the claimed invention was obvious at the date when the application for the European patent was filed but argued that it was not obvious on the claimed priority date of the earlier Biogen 1 application.)

(ii) that Biogen was not entitled to avail of the priority date of the 1978 Biogen 1 application because - in accordance with section 5(2)(a) of the Patents Act 1977 - it *did not support the invention claimed* in the Biogen patent as filed in 1979.

(iii) that the claimed invention was *not an invention* in line with section 1(1) Patents Act 1977

(iv) that the description in the specification was *insufficient* under section 72(l)(c) of the Patents Act 1977.

²² 'Refusal to stop infringement' *The Times*, 1 December 1993, 34.

²³ C. Huhne, 'Patent Challenge' *The Independent*, 4 October 1993, 22 and G. Counsell 'Medeva faces suit over new vaccine' *The Independent* 28 October 1993, 41.

²⁴ L. Jacobs, 'Case Comment: Patents' *E.I.P.R.* 15 (1993), D89.

²⁵ See generally, R.S. Crespi, 'Patenting in Biotechnology—the saga continues,' *Biotechnology and Genetic Engineering Reviews* 15 (1989), 229. 9; H. Kelly, 'Biogen's Hepatitis B Patent Held Valid and Infringed' *E.I.P.R.* 2 (1993), 75.

During a lengthy trial at the Patents Court Aldous J. heard expert evidence about what people skilled in the art of recombinant DNA technology would have thought and done at the time.²⁶ One of the interesting points that came out during expert testimony was that during the period immediately prior to Prof. Murray's 1978 discovery a voluntary moratorium had been in effect on further genetic engineering work by scientists due to concerns about the safety of genetically modified bacteria – which meant that while scientists continued to develop ideas in the abstract, practical research had halted, leaving the methods available to reach desired end-points and goals undeveloped.²⁷ This was relevant to the court's analysis of inventive step, because Aldous J. had to decide whether, in light of prior-existing research, the patent ought to be considered obvious at the claimed priority date of 1978.

Nonetheless, the first thing Aldous J. had to consider was whether claim 1 of the Biogen patent referred to more than one invention. This was important to the insufficiency and obviousness questions because if the patent contained more than one invention - e.g. two - the claims would have to sufficiently disclose each invention; and moreover, each of the inventions would have to be considered in turn with regard to the priority date.²⁸ To the relief of Biogen, Aldous J. ruled that there was only one invention in claim 1 of the Biogen patent. Given this finding, and in light of the evidence presented to him, he further concluded that the requirement of sufficiency was satisfied.²⁹

With respect to obviousness, Aldous J. followed the earlier rulings in *Asahi*³⁰ on assessment of the priority date.³¹ He further voiced support for the idea that a patent application which outlines a new principle, as well as a method by which it may be carried out, can provide support for a claim to that principle, however carried out.³² Along these lines, Aldous J. decided that the

²⁶ Biogen relied on the testimony of Professor Sir Kenneth Murray, Professor Burrell, Professor Villa-Komaroff and Dr. Alan Kingsman. Medeva called Professor Jeffrey Almond, Dr. Cozens and Mr. Ronald Holmes as witnesses.

²⁷ 'From hepatitis B virus antigens to wine and canapés: Biogen v Medeva revisited' *PatLit Blog* 11 February 2015 - <http://patlit.blogspot.co.uk/2015/02/from-hepatitis-b-virus-antigens-to-wine.html>

²⁸ *Biogen Inc v Medeva Plc* [1995] RPC 25, 42-43.

²⁹ *Ibid.*, 44-50.

³⁰ *Asahi Kasei Kogyo KK's Application* [1991] RPC 485.

³¹ *Biogen Inc v Medeva Plc* [1995] RPC 25, 52-56.

principal claims - 1-4 - of the Biogen patent were supported, and thus entitled to the earlier priority date (the Biogen 1 application), although claims 5-6 were not.

In analysing the substantive test for obviousness Aldous J. referred to the classic case of *Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd*³² on the four step approach:

‘The first is to identify the inventive concept embodied in the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being "known or used" and the alleged invention. Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.’³⁴

In line with this, Aldous J. first identified the Prof. Murray's inventive concept as 'the idea or decision to express a polypeptide displaying HBV antigen specificity in a suitable host'³⁵ i.e. making HBV antigens by recombinant DNA technology. He then examined what would have been known to the person skilled in the art. Crucial to this assessment (of obviousness) was the 'Villa-Komaroff paper' - a leading scientific publication on DNA recombination in the period prior to Prof. Murray's application, and thus an element contributing to the state of the art.³⁶

Aldous J., in considering the importance of the Villa-Komaroff paper, remarked:

‘It is accepted that once a decision [had] been made to try expression of the HBV genome, the technique set out in Villa-Komaroff would have been sufficient to enable it to be carried out. Thus the difference between the prior art and the inventive concept is the idea or decision to express a polypeptide displaying HBV antigen specificity in a suitable host.’³⁷

³² *Ibid.*, 56.

³³ *Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd* [1985] RPC 59.

³⁴ *Ibid.*, 73-74.

³⁵ *Biogen Inc v Medeva Plc* [1995] RPC 25, 57.

³⁶ L. Villa-Komaroff et al., 'A bacterial clone synthesizing proinsulin,' *Proc. Nati. Acad. Sci. USA* 75 (1978), 3727.

³⁷ *Biogen Inc v Medeva Plc* [1995] RPC 25, 58.

Aldous J. then examined what strategies would have been available to the skilled person in 1978 who sought to make HBV antigens via recombinant DNA technology.³⁸ He considered that there were two significant possible methods.³⁹ One would have been to try to find out more about HBV and its DNA through gene sequencing, which would provide some useful information regarding the expression of the relevant genes.⁴⁰ The alternative strategy would have been to take the genomic DNA and try to express it in *E. coli*. This is what Prof. Murray had done in the late 1970s. Biogen's argument on this point was that it was not until the sequence had been obtained, with the knowledge that introns - nucleotide sequences within a gene that are removed by RNA splicing - would not be a problem 'that the skilled man would seriously consider expression of HBV antigens'.⁴¹ Aldous J. agreed and held that the strategy taken by Prof. Murray would not have been obvious in 1978:

'In the present case, there is no evidence to suggest that anyone, other than Biogen, contemplated expression of the HBV antigen in December 1978, despite the fact that the skilled man must have read the Villa-Komaroff paper and there was an incentive to do so. The reason may well be that stated in the patent, namely the skilled man was put off by introns.'⁴²

Finally, Aldous J. also rejected the idea that the patent did not describe an 'invention' in line with the earlier case of *Genentech*.⁴³

Thus, the Patents Court ruled in favour of Biogen Inc., holding that the principal claims of the patent were valid and the patent had been infringed.⁴⁴ Precisely because this decision was seen as

³⁸ *Ibid.*, 56-65.

