DOES A REQUIREMENT THAT THE DESCRIPTION FULLY SUPPORTS A PRODUCT CLAIM RAISE AUSTRALIA FROM 'MECHANISTIC AND IMPOVERISHED' PATENT RULES?

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I INTRODUCTION

The *Intellectual Property (Raising the Bar) Act 2012* (Cth) (the 'Raising the Bar reforms') signals a Parliamentary intention to reform in Australian patent law two related grounds of validity; the fair basis of claims in a written description and the adequacy of the written description of the invention as claimed.[1] The reform is variously described in government papers as both raising the standard of validity and harmonising Australian patent validity grounds with their UK counterparts. In this it implies a clear dissatisfaction with the approach taken by the Australian High Court in the two leading cases on point concerning product claims, and a commensurate attraction to a principle in UK law known as *Biogen* sufficiency.[2]

Fair basis and adequacy of description, and the relationship between them, taken together is quite a difficult area of patent law. In part this is because the concepts underpinning the law are intrinsically complex. Also, this law has traditionally served distinct roles in the patents system: (i) facilitating the proper operation of the provisional application, when used, in preserving a priority date earlier than its related complete application; (ii) facilitating the proper operation of priority date rules under the *Paris Convention*,[3] when relied upon; and (iii) as an internal ground of validity for a complete application or granted patent in all cases.[4] Earlier scholarship of McBratney has explored in some depth the history underpinning what were distinct legal approaches in these three settings.[5] Rightly or wrongly, the law in each three cases has become a largely harmonised set of principles and this essay does not question that long-standing development, which can be traced

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1 The *Intellectual Property (Raising the Bar) Act 2012* (Cth) received Royal Assent on 15 April 2012, and the particular sufficiency and fair basis reforms which are the subject of this essay will come into effect on 15 April 2013.

2 Those Australian cases are *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1 ('*Kimberly-Clark*') and *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274 ('*Lockwood v Doric*'); *Biogen* sufficiency has its provenance in *Biogen v Medeva* [1997] RPC 1 ('*Biogen*').

3 *Paris Convention for the Protection of Industrial Property*, opened for signature 20 March 1883, 828 UNTS 305 ('*Paris Convention*').

4 As explained in the leading Australian patent law text book, these principles also are in play when considering the priority dates of divisional applications and the allowability of amendments: Colin Bodkin, *Patent Law in Australia* (Lawbook, 2008) 235–6.

5 Amanda J McBratney, 'The Problem Child in Australian Patent Law: "Fair" Basing' (2001) 12 *Australian Intellectual Property Journal* 211.

to the *Patents Act 1949* (UK).[6] Rather, it takes the laws relating to fair basis and adequacy of description as a largely harmonised set of principles. In so doing, it explores the intentions implicit in the Raising the Bar reforms with a focus upon the requirements as internal validity grounds affecting product claims; such claims giving rise to particularly difficult questions of appropriate claim scope.

The argument to be developed in this essay is that while the aims and objectives of the Raising the Bar reforms are sound insofar as they seek to remove some rank formalism infecting Australian law, settling upon *Biogen* sufficiency as the blueprint for reform is problematic in part because of incoherence revealed by its application in the subsequent *Lundbeck* litigation in the UK.[7] An alternative way of considering the questions of product claim scope will be offered which overcomes some of the intrinsic weaknesses in the *Biogen* sufficiency standard.

II THE DESCRIPTION AND THE CLAIMS IN ANGLO PATENT LAW

In the period after the passing of the *Statute of Monopolies* up until 1734 there was no general requirement to furnish a patent specification describing the invention. Most likely, this was introduced in 1734 'on the government's initiative to make discrimination between superficially similar inventions easier'.[8] The specification requirement was typically expressed as an obligation on the patentee to 'particularly describe and ascertain the nature of the said invention'. In the 1778 case of *Liardet v Johnson*, Lord Mansfield's jury instructions commenced a more substantive role for the specification in patent law, beyond that of mere demarcation.[9] At issue was whether a quite abstract description of the patented method satisfied the specification requirement. Lord Mansfield explained to the first jury that 'the meaning of the specification is that others may be taught to do a thing for which the patent is granted' and that 'if the specification [is] false, the patent is void'.[10] This was because 'the meaning of the specification is that after the term [of the Patent] the public shall have the benefit of the discovery'.[11] As

6 This harmonised approach was first judicially stated in *Stauffer Chemical's Application* [1977] RPC 33, 60 and the post-*European Patent Convention* UK environment has become the norm through the evolution to *Biogen* sufficiency: see below Part IV 'The *EPC* and *Biogen* Sufficiency'. While this was accepted as the norm also in Australia (Bodkin, above n 4, 235 treats the fair basis concept as harmonised across all settings), it has been criticised by one commentator who considers that distinct treatment in the 1949 Act would have resulted in greater doctrinal certainty: McBratney, above n 5, 222–5.

7 *Generics (UK) Ltd v H Lundbeck* [2007] RPC 32 (Kitchin J); *H Lundbeck v Generics (UK) Ltd* [2008] EWCA Civ 311; *Generics (UK) Ltd v H Lundbeck* [2009] UKHL 12 ('*Lundbeck*').

8 Christine MacLeod, *Inventing the Industrial Revolution: The English Patent System 1660–1800* (Cambridge University Press, 1988) 51.

9 The published law reports are collected at (1600–1828) 1 HPC 195. The case is extensively discussed in John N Adams and Gwen Averley, 'The Patent Specification: The Role of *Liardet v Johnson*' (1986) 7 *Journal of Legal History* 156. See also the relevant court books of Lord Mansfield and notes of Buller J, published in James Oldham, *The Mansfield Manuscripts and the Growth of English Law in the Eighteenth Century*, *Volume 1* (University of North Carolina Press, 1992).