³⁹ *Ibid.*, 59.

⁴⁰ *Ibid.*, 59-60.

⁴¹ *Ibid.*, 64.

⁴² *Ibid.*, 65. Aldous J. also rejected Medeva's argument that the first strategy - gene sequencing - was an obvious way of making the antigens. See J. Thomson 'The Grey Penumbra of Interpretation Surrounding the Obviousness Test for Biotech Patents' *E.I.P.R.* 2 (1996), 90.

⁴³ *Genentech Inc. 's Patent* [1989] RPC 147, 272.

⁴⁴ L. Buckingham 'Medeva suffers vaccine pain' *The Guardian*, 5 Nov 1993, 17; G. Foster, 'Medeva shakes dealers' *The Daily Mail* 5 November 1993, 71; R. Hotten, 'Medeva loses patent battle' *The Independent*, 5 November 1993, 34.

highly favourable to the patentee and the defendant - Medeva - suffered a significant financial blow, the case was sent to the appeal court.⁴⁵

(2) At the Court of Appeal

The Court of Appeal - comprised of Nourse L.J., Gibson L.J. and Hobhouse L.J. - unanimously reversed the ruling of Aldous J., finding the patent invalid.⁴⁶ In contrast with the High Court, this court was assisted by scientific expert advisers.⁴⁷ Hobhouse L.J. delivered the judgment of the court. and began his judgment by saying that he did not believe that the court was differing from Aldous J. on any question of the acceptance of the evidence of witnesses or primary scientific fact.⁴⁸ The court nevertheless undertook a thorough re-examination of the evidence on the question of whether the method disclosed in Biogen 1 had fully enabled the making of the invention (HBsAg).⁴⁹ The court came to the conclusion that it had not.⁵⁰ Hobhouse L.J. opined:

‘The outcome of this evidence is that whatever results the plaintiff obtained in 1978 did not amount to evidence justifying a claim to have produced a recombinant DNA molecule which enabled the expression of HBsAg in *E. coli* (or any other host).’⁵¹

Hobhouse L.J. ruled the description in the specification to be insufficient, holding that Claim 1 of the patent referred to more than one invention (product).⁵² The court held that the

⁴⁵ N. Jones ‘Biotechnology patents: a change of heart’ *E.I.P.R.* 1 (1994), 37; I. Judge, S. Cooke, M. Burdon, T. Powell, P. Gilbert and C. Hore. ‘Chiron v Organon and Biogen v Medeva: A Boost for the Biotech Industry’ *Patent World*, December 1993/January 1994, 20-26.

⁴⁶ *Biogen Inc v Medeva Plc* [1995] RPC 25. The hearings at the Court of Appeal took place from 5-28 July and on 27 October 1994; see also ‘Case Note’ [1994] 12 *E.I.P.R.* D316-D317.

⁴⁷ *Ibid.*, 68. See also R.S. Crespi, ‘Recombinant DNA patents in litigation - a comprehensive study of some EPO and UK national court decisions,’ *IIC* 28 (1997), 603, 615,

⁴⁸ *Ibid.*, 68-69. This was remarkable because, as noted recently by Lord Justice Lewison, ‘Appellate courts have been repeatedly warned, by recent cases at the highest level, not to interfere with findings of fact by trial judges, unless compelled to do so. This applies not only to findings of primary fact, but also to the evaluation of those facts and to inferences to be drawn from them’ - *Fage UK Ltd & Another v Chobani UK Ltd & Another* [2014] EWCA Civ 5 at para. 114.

⁴⁹ *Ibid.*, 70-76. See also *May & Baker Ltd. v Boots* [1950] UKHL 1

⁵⁰ *Ibid.*, 111-112.

⁵¹ *Ibid.*, 112.

⁵² See I. Karet ‘Priority and Sufficiency, Inventions and Obviousness’ *E.I.P.R.* 1 (1995), 42, 45.

determination of sufficiency depended on the interaction between the description in the specification and the claim, with reference to the state of the art at the time of the application.⁵³ - Here analysis of the specification and claim revealed that the 1978 Biogen 1 application did not adequately disclose the claimed invention(s).⁵⁴

Hobhouse L.J. further appeared to consider Prof. Murray's strategy to be an obvious one. In this regard, he stated that the decision to adopt the strategy on the part of Murray/Biogen was purely a 'matter of business judgment', a 'mere commercial decision', and that all Biogen had done was 'to pursue an identified goal by known means'.⁵⁵ Moreover, even if the decision was not 'obvious' in a general sense, Hobhouse L.J. remarked that it was analogous to placing a bet on a horse based on the odds of success - 'an unobvious decision which is not an invention'.⁵⁶

Although this type of judicial thinking surprised some commentators,⁵⁷ the fact is that Hobhouse L.J. remarked that he was inclined - and was only restrained by Medeva's counsel's lack of enthusiasm for the point - to rule that it was not an invention at all.⁵⁸ As with the first instance decision, there was a direct impact on both companies' share prices, and Biogen appealed the Court of Appeal's ruling to the House of Lords, where the saga reached its conclusion.⁵⁹

(3) The end of the affair: *Biogen v Medeva* at the House of Lords

As noted earlier, Biogen patented the recombinant method of making the antigens of a hepatitis B virus with a priority date of 22 December 1978 (the UK filing date - Biogen 1). It was accepted that it would have been obvious by 21 December 1979 (the EPO filing date for the Biogen patent). Therefore, the fundamental issue to be resolved by the House of Lords in *Biogen v Medeva* concerned the question of whether the claims of the patent, as granted by the EPO, were

⁵³ [redacted] *Biogen Inc v Medeva Plc* [1995] RPC 25. 78-83.

⁵⁴ [redacted] *Ibid.* 78-82, *Exxon / Fuel oils* OJEP 1994, 653 (T 0409/91).

⁵⁵ *Ibid.*, 114. See also J. Thomson 'The Grey Penumbra of Interpretation Surrounding the Obviousness Test for Biotech Patents' *E.I.P.R.* 1 (1996), 90, 93.

⁵⁶ *Ibid.*, 114.

⁵⁷ T. Cook 'Patents and Novel Insights' *Managing Intellectual Property*, February 1995, 3; J. M. Marshall 'Biotechnology Patents: A Further Twist' *Patent World*, February 1995, 25-28.

⁵⁸ *Biogen Inc v Medeva Plc* [1995] RPC 25. 83.

⁵⁹ N. Bannister, 'Medeva stock boosted by vaccine patent victory' *The Guardian*, 28 Oct 1994, 16.

supported by the previously filed UK patent application (Biogen 1) from which priority was claimed.⁶⁰ The decision of the House of Lords was unanimous, with Lord Hoffmann delivering the major part of the judgment, dismissing the appeal, and maintaining that the claims of the Biogen patent were not supported by the earlier Biogen 1 application.⁶¹ Although it did not give an explicit opinion on the correct approach to obviousness,⁶² the decision acquired a landmark status in patent law because it affected the ways in which patent practice considered fundamental questions such as the meaning of the ‘invention’,⁶³ and the date at which the sufficiency of a specification is to be judged.⁶⁴

Further to this, *Biogen v Medeva* ought to be viewed as a milestone case for patent scholarship because it enables the reader to reconsider many aspects of patent law. For one, it can be seen as a decision in which the institutional politics of patent law were laid bare - in particular, the case sheds light on the dissonance between the legal and scientific burdens of proof.⁶⁵ In addition, although the House of Lords emphasised the position of authority and relevance of EPO decisions, it decided to revoke the very same patent that the EPO had previously upheld, showing once again that the multi-jurisdictional nature of European patent litigation can lead to disharmonious outcomes.⁶⁶

⁶⁰ See R. Binns and B. Driscoll, ‘Biogen v. Medeva — the highest court in the UK delivers judgement’ *Drug Discovery Today*, 2(3), March 1997, 117-121; ‘Biogen and Medeva- the Ultimate Ruling’ *Intellectual Property Newsletter*, 19 (12), December 1996, 1-3; ‘Biotechnology Patent News’ *CIPA Journal*, November 1996, 883.

⁶¹ D. Brahams, ‘Biogen loses “landmark” vaccine patent claim’ *The Lancet*, 16 November 1996, 346(9038), 1375. See also ‘Genetic engineering patent claim was too broad’ *The Times*, 1 November 1996, 34; ‘Medeva survives Hepagene challenge’ *The Times*, 1 November 1996, 34; R. Colbey ‘Patently Sensible’ *The Guardian*, 14 Nov 1996, B4.

⁶² See I. Karet, ‘Delivering the Goods? The House of Lords’ Decision in *Biogen v Medeva*,’ *E.I.P.R.* 1 (1997), 21; 23; see also A. White, *C.I.P.A. Guide to the Patents Act* (London: Sweet & Maxwell. 2001), 98.

⁶³ The Hon Mr Justice Colin Birss, Andrew Waugh, QC, Tom Mitcheson, QC, Douglas Campbell, QC, Justin Turner, QC, Tom Hinchliffe, QC, *Terrell on the Law of Patents* (18th edition: London: Sweet & Maxwell, 2017), including at Chapter 2, section 2: ‘What is an Invention?’ (last accessed via Westlaw, 13 December 2016)..

⁶⁴ *Ibid.*, at Chapter 13, section 3: ‘Biogen Insufficiency’ (last accessed via Westlaw, 13 December 2016).

⁶⁵ ‘Case review: Biogen v Medeva, 20 years on,’ Lifesciences Intellectual Property Review (2015) - <http://www.lifesciencesipreview.com/article/case-review-biogen-v-medeva-20-years-on> - see also A. Pottage and B. Sherman, *Figures of Invention: A History of Modern Patent Law* (New York: Oxford University Press, 2010), 1-29.

⁶⁶ For a commentary of these issues, see I. Karet, ‘English Courts and the EPO: What Next?’, *Intellectual Property Quarterly*.2, (1997), 244-248.

D) READING LORD HOFFMAN'S JUDGMENT

(1) Describing the Patent

One of the remarkable aspects of the judgment is the clarity of Lord Hoffmann's prose. is.⁶⁷ Beginning in the first paragraph with a very short - but well written - passage on 'Genetic Engineering', Lord Hoffmann's neat and lucid description guides the reader through what DNA recombination is, and also covers how the subject of the patented invention - the HBV vaccine - works:

"The code is embodied in a molecule of deoxyribonucleic acid ("DNA") which directs the cell to make the proteins which the organism requires. Genetic engineering or 'recombinant DNA technology' consists of altering the DNA of a suitable cell so that it produces a protein which in nature occurs in another organism. In this way it has been possible to manufacture products of great medical importance which could not have been made by orthodox chemical synthesis."⁶⁸

Going on to describe 'The Patent in suit' in paragraph 2 he stated:

'The principal claim of the patent in suit is for an artificially constructed molecule of DNA carrying a genetic code which, when introduced into a suitable host cell, will cause that cell to make antigens of the virus hepatitis B ('HBV').'⁶⁹

By comparison, the first time Simon Thorley Q.C. - an esteemed patent advocate, acting for the plaintiff (appellant) - described the invention in the list of his arguments (given at the beginning of the judgment as reported in the Reports of Patent, Design and Trade Mark Cases (RPC)) it comes across as over-technical:

⁶⁷ Just a few months after the decision, some scholars already began using the term 'landmark' to describe the case - see M. Kern 'Patentability of Biotechnological Inventions in the United Kingdom: The House of Lords Charts the Course', *IIC* 29 (1998), 247-282, 248; D. Sternfeld 'Biogen loses out in landmark UK biotech case' *Managing Intellectual Property*, February 1997, 32-35. By contrast, see I.C. Baillie, 'Biogen - Is it Possible to be Worse Than it Looks?' *CIPA Journal*, February 1997, 146-147.

⁶⁸ *Biogen Inc v Medeva plc* [1997] RPC 1, 36.

⁶⁹ *Ibid.*, 32.

Lord Hoffmann further explained that these antigens can be used to test whether a patient is suffering from the virus - and, crucially, to make a vaccine. On this, it is worth remarking that as a non-scientist it is very difficult from reading the Court of Appeal judgment⁷⁰ to fully understand what exactly the HBV does - or how it works - yet Lord Hoffmann described this in language suitable to the intricacy of the case and at the same time comprehensible to the non-scientist reader.⁷¹ The achievement is all the more impressive given that Lord Hoffmann was working with the obscurantist, scientific-legal language of patent law – a language that reflects the complexity that inevitably results from the coming together of the (perhaps incompatible) universes of law and science.⁷²

(2) The issue of obviousness

Beginning his assessment of inventive step, Lord Hoffmann emphasised that doing something first is not the same as being inventive, especially in a fast-developing area of science.⁷³

In terms of what Prof. Murray had actually done, Lord Hoffmann explained that he had purified DNA from Dane particles and had cut the DNA into fragments with restriction enzymes, with

⁷⁰ *Biogen Inc v Medeva Plc* [1995] RPC 25, 68-72.