10 Oldham, above n 9, 754 (reproducing Justice Buller's notes of the instructions).

11 Ibid.

Hulme points out, the importance of Lord Mansfield's instruction was to squarely shift the consideration for the patent grant for an invention from its working in England, to its disclosure through the specification.[12] This in turn led to the explicit conception of the 'social contract' theory of patents: disclosure as the quid pro quo for exclusive patent rights. From *Liardet v Johnson* until 1883, failure to make a full written description of the invention was one of several common law grounds on which a patent grant could be repealed by a writ of *scire facias*. In the 1883 statutory regime, those grounds were inscribed by broad reference as grounds of revocation, a position carried forward in the 1907 Act until amended in 1932.[13] The 1932 reforms inserted 16 express grounds of revocation, many of which were codified common law grounds.[14] One of those express grounds was 'that the complete specification does not sufficiently and fairly describe and ascertain the nature of the invention and the manner in which the invention is to be performed', a revocation ground which was carried forward into the *Patents Act 1949* (UK).[15]

While from 1734 a written specification was mandated (and imbued with a disclosure obligation after 1778), patent claims were not required by either statute or case law. The House of Lords in 1890 held that an early statutory requirement that 'a complete specification must end with a distinct statement of the invention claimed' was merely directory — ie some sort of best-practice request by the Parliament.[16] This position was altered by the 1932 reforms to the grounds of revocation mentioned above. That reform also inserted as an express ground of revocation that 'the complete specification does not sufficiently and clearly ascertain the scope of the monopoly claimed.'[17] Shortly after this reform came the quintessential modern dictum that the patent claim defines the scope of the subject matter in Anglo patent:

> The function of the claims is 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. ... A patentee who describes an invention in the body of a specification obtains no monopoly unless it is claimed in the claims.[18]

12 E Wyndham Hulme, 'On the Consideration of the Patent Grant, Past and Present' (1897) 13 *Law Quarterly Review* 313, 317–8.

13 *Patents, Designs and Trade Marks Act 1883*, 46 & 47 Vict, c 57, s 26(3); *Patents and Designs Act 1907*, 7 Edw 7, c 29, s 25(2)(a).

14 *Patents and Designs Act 1932*, 22 & 23 Geo 5, c 32, s 3 added 16 express revocation grounds to the *Patents and Designs Act 1907*, 7 Edw 7, c 29, s 25, including 'that the complete specification does not sufficiently and fairly describe and ascertain the nature of the invention and the manner in which the invention is to be performed'.

15 *Patents Act 1949*, 12, 13 & 14 Geo 6, c 87, s 32(1)(h).

16 *Vickers v Siddell* (1890) 15 App Cas 496 interpreting *Patents, Designs and Trade Marks Act 1883*, 46 & 47 Vict, c 57, s 5(5).

17 *Patents and Designs Act 1932*, 22 & 23 Geo 5, c 32, s 3 adding the express revocation grounds to *Patent and Designs Act 1907*, 7 Edw 7, c 29, s 25.

18 *Electric & Musical Industries Ltd v Lissen* (1939) 56 RPC 23, 39.

This statement has been adopted as authoritative as to the place of patent claims in modern English patent law; claims are fence posts rather than sign posts.[19] This role of claims was carried forward into the 1949 Act, and indeed amplified insofar as much of that Act was drafted so as to reflect a legislative assumption that claims defined the subject matter of the grant.[20]

Once specifications were unambiguously obliged by the 1932 UK reforms to 'ascertain the scope of the monopoly claimed', the courts soon developed a formal doctrine which ensured a correlation between the description of the invention and that claim. This ensured discipline on an applicant to claim no more than the invention disclosed. In *Mullard v Philco* the House of Lords required that a claim be no more than co-extensive with the invention disclosed. Lord Macmillan asked 'is the claim justified by the inventive idea which the patentee has disclosed?' and then observed:

> A patentee may make a most meritorious discovery and may give an entirely adequate description of his inventive idea ... but when he comes to formulate the claim to his invention he may claim a monopoly wider in extent than is warranted by what he has invented.[21]

In that case a product was claimed by reference to a desirable attribute, rather than the combination of features that went to deliver that attribute. Finding the claim to be impermissibly wide, Lord Macmillan stated: 'I do not think [the patentee] is entitled to claim the article at large apart from the juxtaposition which is essential to the achievement of the result'; the claim 'covers things quite unrelated to [the patentee's] inventive idea'.[22] In a concurring judgment (which described the unduly broad claim as a 'covetous claim'[23]), Lord Alness concisely put the same point thus: 'the invention and the claim do not equiparate'.[24]

One final rider to this brief historical overview is to describe the controversial nature of the product claim. This arises from the inherent breadth of the patent rights associated with a so-called per se product claim. If an inventor devises an inventive method and from that method produces a new and useful product that was not hitherto available, prima facie the inventor is entitled to (aside from claiming the method) make a claim to the product per se. That is to say the product is regarded as *the invention*, and so the patentee may exclude all others from making the product by whatever alternative method (including methods never thought of by the inventor) and exclusive rights extend to all alternative uses for the product (including uses never thought of by the inventor). While the subsequent devisors of new methods of making the product or new uses for the product might be entitled to their own patent rights in those methods or uses, in

19 Lord Hoffmann in *Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] 1 All ER 667, 677 describes Lord Russel's dictum as 'the best-known statement of the status of the claims in UK law'.

20 Hence the expression 'the invention, so far as claimed in any claim ...' is introduced: *Patents Act 1949*, 12, 13 & 14 Geo 6, c 87, s 32.

21 (1936) 53 RPC 323, 345.

22 Ibid 347.

23 Ibid 349.

24 Ibid 348.

all cases during the product patent term they will need to obtain a licence from the pioneer inventor.[25]

III FAIR BASIS AND SUFFICIENCY: UK LAW FROM 1949 TO THE *EPC*

From *Liardet v Johnson* and until long after the enactment of the *Patents Act 1977* (UK) 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.[26] Blanco White stated the sufficiency rule as requiring a description that will enable the skilled addressee to produce 'something' within each claim without an act of further invention.[27] As emphasised by the Australian High Court in 2001, it remains good Australian law — at least until the coming into effect of the Raising the Bar reforms. Lord Hoffmann's 1996 judgment in *Biogen* altered UK law so that 'full width' sufficiency became a requirement of UK law — the description now had to enable the skilled addressee to produce 'everything' with each claim without an act of further invention. This caused one judge to coin the expression 'classic sufficiency' to distinguish the earlier sufficiency rule from '*Biogen* sufficiency'.[28] How this occurred requires an explanation based upon the treatment of the lack of fair basis ground of revocation, which formed part of UK patent law from 1949 to 1977, and the reception within the UK of changes mandated by the UK joining the *European Patent Convention* ('*EPC*').[29]

The 1947 Swan Committee Reports on the *Patents and Designs Act 1942* (UK) — which precipitated the reforms comprising the *Patents Act 1949* (UK) — did not include a recommendation to include lack of fair basis as a revocation ground.[30] However the wholesale patent reforms of 1949 did include within s 32 as a new ground of revocation 'that any claim of the complete specification is not fairly

25 A matter considered both in William Cornish, *Intellectual Property: Omnipotent, Distracting, Irrelevant?* (Oxford University Press, 2004) ch 1 and in obiter dicta by Lord Hoffmann and Jacob LJ in *H Lundbeck v Generics (UK) Ltd* [2008] EWCA Civ 311.

26 A patentee who had disclosed in its description one means to make a new product could make a valid per se product claim, so long as the claim was to the functional features which delivered the 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).

27 T A Blanco White, *Patents for Inventions and the Protection of Industrial Designs* (Sweet and Maxwell, 5th ed, 1983) 128.

28 Justice Neuberger, trial judge in *Kirin-Amgen v Roche Diagnostics GMBH* [2002] RPC 1, sought to distinguish *Biogen* insufficiency issues from what was considered to be insufficiency prior to the 1977 Act, by describing the latter as 'classic insufficiency': at 83 [300].

29 *Convention on the Grant of European Patents*, opened for signature 5 October 1973, 1065 UNTS 199 (entered into force 7 October 1973) ('*European Patent Convention*').

30 UK Board of Trade, *Patents and Designs Act: Final Report of the Departmental Committee*, Cmd 7206 (1947) 21.

based on the matter disclosed in the specification'.[31] While Hansard is laconic on this specific point, it seems clear enough that the holding in *Mullard v Philco* was in effect codified in section to become the validity ground of fair basis in the *Patents Act 1949* (UK).[32] This provenance of the revocation ground of lack of fair basis is supported by subsequent authority, although it was not until twenty years later that fair basis was first judicially considered as a s 32 ground of revocation. In the 1969 case of *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd*, Graham J agreed with counsel that the revocation ground of lack of fair basis 'covers the objection discussed at length in the case of *Mullard v Philco* that a claim which is a "covetous" claim, or one in which the claim does not "equiparate" with the consideration given by the disclosure, is a bad claim'.[33] Later Graham J returned to Lord Allness' judgement in *Mullard v Philco* to apply the s 32 ground to the patent claim before him.[34] Likewise Buckley LJ, within a unanimously supported judgment of the Court of Appeal in 1975, made the following observation:

> As regards the ground of objection that claim 1 is not fairly based on the matter disclosed in the specification, the learned judge cited a long passage from the speech of Lord Macmillan in [*Mullard v Philco*]. It seems to me that Lord Macmillan stated in concise and simple terms the effect of the relevant part of section 32(1)(i) in one sentence ... 'He (the inventor) is not entitled to claim a monopoly more extensive than is necessary to protect that which he himself has said is his invention'.[35]

It is difficult to avoid the conclusion that the fair basis ground of revocation was judicially regarded as the codification of the principle which emerged from *Mullard v Philco*. This conclusion is buttressed by very limited further development of that principle in the hands of English judges from 1949 until its removal as a revocation ground in the *Patents Act 1977* (UK) — a removal mandated by the UK's accession to the *EPC*. Leaving aside one aspect of the judgment in *Olin Mathieson v Biorex* which will be discussed below,[36] there is scant useful guidance by the courts (beyond reciting *Mullard v Philco* passages) on the content of fair basis as a statutory requirement under the 1949 Act. Indeed, Whitford J observed in the mid-1970s that there was 'really no authority' on lack of fair basis as a s 32 revocation ground under the 1949 Act.[37] Thus from the

31 *Patents Act 1949*, 12, 13 & 14 Geo 6, c 87, s 32(i).

32 McBratney, above n 5, 222–5; House of Commons Standing Committee D, Patents and Designs Bill, 7–14 July 1949.

33 [1969] FSR 361, 370 ('*Olin Mathieson v Biorex*').

34 Ibid 384.

35 *Poseidon Industri AB v Cerosa Ltd* [1982] FSR 209, 222.

36 See below Part VIII 'A Concluding Suggestion'.

37 *American Cyanamid Co v Berk Pharmaceuticals* [1976] RPC 231, 259. One line of authority had suggested that the fair basis ground when deployed for *Paris Convention* purposes to enable claims to take a priority date from an earlier, foreign filing had something to do with a normative characterisation of the patentee's conduct: *Letraset Ltd v Rexel Ltd* [1974] RPC 175, 196–7 (Graham J); *Farbenfabriken Bayer's Application* [1973] RPC 698, 703–4; *Stauffer Chemical's Application* [1977] RPC 33, 42. This approach was rejected by the Court of Appeal: at 60–1.

jurisprudence that there is, it is possible to state two fair basis principles which merely restated the effect of *Mullard v Philco*:

1. The issue 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';[38] and
2. This assessment was to occur irrespective of patentee conduct or nebulous considerations of fairness.[39]

IV THE *EPC* AND *BIOGEN* SUFFICIENCY

Under the 1949 Act, the requirement that claims be fairly based was a ground of examination and revocation, but not a ground of opposition.[40] The s 14 opposition grounds did however include insufficiency — an important matter which will be returned to below.

The *EPC* does not permit lack of fair basis to be a ground of opposition or revocation.[41] The *EPC* equivalent to fair basis — a requirement that a claim be 'supported by the description' — is a matter only able to be assessed on examination.[42] Thus the *EPC*-compliant *Patents Act 1977* (UK) could not include lack of fair basis (or, to use the *EPC* language, lack of support for claims) as a revocation ground. The denial of the fair basis revocation ground as an opposition ground within the *EPC* was explained in these terms during the treaty-making process:

> 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.[43]

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

39 *American Cyanamid Co v Upjohn Company* (1970) 1 WLR 1507, 1511; *Stauffer Chemical's Application* [1977] RPC 33, 60–1.

40 *Patents Act 1949*, 12, 13 & 14 Geo 6, c 87, s 14 opposition grounds did not include lack of fair basis.

41 *European Patent Convention* arts 100 (grounds for opposition), 138 (grounds for revocation).

42 Ibid arts 97 (refusal or grant), 84 (the claims).

43 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) 72 (from the Report by the United Kingdom Delegation on Opposition Procedure).

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 traditionally was concerned that textual matters did not get in the way of affording protection to substantive inventive contribution.[44] This led the UK side to push for ambiguity and lack of fair basis as revocation grounds (to deal inter alia with the vague or unduly broad claim), and 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. While conceding ambiguity and 'lack of support' (a 'lack of fair basis' simile) as examination matters, the Continental side largely won the debate in that 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 a deliberate aspect of logic underpinning the pro-patentee nature of the *EPC*.[45]

It is understandable that, when a pillar of domestic law is knocked away by external forces, local patent experts see it as a problem.[46] In 1981, Cornish concluded his textbook discussion on 'Claims and disclosure' under the *Patents Act 1977* (UK) by offering the opinion that '[p]erhaps 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'.[47] 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

44 Hence the respective conceptions of claims as 'fence posts' on the Anglo side, and as 'sign posts' on the Continental side: see generally David J Brennan, 'The Evolution of English Patent Claims as Property Definers' [2005] *Intellectual Property Quarterly* 361, 383–4.