⁷¹ A similar view has been expressed by Alan White - 'Lord Hoffmann prefaces his judgment in the House of Lords with a very clear exposition of the fundamentals of biotechnology and genetic engineering. His judgment is worth reading solely as a primer to this arcana area of modern science' in A.W. White 'House of Lords Disapproves of Free Beer' *CIPA Journal*, December 1996, 1020-1028, 1023.

⁷² A. Pottage and B. Sherman, *Figures of Invention: A History of Modern Patent Law* (New York: Oxford University Press, 2010), 181-206.

⁷³ *Biogen Inc v Medeva plc* [1997] RPC 1, 33-34.

the aim of producing large fragments containing the relevant gene (which would make it easier to experiment on the fragments later on).⁷⁴ Lord Hoffmann went on to say:

'By the time of the EPO patent application, the claims make it clear that they cover not only the polypeptide but also fragments which exhibit the relevant properties. **But Biogen 1 does not make anything of this point.**'⁷⁵ (emphasis added)

Early on, and without yet exploring the issue fully, Lord Hoffmann was already signalling that he considered the Biogen 1 application to be somewhat deficient - in fact, insufficient.⁷⁶ However, before examining this further he turned to the specifics of the Biogen patent's claims, noting that what was claimed was 'a product, a molecule identified partly by the way in which it has been made ("recombinant DNA") and partly by what it does'.⁷⁷ In this respect the patent claimed a broad monopoly over 'any recombinant DNA molecule which expressed the genes of any HBV antigen in any host cell' and for 'any method of making a DNA molecule which would achieve the necessary expression' (emphasis added).⁷⁸

As we shall see, the claim to *any* method would prove to be of great significance to the question of whether the claims properly supported the invention. But before addressing that question, Lord Hoffmann put forward a number of important points about the interpretation of 'invention' under s.1(1) of the Patents Act 1977. Regarding the question of 'what is an invention?' as separate from the four key requirements of patentability - which had been a crucial issue in *Genentech*⁷⁹ - he stated that the four requirements probably covered every possible meaning of invention and that the separate question should not be a primary focus, and should only be contemplated if analysis of the four requirements has left some ambiguity as to the nature of the

⁷⁴ *Ibid.*, 39.

⁷⁵ *Ibid.*, 39.

⁷⁶ *Ibid.*, 39.

⁷⁷ *Ibid.*, 40.

⁷⁸ *Ibid.*, 40.

⁷⁹ *Genentech Inc.'s Patent* [1989] RPC 147.

invention at hand (leaving open the possibility, however remote, that there could be issues of 'invention' separate to the four requirements).⁸⁰

Thus, one considerable virtue of Lord Hoffmann's ruling is the removal of the awkward requirement from *Genentech* that a judge had to consider whether the patent covered an 'invention' before he/she analysed the various categories of novelty, inventive step, industrial application etc.⁸¹

Having dealt with the somewhat pedantic question of 'what is an invention?' as removed from analysis of the key requirements of an invention, Lord Hoffmann moved on to explain his consideration of one of the critical issues at hand: whether Prof. Murray had performed an inventive step.⁸² He expressed his dissatisfaction with the conclusions reached by Aldous J. at the Patents Court, arguing that Aldous J. had taken an over-broad approach to defining the inventive concept as the mere idea of making HBV antigens by recombinant DNA technology.⁸³

' Rather than putting it so broadly, Lord Hoffmann remarked that the inventive concept in the present case ought to be described as 'the notion that Professor Murray's method of achieving the goal - creating large fragments of genomic DNA, ligating them to pBR322 and introducing the hybrid molecule into E. coli - would work'.⁸⁴

In other words, it was the operative part of the invention that Aldous J. had missed. Yet, although he was not satisfied by Aldous J.'s assessment, it is notable that Lord Hoffmann also

⁸⁰ *Biogen Inc v Medeva plc* [1997] RPC 1, 41.

⁸¹ *Genentech Inc.'s Patent* [1989] RPC 147, 264.

⁸² *Biogen Inc v Medeva plc* [1997] RPC 1, 42-43.

⁸³ *Ibid.*, 43.

⁸⁴ *Ibid.*, 43.

heavily criticised elements of the approach taken by the Court of Appeal - specifically the appeal court's reference to the fact that Biogen had made an initial decision, based on commercial concerns, to 'pursue an identified goal by known means'.⁸⁵ Nor did he find the 'placing a bet' analogy useful.⁸⁶ For Lord Hoffmann, the company's commercial decision-making process was simply not relevant to the question of patentability:

'The fact that a given experimental strategy was adopted for commercial reasons, because the anticipated rewards seemed to justify the necessary expenditure, is no reason why that strategy should not involve an inventive step. An inventor need not pursue his experiments untouched by thoughts of gain. Most patents are the result of research programmes undertaken on the basis of hard-headed cost-benefit analysis'.⁸⁷

However, he was in general agreement with the approach taken by Hobhouse L.J. to the patentability question – that the strategy of Prof. Murray was to pursue an identified goal by known means even though he deepened the analysis in his characteristic style:

'A proper statement of the inventive concept needs to include some express or implied reference to the problem which it required invention to overcome. The reasons why the expert witnesses thought it was not obvious to try the expression of genomic HBV DNA in *E. coli* were for the most part concerned with the uncertainties, in the absence of sequence information, about the presence of the HBV antigen genes in the Dane particle DNA, the perceived difficulties of expressing genomic eukaryotic DNA in a prokaryotic host, and, specifically, the problem of introns. It seems to me, therefore, that a more accurate way of stating the inventive concept as it appeared to Aldous J. is to say that it was the idea of trying to express unsequenced eukaryotic DNA in a prokaryotic host'.⁸⁸

Thus, Lord Hoffmann not only identified the bare bones of the inventive concept - as it had appeared to Aldous J. - he also fleshed it out, describing its operative elements with typical

⁸⁵ *Ibid.*, 44.

⁸⁶ *Ibid.*, 44.

⁸⁷ *Ibid.*

⁸⁸ *Ibid.*, 44-45.

clarity, and making reference to the usefulness of the scientific expert witness testimony.⁸⁹ Indeed, Lord Hoffmann was satisfied with the assumption that what Prof. Murray did was not obvious, and was, therefore, inventive. In this, although he neatly sidestepped both prior judgments, he ended up much closer to Aldous J.'s view on obviousness than that of Hobhouse L.J.

Lord Hoffmann summed up his view by saying that the patent's inventiveness was 'of a very unusual kind' because it involved trying something 'which a man less skilled in the art might have regarded as obvious, but which the expert would have thought so beset by obstacles as not to be worth trying'.⁹⁰

What makes Lord Hoffman's judgment a landmark on the point of inventiveness is therefore twofold: first, we know from the judgment that analysing the four patentability requirements will comprehensively deal with the question of 'what is an invention?' in the vast majority of cases, and there is no need for a separate *Genentech*-style assessment; and second, Lord Hoffmann provided detailed guidance to patent assessors and judges regarding how they should apply the *Windsurfing* test to biotechnological inventions, emphasising the importance of expert testimony regarding the person skilled in the art.⁹¹

(3) Support and 'Biogen Insufficiency'

Key to Lord Hoffmann's ultimate decision on the patent's validity was his consideration of the question of whether the Biogen 1 application (from December 1978) supported the invention claimed in the Biogen patent (filed December 1979). On this point Lord Hoffman emphasised that 'the specification must enable the invention to be performed to the full extent of the

⁸⁹ *Ibid.*, 44-45.

⁹⁰ *Ibid.* 46.

⁹¹ *Ibid.*, 43-48. *Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd* [1985] RPC 59 and *Genentech Inc.'s Patent* [1989] RPC 147.

monopoly claimed'.⁹² Lord Hoffmann further opined that in a case where the claims include a number of products, the patent must enable the invention 'to be performed in respect of each of them'.⁹³ Crucial here was analysing whether (i) the patent described a product which has a beneficial effect, but nonetheless did not demonstrate a common principle corresponding to other products which will share the beneficial effects (products of the same class), or (ii) whether the patent disclosed a 'beneficial property which is common to the class' of products.⁹⁴ In the former case, the patentee would only be entitled to a patent for the single described product – but with the latter the patentee could claim a monopoly on all products of the class.⁹⁵

Here Lord Hoffmann also explained that a patent be over-broad if it claims 'every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which make no use of the invention'.⁹⁶

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Finally, he examined the Biogen 1 on the question of support:

‘As I have said, I accept the judge's findings that the method was shown to be capable of making both antigens and I am willing to accept that it would work in any otherwise suitable host cell. **Does this contribution justify a claim to a monopoly of any recombinant method of making the antigens? In my view it does not. The claimed invention is too broad. Its excessive breadth is due, not to the inability of the teaching to produce all the promised results, but to the fact that the same results could be produced by different means.**'⁹⁷
(emphasis added)

⁹² *Ibid.*, 48. See also *Asahi Kasei Kogyo KK's Application* [1991] RPC 485.

⁹³ *Ibid.*, 49.

⁹⁴ *Ibid.*, 49.

⁹⁵ *Ibid.*, 49. See also *May & Baker Ltd v Boots Pure Drug Co Ltd* (1950) 67 RPC 23.

⁹⁶ *Ibid.*, 51.

⁹⁷ *Ibid.*, 52.

Here Lord Hoffmann referred to the fact that, although Prof. Murray had done something brilliant 'in cutting through the uncertainties' of the day to achieve a positive result, he did not actually 'establish any new principle which his successors had to follow if they were to achieve the same results'.⁹⁸ Specifically, despite the fact that Prof. Murray had in the patent, described a way of choosing restriction enzymes that would cleave the DNA of the Dane particle into large fragments, once the DNA had been sequenced there was no need to choose to follow Prof. Murray's method – scientists could instead choose 'those which digested the sites closest to the relevant gene or the part of the gene which expressed an antigenic fragment of the polypeptide'.⁹⁹

As Lord Hoffmann put it:

"The metaphor used by one of the witnesses was that before the genome had been sequenced everyone was working in the dark. Professor Murray invented a way of working with the genome in the dark. But he did not switch on the light and once the light was on his method was no longer needed."¹⁰⁰

Lord Hoffmann went on to express his concerns about awarding too wide a monopoly to a single inventor, emphasising that although Prof. Murray had led the way, other researchers could follow what he had done by different routes – and he did not consider that simply leading the way was 'enough to justify a monopoly of the whole field'.¹⁰¹ On this, Lord Hoffmann further remarked:

"The technical contribution made in such cases deserves to be recognised. **But care is needed not to stifle further research and healthy competition by allowing the first person who has found a way of achieving an obviously desirable goal to monopolise every other way of doing so**."¹⁰² (emphasis added)

⁹⁸ *Ibid.*, 52.

⁹⁹ *Ibid.*, 52.

¹⁰⁰ *Ibid.*, 52.

¹⁰¹ *Ibid.*, 52

¹⁰² *Ibid.*

Therefore, Lord Hoffmann held that the Biogen 1 application did not support the invention as claimed in the later filed European Patent, and for this reason it could not claim the priority date of Biogen 1. Moreover, because it had already been conceded that the invention was obvious when the Biogen patent was filed at the EPO in 1979, the patent was deemed to be invalid.¹⁰³

While Lord Hoffmann accepted that the patent, lacking the support of the earlier priority date, was obvious, and thus invalid, he considered that his reasoning in making this decision meant that it was necessary to discuss what would become known as the landmark principle of (Biogen) insufficiency:

'In other words, the application may not add new matter to make an insufficient application sufficient. It seems to me in accordance with this scheme that an insufficient application should also not become sufficient because of general developments in the state of the art after the filing date'.¹⁰⁴

‘

In the view of Lord Hoffman, Claim 1 of the Biogen patent (a product) generalised the teachings of the Biogen 1 application.¹⁰⁵ It did so because the Biogen 1 application referred to a *particular* form of a product.; yet, Claim 1 of the patent referred to *any* form of the product. In addition, Lord Hoffmann held that the method which was used was also generalised - in the Biogen 1 application, the particular product was made from a particular process. However, the patent's claims as granted covered *any* method of making *any* form of the product.. For this reason Lord Hoffmann ruled that the technical contribution disclosed in the Biogen 1 application did not correspond to the broad monopoly sought by Claim 1 of the Biogen patent i.e. the Biogen patent's claims lacked sufficient support from the Biogen 1 application.¹⁰⁶ Thus the claim was

¹⁰³ *Ibid.*, 52-53.

¹⁰⁴ *Ibid.*, 54.

¹⁰⁵ *Ibid.*, 54.