45 M van Empel, *The Granting of European Patents* (AW Sijthoff, 1975) 299.

46 W R Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (Sweet & Maxwell, 1st ed, 1981) 189: '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'.

47 Ibid.

> claim is regarded as insufficient if the disclosure does not provide enough instructions for the full width of the claim.[48]

This 1993 prophecy was made good by the creation of *Biogen* sufficiency three years later by the House of Lords. It was perhaps the deliberateness of this judicial circumvention of the *EPC* that caused the Australian High Court to somewhat acerbically adopt the following characterisation of the UK approach: 'Since the fair basis doctrine no longer exists, it is necessary to invent it.'[49]

However, prior to Robin Jacob's 1993 address, the House of Lords in *Asahi Kasei Kogyo KK's Application* had already commenced down this path through amplifying the concept of sufficiency to mean 'an enabling disclosure'.[50] In *Asahi* the House of Lords found that a piece of prior art (an earlier patent filing) which claimed the same products as those claimed by the patentee, but not how those products were made, did not destroy the novelty of the patentee's claim. That was because although the prior art disclosed the claimed invention, it did not enable it. Something will comprise an enabling disclosure when it contains 'clear and unmistakeable directions to do what the patentee claims to have invented'.[51] By way of obiter Lord Oliver considered that standard of an 'enabling disclosure' was considered to also define what is meant by two description requirements for a valid patent application: (i) the sufficiency requirement (a disclosure of 'the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art'), and (ii) the requirement that the claim or claims 'be supported by the description'.[52]

In *Biogen* a further step was taken by Lord Hoffmann. Under the 1977 Act and prior to *Biogen*, attempts to get sufficiency to perform the 'lack of fair basis' role suggested by Jacob (ie the requirement of 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, Aldous J at trial rejected the proposition that sufficiency could be the vehicle for the type of 'the judicial massage' suggested by Jacob.[53] 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 stretch sufficiency in the precise way suggested by Jacob in 1993.[54]

48 Robin Jacob, 'The Herchel Smith Lecture 1993', [1993] *European Intellectual Property Review* 312, 314–5.

49 *Lockwood v Doric* (2004) 217 CLR 274, 300.

50 *Asahi Kasei Kogyo KK's Application* [1991] RPC 485 ('*Asahi*').

51 Ibid 544 (Lord Jauncey) endorsing a statement from the Court of Appeal in *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457, 485.

52 *Asahi* [1991] RPC 485, 535–7.

53 *Chiron Corporation v Organon Teknika Ltd [No 3]* [1994] FSR 202, 242. However, Whitford J at trial in *Genentech Inc's Patent* [1987] RPC 553, 592 took a different view, which in turn was overturned (albeit in a quite ambiguous way) by the Court of Appeal: [1989] RPC 147, 261 (Mustill LJ), 235–7 (Dillon LJ), 198–200 (Purchas LJ). *Genentech Inc's Patent* is discussed further below.

54 *Biogen v Medeva* [1995] RPC 25, 43–5 (Aldous J); 95–9 (Court of Appeal); [1997] RPC 1, 53–4 (House of Lords). In *Chiron Corporation v Murex Diagnostics* [1996] FSR 153, 178–86 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.

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'.[55] 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.

Lord Hoffmann's judgment relied upon two EPO Technical Board decisions in the examination appeals *EXXON/Fuel Oils* and *GENENTECH I/Polypeptide 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.[56] 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.[57] 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/Polypeptide Expression* the applicant disclosed a particular recombinant technique capable of application across a class of settings.[58] 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.[59] 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 disclosed a principle capable of such general application.[60] 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 capable of characterisation under the *EPC* as both a lack of support issue and an insufficiency issue.[61] In *GENENTECH I/ Polypeptide 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'.[62] The assertion that full claim width sufficiency had 'long been established' was the subject of research in a previous article which concluded that Lord Hoffmann was correct in so far as a relatively obscure line of pre-*EPC* authority (and indeed two cases were pre-

55 [1997] RPC 1, 48, 53. There Lord Hoffmann equated the approach to ascertaining support for *Paris* priority to the approach to ascertaining sufficiency more generally.

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

57 Ibid 155–6.

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

59 Ibid 7.

60 Ibid 7–12.

61 *Biogen* [1997] RPC 1, 54.

62 Ibid 48.

Mullard v Philco) did exist to that effect.[63] Those cases stood for the proposition that a person alleging insufficiency could also argue that although the description enables one embodiment, the claims are so widely drawn that they must be regarded as speculative.[64]

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/Polypeptide Expression* and the broad claim made in *Biogen* was not fully enabled.[65] Valid jurisdiction therefore existed for the claim to be revoked for insufficiency; the requirement of *Biogen* sufficiency was born — albeit as obiter.[66] That was because the claims were found to lack an inventive step because the foreign priority document relied upon by the patentee was expressly required by s 5 of the *Patents Act 1977* (UK) to provide support for the claims and failed to provide such support 'to the full extent of the monopoly claimed'.[67] *Biogen* sufficiency was defined in obiter by equating it with the requirement of support for claims from *Paris Convention* filings.[68] Or, to put it another way, previous authority had harmonised the test for claim support and sufficiency as requiring under both grounds an 'enabling disclosure', and *Biogen* advanced that law further by holding that for both grounds any such disclosure must enable the full width of the claim.[69]

V FAIR BASIS AND SUFFICIENCY: AUSTRALIAN LAW

The Australian Patents Acts of 1952 adopted the same drafting logic as that arrived at in the 1949 UK Act.[70] This regime has been essentially carried forward by the *Patents Act 1990* (Cth), Australia being not required to make the types of

63 *Eastman Kodak Company's Application* [1970] RPC 548, 563–4; *Re Shell Development* (1947) 64 RPC 151; *Re British Celanese* (1934) 51 RPC 192; *Re A Patent by Abraham Esau and C Lorenz Aktiengesellschaft* (1931) 49 RPC 85, discussed in David J Brennan, '*Biogen* Sufficiency Reconsidered' [2009] *Intellectual Property Quarterly* 476.

64 Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents, above n 43, 71.

65 *Biogen* [1997] RPC 1, 51–2.

66 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: [2005] RPC 9, 201–2 [110]–[117].

67 *Biogen* [1997] RPC 1, 49–52.

68 Ibid 53–4. *Paris Convention* art 4H provides that an earlier priority date can be derived from a foreign filing in a *Paris Convention* member state if the priority documents 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 *European Patent Convention* art 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.