¹⁰⁶ *Ibid.*, 53-54.

held to be not fully enabled by the specification - the only thing that could be validly claimed was the production of the antigen by the particular means disclosed. The overall principle of *Biogen* insufficiency can therefore be described as follows: the patent's claims must be supported by the description of the invention - as contained in the patent specification - or else the patent will be held invalid for insufficiency.¹⁰⁷

As with the earlier decisions, the House of Lords' ruling had an immediate impact on the companies' share prices, with the value of Biogen falling by just over 4% and Medeva's showing a small rise.¹⁰⁸

(4) Reconciling Lord Hoffmann's view with the EPO's decisions

Having declared the patent invalid, Lord Hoffman had to explain how he could reconcile this decision with the EPO Technical Board's earlier decision that the patent was, in fact, valid.¹⁰⁹ Lord Hoffmann did this in a particularly elegant way, noting that the decision of the EPO in that decision did not actually proceed on any principle different from those he endeavoured to apply.¹¹⁰ He noted that, like him, the Technical Board had decided that the invention in Biogen 1 was not obvious – however, the Technical Board had held that the disclosure in Biogen 1 corresponded to the same invention claimed in the patent, and that the patent's disclosure was sufficient to 'enable the invention to be performed to the full extent of the claims'.¹¹¹ Here, Lord Hoffmann's view diverged from that of the Technical Board – according to Lord Hoffmann the Technical Board had failed to assess 'whether the claims were too broad because expression could also be achieved without the use of the teaching which it contained'.¹¹²

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Ibid. 54.

¹⁰⁸ 'Medeva Wins in Court Battle With Biogen' *The New York Times*, 1 November, 1996.

¹⁰⁹ See also *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76.

¹¹⁰ The Court of Appeal decision had been criticised for not engaging with EPO case law - see B.C. Reid, 'Biogen in the EPO: The Advantage of Scientific Understanding,' *E.I.P.R.* 2 (1995), 98 and C. Colston, 'Genetic Engineering – Failure to Invent? The House of Lords' decision in *Biogen Inc v. Medeva plc*,' *Intellectual Property Quarterly* (1997), 521.

¹¹¹ *Biogen Inc v Medeva plc* [1997] RPC 1, 53.

¹¹² *Ibid.*, 53.

In making this argument Lord Hoffmann explicitly referred to two key EPO decisions in *Genentech*¹¹³ and *Exxon*.¹¹⁴

'But the principle upon which I have come to the conclusion that on this ground the patent is invalid is also, as I have said, clearly stated in decisions of the EPO such as *Genentech I* and *Exxon*. I would not therefore regard the outcome of this appeal as suggesting any divergence between the jurisprudence of this court and that of the EPO'.¹¹⁵

Rather than ignoring the EPO Technical Board, as the Court of Appeal had done, Lord Hoffmann cleverly integrated its reasoning in the earlier cases of *Genentech* and *Exxon* in order to come to a conclusion that differed from the EPO's *Biogen* decision, but which nonetheless fulfilled the expectation that national courts should take into account EPO decisions when national litigation takes place over a European Patent.¹¹⁶

(5) **Biogen Insufficiency Reconsidered**

Late in his judicial career, Lord Hoffmann was given the opportunity - more than a decade after *Biogen* - to reconsider his earlier ruling. From the bench of the Court of Appeal, Lord Hoffman gave the judgment in *Lundbeck v Generics (UK) Ltd*.¹¹⁷ Here, he severely narrowed the scope of his own doctrine of *Biogen* insufficiency - effectively distinguishing it on its own facts.

In *Biogen v Medeva*, Lord Hoffman had ruled that it was insufficient for a patentee to merely disclose one way of performing the invention. In other words, if it was 'possible to envisage other ways of achieving [its result] which make no use of the invention' the patent would be invalid for being 'wide or speculative'.¹¹⁸ Overall, his view had been that the patent monopoly must correspond exactly with the claims of the invention. In this, Lord Hoffmann emphasised the need to allow subsequent research and to ensure competition between scientific bodies.

¹¹³ *GENENTECH I/Polypeptide Expression T292/85* [1989] EPOR 1.

¹¹⁴ *EXXON/Fuel Oils T409/01* [1994] EPOR 149.

¹¹⁵ *Biogen Inc v Medeva plc* [1997] RPC 1, 53.

¹¹⁶ *Ibid.*, 53.

¹¹⁷ *H Lundbeck A/S v Generics (UK) Ltd*. [2008] EWCA Civ 311, [2008] RPC 19 as affirmed by the House of Lords in *Generics (UK) Ltd v H Lundbeck A/S* [2009] UKHL 12, [2009] 2 All ER 955.

¹¹⁸ *Biogen v Medeva* [1997] RPC 1, 22.

What led to criticism of the judgment - and eventually to Lord Hoffmann's own decision in *Generics v Lundbeck* to drastically reduce the scope of Biogen insufficiency - was a realisation that the UK Patents Act, following the EPC, requires protecting patents for products 'as such'.¹¹⁹ In this respect, two things became increasingly clear in the aftermath of *Biogen*: (i) in the case of a product patent it is inevitable that the monopoly conferred will include *all* ways of making and using the product - otherwise it would not truly be a product patent;¹²⁰ and (ii) when preparing, writing and filing the patent application, the teaching disclosed in the claims of the patent cannot conceivably cover every single way of making/using the product.

Thus, a clear conflict was visible between what the law said should be protectable, and what Lord Hoffmann in *Biogen v Medeva* considered ought to be covered by the scope of the patent's claims. In *Generics v Lundbeck*, Lord Hoffmann acknowledged this and recast his earlier ruling in light of this:

'Parliament has chosen to allow product claims and the jurisprudence of the EPO, which we have always regarded as carrying great weight, shows that such claims can be made in the latter case as well. It is too late to have regrets about the breadth of the monopoly which such claims confer'.¹²¹

Despite it being 'too late', it is clear from the above that even as when reconsidering his own earlier ruling, Lord Hoffmann could not quite shrug off a lingering regret about the legislative breadth of the patent monopoly and its consequent effects on competition.

D. THE LEGACY OF THE CASE: THE PARTICIPANTS' PERSPECTIVE

In February 2015 several of those involved in the initial Patents Court trial in *Biogen v Medeva* participated in a discussion panel in central London organised by a leading intellectual property

¹¹⁹ Patents Act 1977 s 60.

¹²⁰ J. Pila, 'Lord Hoffmann and Purposive Interpretation in Intellectual Property Law,' *Oxford Legal Studies Research Paper* No 10/2015, 1, 1-23 - also available in P.S. Davies and J. Pila (eds), *The Jurisprudence of Lord Hoffmann* (Oxford: Hart Publishing, 2015). See also S. Thambisetty, 'The Evolution of Sufficiency in Common Law' *LSE Law, Society and Economy Working Paper* No. 6/2013.