69 Endorsing both the 'enabling disclosure' test, and its application to both claim support and sufficiency for application purposes, Lord Hoffmann extended it incrementally in *SmithKline Beecham plc's (Paroxetine Methanesulfonate) Patent* [2006] RPC 10, 335 by suggesting at [27] that the test applied equally to determine the question of sufficiency as a revocation matter.

70 McBratney, above n 5, 231.

changes that the *EPC* obliged the UK to make. However there was little High Court jurisprudence on either sufficiency or fair basis until the last decade. Then two High Court authorities orientated Australian law starkly away from the philosophy underpinning *Biogen* sufficiency — with the 2004 decision doing so with unmistakeable assertiveness. The force of those authorities can be seen as provoking the sufficiency and fair basis Raising the Bar reforms in which the legislature in turn can clearly be seen to be rejecting that orientation in favour of that taken in *Biogen*.

In the 2001 *Kimberly-Clark* decision the High Court considered at length the question of the Australian legal standard for a sufficient disclosure of the invention. In so doing it adopted as correct the statement of Blanco White that a sufficient description is one that will enable the skilled addressee to produce 'something' within each claim without an act of further invention — ie a single embodiment rule.[71] The full implication of this adoption was sheeted home in the 2004 *Lockwood v Doric* decision when the High Court sought to make explicit how this proposition drawn from Blanco White separated Australian and UK patent law:

> The inapplicability in Australia of the reasoning in *Biogen* is heightened by the fact that Lord Hoffmann applied the words 'mechanistic and impoverished', not to the patentee's argument under consideration, but to a 'general rule of European patent law that an invention was sufficiently disclosed if the skilled man could make a single embodiment'. That happens also to be the rule recognised in ... *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd*.[72]

The court emphasised two further points in *Kimberly-Clark* itself. The first was generally accepted; the test of sufficiency asks whether the person skilled in the art will be enabled, assuming that person is seized of the common general knowledge in the field at the priority date of the claim.[73] The second was newly clarified law; whether such a person is enabled to make 'something' within a claim, both the description and the claims 'must be read as a whole' — ie an assessment must not be limited to the description alone.[74]

Fair basis, as a revocation ground in Australia, has been considered at length by the High Court twice; once in the 1977 decision *Olin Corporation v Super Cartridge Co Pty Ltd*,[75] and again in the 2004 *Lockwood v Doric* decision. The approaches adopted in these two cases are inconsistent with the latter adopting (in essence) of the reasoning of Barwick CJ's dissent in *Olin v Super Cartridge*. Aside from these, there is a 1958 priority case involving whether a divisional application was 'in respect of an invention disclosed in' an earlier filing, and two fair basis cases from 1971 decided by Gibbs J — one being a priority case,

71 *Kimberly-Clark* (2001) 207 CLR 1, 17 [25].
72 (2004) 217 CLR 274, 299–300 [67].
73 (2001) 207 CLR 1, 17 [27].
74 Ibid 13 [16].
75 (1977) 180 CLR 236 ('*Olin v Super Cartridge*').

the other dealing with fair basis as an opposition ground. Australian High Court jurisprudence on fair basis — like that of the UK from the 1950s to the 1970s — is not extensive.

In the 1958 *Société des Usines Chimiques Rhône-Poulenc v Commissioner of Patents* decision, Fullagar J was dealing with a divisional application seeking to derive priority from an earlier filing.[76] The 1952 Act required that the filing must have 'disclosed' the invention claimed in the divisional. For this Fullagar J explained — almost as an aside: 'There must, of course, be a real and reasonably clear disclosure'.[77] This sentence has assumed the status of being a definitive statement of the law of fair basis — notwithstanding it being directed to a sufficiency-style requirement of description.

In the first of the 1971 decisions of Gibbs J was also a priority setting.[78] The *Mond Nickel* rules were applied to ask whether the claims of a local application could take their priority from earlier foreign filings under the *Paris Convention* arrangements.[79]

More significant was the second 1971 decision of Gibbs J in *Montecatini Edison Spa v Eastman Kodak Co*.[80] This was an opposition appeal where lack of fair basis was an opposition ground at issue. This was an Australian sister case to one of the UK cases referred to above as one in an obscure line of UK sufficiency authorities; *Re Eastman Kodak*.[81] It may be recalled that the line stood for the proposition that a person alleging insufficiency could also argue that although the description enables one embodiment, the claims were so widely drawn that they must be regarded as speculative. It was this line of authority apparently relied upon by Lord Hoffmann to justify the assertion that *Biogen* sufficiency was consistent with pre-*EPC* UK patent law. Gibbs J noted that the corresponding UK case was also an appeal from an opposition, but one in which Whitford J could not consider lack of fair basis because that was not an opposition ground under the *Patents Act 1949*. Therefore, Whitford J accepted an argument of insufficiency based upon the claims being unduly broad and speculative. Gibbs J observed in relation to Whitford J's decision that 'it is very difficult to separate [the question of fair basing] from insufficiency, in a case of the present kind'.[82] In this statement Gibbs J undertakes the same mental exercise as Lord Hoffmann did in *Biogen* — and indeed which all Australian courts do when they rely upon Fullagar J's *Rhône-Poulenc* sentence in fair basis contexts — by acknowledging that in certain respects sufficiency and fair basis can legitimately be considered

76 (1958) 100 CLR 5 ('*Rhône-Poulenc*').

77 Ibid 11.

78 *F Hoffman-La Roche & Co AG v Commissioner of Patents* (1971) 123 CLR 529.

79 Ibid 538–9. These rules, derived from a decision of the UK Patents Appeal Tribunal in *Re Mond Nickel Company's Application* [1956] RPC 189, were: (1) is the alleged invention as claimed broadly (ie in a general sense) described in the basic application?; (2) is there anything in the basic application which is inconsistent with the alleged invention as claimed?; and (3) does the claim include as a characteristic of the invention a feature as to which the basic application is wholly silent?

80 (1971) 1B IPR 656 ('*Montecatini Edison v Eastman Kodak*').

81 [1970] RPC 548; see above n 63.

82 *Montecatini Edison v Eastman Kodak* (1971) 1B IPR 656, 661.

as corollaries. Moreover, Gibbs J went on to explain — with reference to both *Mullard v Philco* and *Re Eastman Kodak* — that fair basis should be regarded as forbidding claims which cover things quite unrelated to the inventor's inventive idea, and that 'the consideration' given by the patentee in the inventive disclosure cannot be exceeded by the scope of protection claimed.[83] In effect, this was an assertion — consistent with Lord Hoffmann's position — that fair basis and the identified line of sufficiency cases could be equated. Moreover, it was applied in the case to find a lack of fair basis for a claim to a new polypropylene which was defined by its static attributes, but the inventive step involved with the claim related to the use of a particular catalyst in the process of manufacture. The patentee was 'entitled to claim a polypropylene produced by the use of the new catalyst, but is not entitled to claim a polypropylene produced in some different and totally unrelated way'.[84] It was a position repeated by Gibbs J as part of the majority view in *Olin v Super Cartridge*.

The majority holding and Barwick CJ's dissent in relation to four product claims in *Olin v Super Cartridge* offer the most important window into the competing philosophies about fair basis and sufficiency in Australian patent law.[85] The inventive step was identified by the majority to be process-based — a compressive means of making from particular plastics a one-piece moulded shell case for ammunitions. Claims 10–13 were product claims to a one-piece moulded shell case exhibiting certain characteristics, but not qualified by its means of making. It was clear that such a shell was new, useful and resulted from the inventive process. It was equally clear that the same shell could result from a different process. As to whether the four product claims were fairly based, the view of Gibbs J echoed his position in *Montecatini Edison v Eastman Kodak*:

> But the question is whether the claims extend beyond the subject of the invention. In my opinion the inventive step lay in the discovery of the manner of making the articles. The appellant was entitled to a monopoly in respect of an article which carried its invention into effect — that is, an article made in accordance with the process it discovered — but not in respect of an article which might possibly be made by a process entirely different from that invented by the appellant. The principles applicable are stated in the authorities cited in *Montecatini Edison v Eastman Kodak*. Claims 10–13 are not limited to products made in accordance with the processes invented by the appellant; the claims are framed in terms quite unrelated to the appellant's inventive idea. The claims are accordingly not fairly based on the specification.[86]

To similar effect was the joint judgment of Stephen and Mason JJ. After adopting an extensive passage from Lord Macmillan's judgment in *Mullard v Philco* as

83 Ibid 663.

84 Ibid.

85 (1977) 180 CLR 236.

86 Ibid 250–1.

the relevant exposition of the Australian law of fair basis,[87] the joint judgment reasoned:

> The invention supplied a process for the production of the article and at the relevant time it was the only process by which the article could be produced.
>
> Is this enough to justify the appellant obtaining a monopoly for the production of the article whether it be produced by its process or not? We do not think it is. It would enable the appellant to assert its monopoly against others who develop other, more efficient and more economic means of manufacturing the product, thereby giving it a reward greater than the consideration which it has provided in the form of the disclosure which it has made. It would tend to discourage research and development in the same field, much to the disadvantage of the public, and to that of manufacturers who are minded to develop improved versions of the product.[88]

In contrast, Barwick CJ dissented in relation to the fair basis of claims 10–13. The substantive part of the analysis commenced with a passage that would come to achieve a talisman-like status in Australian fair basis law — similar to that achieved by Fullagar J's *Rhône-Poulenc* sentence:

> The question whether the claim is fairly based is not to be resolved, in my opinion, by considering whether a monopoly in the product would be an undue reward for the disclosure. Rather, the question is a narrow one, namely whether the claim to the product being new, useful, and inventive, that is to say, the claim as expressed, travels beyond the matter disclosed in the specification.[89]

Barwick CJ found that the four claims before him were not limited to the production of the stated physical characteristics by the disclosed method:

> But that, in my opinion, does not mean that a claim for the resultant physical characteristics, if suitably described, was not fairly based on the disclosure ... [The inventor] has, in my opinion, given to the public the structure as well as inventing one means of producing those physical characteristics which constitute invention.[90]

The nub of the divergence was thus clearly set out. The majority in *Olin v Super Cartridge* identified that the inventive step disclosure was of a compressive process of manufacture, rather than being a 'revolutionary product'.[91] Therefore,

87 Ibid 263.

88 Ibid 264.

89 Ibid 240.

90 Ibid 242.

91 Ibid 264 (Stephen and Mason JJ):

> This is not a case in which the inventor has conceived of and brought into existence an entirely new or revolutionary product which stands so far in advance of, and apart from, previous developments that it works a radical transformation in the field in which it is introduced, as, for example, the invention of the electric light globe.

the product claims must be confined by the nature of the advance disclosed. Claims 10–13 to a product limited merely by characteristics were held to be unduly broad and lacking a fair basis; a product claim (claim 17) was fairly based because it could be construed as being limited to products made by the compressive process. Barwick CJ's dissent on claims 10–13 foreshadows the High Court's views in *Kimberly-Clark* and *Lockwood v Doric*; the inventor was entitled to stake the broad product claims having disclosed a method of producing one thing within each claim.

In *Lockwood v Doric* the High Court considered a claim to door locks which included the novelty-conferring integer of an internal deadlock 'release means' activated by external key-entry.[92] While the specific mechanical operation of such a release means was described in the body of Lockwood's specification, in the patent's claim 1 this was claimed in the abstract so as to cover any internal deadlock release means capable of external activation. Revocation was sought on the ground that the claim was unduly broad insofar as it lacked a fair basis. Doric argued that the patentee had disclosed a specific mechanism, but had too broadly claimed any products achieving that mechanism's result regardless of whether that mechanism was employed. All four Federal Court judges considering the case agreed with that argument.[93] A five-member High Court unanimously overturned this decision. In so doing three assertions were made:

1. The drafting of the Australian patent statute 'compelled' a holding that no overlap existed whatsoever between the grounds of lack of fair basis and insufficiency;[94]

2. *Mullard v Philco* should be treated 'with great care' and was of 'very limited assistance' in the construction lack of fair basis in the Australian patent statute;[95]

3. That the result in *Olin v Super Cartridge* was explained on the basis that claims 10–13 were claims not limited by key elements forming aspects of the process disclosed in the body of the specification, and that Barwick CJ's dissent was not on a matter of principle but rather on a matter of claim construction.[96]

The first assertion is unsupported by anything related to patent law history. The second proposition is entirely inconsistent with patent law history in which fair basis emerged as the codification of the holding in *Mullard v Philco*. But it is the third of these propositions — the treatment of the *Olin v Super Cartridge* authority — which is the most startling. Rather than grapple with the clear difference as a matter of principle separating the majority and minority in *Olin v Super Cartridge*, the *Lockwood v Doric* High Court chose almost to pretend

92 (2004) 217 CLR 274.

93 *Doric Products Pty Ltd v Lockwood Security Products Pty Ltd* (2001) 192 ALR 306 (Hely J); *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2003) 56 IPR 479 (Wilcox, Branson and Merkel JJ).

94 (2004) 217 CLR 274, 293 [49].