¹²¹ *H Lundbeck A/S v Generics (UK) Ltd.* [2008] RPC 19, 437, 450.

solicitors firm (Rouse).¹²² Although the spokeswoman for Medeva and the chief-executive of Biogen had already expressed their views immediately after the decision was handed over by the Lords,¹²³ it is nevertheless interesting to consider how the participants viewed the saga of the case almost twenty years after it was concluded, particularly since several fascinating points were raised that are not contained within the public records of the case.¹²⁴

One of these aspects relates to the cultural gap between US lawyers and British barristers. Andrew Waugh Q.C., who had participated as a junior counsel for Biogen, recalled that during the initial Patents Court trial - where Hugh Laddie Q.C. (later to become Sir Hugh Laddie) had taken the lead in arguing the case for Biogen - the tension level between Biogen's different sets of transatlantic lawyers was often very high. For him, the most traumatic incident occurred one morning just before the trial was about to recommence, when a 'momentous row' erupted outside the courtroom between Laddie and Jim Haley, a US attorney working for Biogen, concerning the sharing of cross-examination notes.¹²⁵ Suffice to say, Waugh felt the public nature of the argument was damaging to morale on the Biogen side and gave a boost to the other side (Medeva).

Another aspect that nobody who participated in the trial could possibly forget was the difficulties involved in analysing and weighing up the value of complex scientific evidence in the legal context : specifically, was a hepatitis B surface antigen expressed by doing what the patent described?¹²⁶ In this regard, Prof. Jeffrey Almond – who was then working as a Professor of Microbiology at the University of Reading who testified for Medeva - had cast doubt on the reliability of the autoradiographs that Biogen had presented as evidence (demonstrating the expression of the hepatitis B surface antigen). Here, Hugh Laddie Q.C. for Biogen had focused the court's attention on a number of highlighted dark areas in the autoradiographs which apparently showed where the radioactive label had been bound to the apparently expressed

¹²² 'Case review: Biogen v Medeva, 20 years on,' Lifesciences Intellectual Property Review (2015) - <http://www.lifesciencesipreview.com/article/case-review-biogen-v-medeva-20-years-on>

¹²³ M. Grimond, 'Medeva wins court case' *The Independent*, 1 November 1996,26;

¹²⁴ 'Case review: Biogen v Medeva, 20 years on,' Lifesciences Intellectual Property Review (2015) - <http://www.lifesciencesipreview.com/article/case-review-biogen-v-medeva-20-years-on>

¹²⁵ *Ibid.*

¹²⁶ Biogen relied on the testimony of Professor Sir Kenneth Murray, Professor Burrell, Professor Villa-Komaroff, Dr. Alan Kingsman. Medeva called Professor Jeffrey Almond, Dr. Cozens and Mr. Ronald Holmes as witnesses.

surface antigen. Yet, to the naked eye these dark areas looked like mere black smudges. Thus during Prof. Almond's testimony, Peter Prescott Q.C. for Medeva had belittled the autoradiographs as mere 'smudgegrams'.¹²⁷

Prof. Almond also recalled that he had found assessing this surface antigen expression question as an expert at a legal trial a strange experience: as a scientist, he had been trained to be wary of making conclusions based on partial evidence; yet at the trial his duty was to give his conclusive analysis - that he was unconvinced that the surface antigen expression had occurred - without the benefit of pressing for further scientific tests.¹²⁸ Ultimately, Prof. Almond came away from the trial with a profound understanding of how dissimilar the fields of law and science are from a methodological point of view, with each field possessing its own rational processes and own standards of acceptable proof.¹²⁹ Of course, Prof. Almond is certainly not the first person to have made this point; in fact, as noted earlier, it is this dissonance makes patent law a particularly fascinating area, and a hugely challenging one.¹³⁰

Despite the lack of harmony between the fields of law and science, the Biogen case makes clear just how important expert testimony is in patent litigation – put simply, the only way the Patents Court, Court of Appeal and House of Lords could make sense of the legal issues was to rely on the views of scientific experts about the art of biotechnology.¹³¹

Furthermore, despite being an outsider to the law, Prof. Almond remembered how quickly he had become gripped by the drama of the courtroom. In particular, he came to realise that in the

¹²⁷Here, it is worth noting that Peter Prescott Q.C. and Prof. Almond were both involved in the Patents Court case of *Chiron Corp. v Organon Teknika Ltd. (No. 3)* [1994] FSR 202 which was heard concurrently with *Biogen* by Aldous J. Moreover, Dr Brenner, one of the advisers of the Court of Appeal in *Biogen*, had also sat with Aldous J. during the *Chiron* case. -

¹²⁸ 'Case review: Biogen v Medeva, 20 years on,' *Lifesciences Intellectual Property Review* (2015) - <http://www.lifesciencesipreview.com/article/case-review-biogen-v-medeva-20-years-on>

¹²⁹ A. Pottage and B. Sherman, *Figures of Invention: A History of Modern Patent Law* (New York: Oxford University Press, 2010), 1-29 and 181-206.

¹³⁰ *Ibid.*, 9-10 and 181-206.

¹³¹ For some interesting references of the expert's role in patent law, see R.E. Hofer, 'Experts in Patent Cases' *Litigation* 8 (Winter 1982), 44-46, 61-62 (US) and L. Heald 'The function of the expert witness in litigation' (Lectures, monographs and reports / The Royal Institute of Chemistry, 1949).

litigation arena even a casual remark exchanged between experts on opposing sides might have serious consequences.¹³² Before testifying, Prof. Alan Kingsman - the main scientific expert for Biogen, who later went on to found his own biotech company, Oxford BioMedica - had remarked in a relaxed conversation with his erstwhile professional acquaintance and fellow expert, Prof Almond (perhaps naively, since Almond was due to testify for Medeva), that much of his scientific report had been co-authored by Biogen's legal team.¹³³ Almond reported this comment back to his own legal team (Medeva) - and at the cross-examination Peter Prescott Q.C. did not hesitate to use it as a weapon, quietly but stealthily putting Kingsman 'under the cosh' by asking whether a key passage of the report was Kingsman's own testimony or 'something a lawyer has written for you'.¹³⁴ A flustered Kingsman had immediately shot a cold dagger look across at Almond - one Almond has never been able to put out of his mind.¹³⁵

Interestingly, later in the trial, when it was Prof. Almond's turn to be cross-examined, he faced his own difficult moment on the stand: Hugh Laddie Q.C. unexpectedly dug out Almond's CV from a bundle of papers and asked him why, since he claimed to be an expert in the DNA field in the late 1970s, his own CV showed that he had attended an entry-level course on the subject during the period that Prof. Murray was conducting the experiments that led to the 1978 Biogen 1 application.¹³⁶ Prof. Almond noted that the 'CV ambush' experience, like Kingsman's cold dagger look, is something he has never forgotten.¹³⁷