95 Ibid 295–6 [56]–[57].

96 Ibid 296.

that no such difference exists. Manifestly the *Olin v Super Cartridge* majority reasoning was doing the very thing that was done in *Mullard v Philco* and *Biogen*; to assess the breadth of the claim against the nature of the inventive disclosure. To be sure the High Court may choose to reject such an approach; but it should then candidly acknowledge that it disagrees as a matter of principle with the approach taken by the *Olin v Super Cartridge* majority. The failure to do so enabled the *Lockwood v Doric* court both to adopt the dissenting Barwick CJ position in *Olin v Super Cartridge* and to simultaneously posture as though the Australian law of fair basis had remained constant. But this sort of judicial methodology comes with a price.[97]

Regardless of methodology, the result in *Lockwood v Doric* is clear; the broad claim was fairly based because the inventor had disclosed one release means. Although full-scope enablement as the standard for fair basis (*Biogen* sufficiency) sits comfortably with the holdings in *Montecatini Edison v Eastman Kodak* and *Olin v Super Cartridge*, that standard was forcefully rejected in *Lockwood v Doric*. Rather, the test emerges as one predominately of form rather than substance; a claim will be fairly based if the other matter in the specification shows that the invention disclosed is not narrower than what is claimed. To underscore its rejection of full-scope enablement, the final passages of the reasoning returned to *Kimberly-Clark*. In rejecting an argument by Doric that the broad, indeterminate and abstract claim 1 was not fairly based in view of the specific nature of Lockwood's disclosure:

> One source of these unfairnesses was said to be the fact that [sufficiency], on the construction given by this Court in *Kimberly-Clark*, is complied with if the complete specification enables the addressee to produce something within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty: but Doric, whilst willing to attempt to sap life from *Kimberly-Clark*, prudently eschewed any attack upon that binding authority.[98]

Five years later, the very first issue that IP Australia identified in seeking to raise Australian patentability standards was full description and fair basis. That government agency took direct aim at the outcome arrived at by the High Court in *Kimberly-Clark* and *Lockwood v Doric*, and the resultant Raising the Bar reforms represent a legislative means to 'sap life' from both authorities.

97 It is, for example, difficult to take seriously the Court's assertion that to find a lack of fair basis in claim 1 would 'radically change the law': *Lockwood v Doric* (2004) 217 CLR 274, 311. A vivid and acerbic reaction to the decision is offered by David Catterns, '*Lockwood v Doric* — Fair Basis and the High Court' (2006) 65 *Intellectual Property Forum* 34.

98 *Lockwood v Doric* (2004) 217 CLR 274, 311–12. However, doubt remains in lower courts about the application of the law of fair basis there stated. In *Pfizer Overseas Pharmaceuticals v Eli Lilly* (2005) 225 ALR 416, which involved claims to the use of a product, rather than the product per se, the patent specification disclosed that the use of a compound exhibited a particular biochemical activity that was useful in treating male impotence. A claim to the use of any compound that exhibited the same biochemical activity as the disclosed compound divided the Full Federal Court on the issue of fair basis. The majority (French and Lindgren JJ) agreed with the trial judge that the broad use claim was not fairly based: at 471–4 [268]–[277]; Crennan J dissented: at 498–502 [409]–[423]. Both majority and minority applied the High Court's 2004 *Lockwood v Doric* decision.

VI RAISING THE BAR TO *BIOGEN* SUFFICIENCY

The Raising the Bar reforms replace the existing statutory text of the sufficiency and fair basis requirements. Sufficiency — currently expressed as 'describe the invention fully' — will be replaced with 'disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art'.[99] Fair basis — which is presently that 'the claim or claims must be ... fairly based on the matter described in the specification' — will become 'the claim or claims must be supported by matter disclosed'.[100] The new statutory text and its context point unmistakably to a desire to adopt *Biogen* sufficiency as the new, more rigorous standard for Australian patent law.

The reform process commenced with an IP Australia consultation paper published in March 2009. It correctly observed the effect of *Kimberly-Clark* and *Lockwood v Doric* and proposed that s 40 of the Act be amended to 'introduce descriptive support requirements analogous to those applied in other jurisdictions including that the whole scope of the claimed invention be enabled'.[101] A follow-up consultation paper in November 2009 refined this to two specific reform proposals: (i) for sufficiency to be expressed as a rule that required 'the applicant to describe the invention fully in a manner which enables the invention to be performed across the whole scope of the claim or claims by a person skilled in the relevant art without undue experimentation'; and (ii) for fair basis to become a requirement that the claims be 'supported by' the matter described in the specification.[102] An Exposure Draft of the Raising the Bar reforms released in early 2011 included the amendments to sufficiency and fair basis set out above. It was accompanied by a Draft Explanatory Memorandum which stated in relation to the sufficiency reforms:

> The item is intended to modify the wording of s 40(2)(a) of the Act so as to require enablement across the full scope of the claim, while adopting language that is consistent with that applying in other jurisdictions. The wording in the amendment is similar to s 14(3) of the UK patents legislation, which has been interpreted as imposing this requirement.[103]

The case cited as requiring full-scope enablement was *Biogen*. In the final Explanatory Memorandum this text remained, however another House of Lords authority was added as a citation; *Lundbeck*.[104] This case is discussed below, and suggests that the concept of full scope enablement is not clear-cut.[105] The new

99 *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) sch 1 item 8.

100 Ibid sch 1 item 9.

101 IP Australia, 'Getting the Balance Right: Toward a Stronger and More Efficient IP Rights System' (Consultation Paper, March 2009) 8.

102 IP Australia, 'Toward a Stronger and More Efficient IP Rights System' (Consultation Paper, November 2009) 5.

103 Draft Explanatory Memorandum, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth) 21.

104 Explanatory Memorandum, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth) 47 n 65.

105 See below Part VII 'The *Lundbeck* Dilemma'.

'supported by matter disclosed' standard was explained in the Draft Explanatory Memorandum as requiring:

> [That] the scope of the claims must not be broader than is justified by the extent of the description, drawings and contribution to the art[;] ... a degree of enablement, which is not necessarily present in the concept of 'fair basis'[; and that] ... the full scope of the claims must be enabled ... by what is disclosed in the description and drawings.[106]

The third explanation listed above was cross-referenced explicitly to the new sufficiency requirement. In the Final Explanatory Memorandum explanations two and three were removed, but in their place was the following quite explicit statement of Parliamentary intention: 'This item is intended to align the Australian requirement with overseas jurisdictions' requirements (such as the UK).'[107] This latter point was buttressed in the Second Reading Speech.[108]

It is impossible to avoid the conclusion that in the Raising the Bar reforms the Australian Parliament has rejected as 'mechanistic and impoverished' the High Court's approach in *Kimberly-Clark* and *Lockwood v Doric*, preferring in its place the principle of *Biogen* sufficiency. That principle — as enunciated by Lord Hoffmann — explicitly integrates sufficiency and support for claims as reciprocal concepts, and where each requires full-scope enablement.