Finally, Andrew Waugh Q.C. made a significant retrospective point about the law: in *Biogen* the initial trial verdict was overturned on appeal - a situation identical to all of the subsequent landmark biotechnology cases (*Kirin-Amgen v TKT*,¹³⁸ *Conor v Angiotech*,¹³⁹ *Generics v Lundbeck*,¹⁴⁰

¹³² *Ibid.*

¹³³ Prof. Kingsman would found Oxford BioMedica in 1995 – a full description of his achievements is available here http://www.sbs.ox.ac.uk/sites/default/files/Entrepreneurship_Centre/Docs/alan-kingsman.pdf

¹³⁴ Case review: *Biogen v Medeva*, 20 years on,' *Lifesciences Intellectual Property Review* (2015) - <http://www.lifesciencesipreview.com/article/case-review-biogen-v-medeva-20-years-on>

¹³⁵ ' *Ibid.*

¹³⁶ *Ibid.*

¹³⁷ *Ibid.*

¹³⁸ *Kirin-Amgen v TKT* [2004] UKHL 46, [2005] 1 All ER 667.

¹³⁹ *Conor v Angiotech* [2008] RPC 28, [2008] UKHL 49.

and *Human Genome Sciences v Eli Lilly*¹⁴¹) breaking the initial pattern established by *Genentech*,¹⁴² where the initial trial verdict was upheld. As a result, Waugh quipped that in complex biotech cases he had learned a valuable lesson:

'Where the law is new and the facts are difficult, lose at first instance: the prospects of winning on appeal are much better'.¹⁴³

This comment reflects two central concerns that illustrate why *Biogen* is a milestone case: first, accommodating biotechnological inventions within patent law required something 'new' conceptually (in terms of expanding the notion of the 'invention' to allow organisms to be seen as 'manufactured', and thus, 'invented'); and second, it required a reliance on technology and scientific expertise (for assessing what the 'difficult' facts were concerning the new 'intellectual possessions').¹⁴⁴ That all the key subsequent UK biotech patent cases have been overturned on appeal may demonstrate that the participants and arbiters of the legal process – lawyers and judges – require time, and perhaps the benefit of distance from the initial trial, to fully process the profound changes that happen when a new field of science comes to law. *Biogen v Medeva* is certainly one case that reflects this, and it ought to be seen as a true landmark.

E. CONCLUSION

Even 20 years on, reading though the *Biogen v Medeva* judgments - at the Patents Court, Court of Appeal and House of Lords levels - is a rich experience for the patent lawyer. In particular, Lord Hoffmann's judgment in the House of Lords guides us vividly through several of the key questions at the heart of patent law: what does obviousness mean? What happens when

¹⁴⁰ *Generics (UK) Ltd v H Lundbeck A/S* [2009] UKHL 12, [2009] 2 All ER 955.

¹⁴¹ *Human Genome Sciences Inc v Eli Lilly & Co.* [2011] UKSC 51, [2012] RPC 6.

¹⁴² *Genentech Inc.'s Patent* [1989] RPC 147.

¹⁴³ 'Case review: *Biogen v Medeva*, 20 years on,' *Lifesciences Intellectual Property Review* (2015) - <http://www.lifesciencesipreview.com/article/case-review-biogen-v-medeva-20-years-on>

¹⁴⁴ A. Pottage and B. Sherman, *Figures of Invention: A History of Modern Patent Law* (New York: Oxford University Press, 2010), 181-193.

avowedly commercial strategies lead to scientific inventiveness? Who is the person skilled in the art? What does sufficiency of disclosure mean? How can UK litigation and EPO rulings be reconciled? What are the consequences of patent monopolies on scientific competition? How should patent law respond to new forms of scientific innovation? These are recurring questions in patent jurisprudence, and they are unlikely to ever be solved definitively; but there is little doubt that in *Biogen* Lord Hoffmann gives as lucid an explanation of them as any ever set down in law, rivalling the US Supreme Court decision of *Diamond v Chakrabarty*.¹⁴⁵

Moreover, tracing the legacy of Lord Hoffmann's statement on 'Biogen insufficiency' - from the earlier decision in *Genentech* to the subsequent case of *Generics v Lundbeck* - gives the scholar of patent law much food for thought, particularly concerning the political and legislative context that sometimes leads judges to revise their earlier opinions.¹⁴⁶ Indeed, *Biogen* reminds us of the sheer complexity of biotechnology cases as an area where the law has often had to grapple with apparently unprecedented leaps in scientific knowledge, and where appeals and reversals are not only not uncommon: they are the norm.¹⁴⁷

Ultimately, the analysis given over the course of this chapter shows that this landmark case still has much to teach us, not least about how dissimilar the areas of law and science are from a methodological point of view, with each field possessing its own rational processes and own standards of acceptable proof.¹⁴⁸ On this, one can say that *Biogen v Medeva* provides firm evidence – to scholars of science and law alike - that it is precisely this dissonance that makes patent law both a fascinating area and a hugely challenging one. The complexity involved in the analysis of patent law in biotech cases may demonstrate that the participants and arbiters of the legal process – lawyers and judges – require time, and perhaps the benefit of distance from the initial trial, to fully

¹⁴⁵ ***Diamond v Chakrabarty* 447 U.S. 303 (1980) .**

¹⁴⁶ *Genentech Inc.'s Patent* [1989] RPC 147, 272. *H Lundbeck A/S v Generics (UK) Ltd.* [2008] EWCA Civ 311, [2008] RPC 19 as affirmed by the House of Lords in [2009] UKHL 12, [2009] 2 All ER 955.

¹⁴⁷ *Kirin-Amgen v TKT* [2004] UKHL 46, [2005] 1 All ER 667; *Conor v Angiotech* [2008] RPC 28, [2008] UKHL 49; *Generics (UK) Ltd v H Lundbeck A/S* [2009] UKHL 12, [2009] 2 All ER 955; and *Human Genome Sciences Inc v Eli Lilly & Co.* [2011] UKSC 51, [2012] RPC 6.

¹⁴⁸ A. Pottage and B. Sherman, *Figures of Invention: A History of Modern Patent Law* (New York: Oxford University Press, 2010), 181-193.

process the profound changes that happen when a new field of science comes to law, and demands adjudication.¹⁴⁹

¹⁴⁹ 'Case review: *Biogen v Medeva*, 20 years on,' *Lifesciences Intellectual Property Review* (2015) - <http://www.lifesciencesipreview.com/article/case-review-biogen-v-medeva-20-years-on>