VII THE *LUNDBECK* DILEMMA

It was noted above that in the final Raising the Bar Explanatory Memorandum the UK concept of full-scope enablement was linked to an additional case that did not feature in the Draft Explanatory Memorandum; *Lundbeck*. In *Lundbeck* both Lord Hoffmann and Jacob LJ sat together on the Court of Appeal,[109] prior to being upheld by the House of Lords.[110] It was a case which provided an opportunity for them to reassess their views on sufficiency. This was because it involved an appeal from a judge who had found as *Biogen* insufficient a claim to an organic chemical product.[111]

In *Lundbeck* at trial, Kitchin J found that a claim to a known enantiomer, escitalopram, first isolated from a known racemate, citalopram, could give

106 Draft Explanatory Memorandum, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth) 22–3.

107 Explanatory Memorandum, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth) 49.

108 Commonwealth, *Parliamentary Debates*, Senate, 22 June 2011, 3485–9 (Kim Carr): 'Importantly, the amended provisions mirror similar provisions in the United Kingdom and Europe. It is intended that Australian courts will have regard to developments in the law in the courts of these other jurisdictions when interpreting the new provisions, and will develop Australian law in a consistent fashion'.

109 *H Lundbeck v Generics (UK) Ltd* [2008] EWCA Civ 311.

110 *Generics (UK) Ltd v H Lundbeck* [2009] UKHL 12.

111 *Generics (UK) Ltd v H Lundbeck* [2007] RPC 32 (Kitchin J).

no rights to escitalopram per se.[112] 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. When reading Kitchin J's reasoning, it is difficult to avoid the conclusion that he was merely making a fair fist of applying *Biogen* sufficiency, as he was required to do under the doctrine of precedent. It is also possible to see in that approach much similarity with the approach of the *Olin v Super Cartridge* High Court majority's reasoning in holding that the claims to the cartridge per se, identified merely by attributes, lacked a fair basis. In both instances the courts identified that, for the product claims, the disclosed inventive contribution had a strongly performative or process-based nature, and a product claim unconstrained by that nature went beyond that inventive foundation.

In *Lundbeck*, when 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 Jacob LJ qualify what is meant by full-width enablement. Lord Hoffmann stated, supported by the Court, that where a product is the invention, '[i]t is sufficiently enabled if the specification and common general knowledge enables the skilled person to make it. One method is enough.'[113] Jacob LJ, while in agreement with Lord Hoffmann, made explicit the consequences 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.[114]

The conclusion of the Court of Appeal was endorsed unanimously by the House of Lords.[115] In both appellate courts *Biogen* was not distinguished on the ground that it had biotechnology as its 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.[116] Instead, *Biogen* was distinguished on the ground that biotechnology products there were claimed by being the result of recombinant technology — ie a process. Once any element of a product was defined by a process, it was accepted that for the claim to be *Biogen* sufficient the product claim must be limited to the disclosed process. The product claim in *Lundbeck* was not considered to be of this nature, and therefore escaped the logic

112 Ibid [250]–[265].

113 *H Lundbeck v Generics (UK) Ltd* [2008] EWCA Civ 311, [27].

114 Ibid [54].

115 *Generics (UK) Ltd v H Lundbeck* [2009] UKHL 12.

116 *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) annex 1C ('*Agreement on Trade-Related Aspects of Intellectual Property Rights*') art 27(1).

of *Biogen* altogether.[117] Thus, UK sufficiency patent law in *Biogen-Lundbeck* has an almost Janus-like quality. One strict rule for product claims with a process element — ie *Biogen* sufficiency applies — whereas a relaxed rule is in place for per se claims lacking a process element. For the latter claims classic sufficiency applies.

The distinction drawn in *Lundbeck* between product claims which involve a process element and those which do not, strains credulity. The claim to escitalopram in *Lundbeck* was not anticipated by citalopram because it was interpreted to mean escitalopram 'isolated' from citalopram.[118] 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. And indeed it was in that very process where, at least in the English courts,[119] the inventive step was found to reside. Why should a claim to an 'isolated' molecule escape the logic of *Biogen* sufficiency when a claim to a 'synthetic' molecule does not? In truth both products result from a process, regardless of the claiming linguistics.

It is worthwhile to reconsider *Olin v Super Cartridge* and *Lockwood v Doric* on the basis that the Australian Parliament's intention in reforming sufficiency and fair basis is to have us arrive at a point legally equivalent to that set under the *Biogen-Lundbeck* approach.

As explained above, in *Olin v Super Cartridge* the majority identified that it was an inventive breakthrough in a compressive injection moulding process that enabled the making of a new type of plastic munitions shell. The four product claims which were not limited to being the result of the compressive process were revoked; however a product claim which was construed to be so limited was found to be fairly based.[120] The dissenter Barwick CJ objected — pertinently — to the revocation of the four claims by referring to one of those claims in the following terms:

> It is apparent that this claim is not limited to a product being the result of the use of the appellant's process. To have so limited the claim would have added little, if anything, to the monopoly given by a patent for the process.[121]

Under the *Biogen-Lundbeck* approach how would the four claims be regarded? This is unclear. It seems it all depends upon whether the claims are interpreted as being defined by the process as a limiting integer. If so, the claims must satisfy *Biogen* sufficiency and not implicate within their scope any product made through

117 [2008] RPC 19, 449 [42] (Lord Hoffmann); [2009] UKHL 12, [24]–[27] (Lord Walker), [49]–[52] (Lord Mance), [99] (Lord Neuberger).

118 [2008] EWCA Civ 311, [12] (Lord Hoffmann); [50] (Jacob LJ).

119 Compare the quite different way Lindgren J conceived of the inventive step under Australian law being that the goal of obtaining the isomer would not have been adopted 'as a matter of routine' with an expectation of yielding an improved drug: *Alphapharm v H Lundbeck* (2008) 76 IPR 618.

120 *Olin v Super Cartridge* (1977) 180 CLR 236, 250–1 (Gibbs J); 263–5 (Stephen and Mason JJ).

121 Ibid 240.

the agency of a different process. If not, a per se product claim is allowed insofar as it merely needs to satisfy the classic sufficiency standard.

In *Lockwood v Doric* the High Court found (in a subsequent appeal) that, as against the common general knowledge in the field of lock designs, an inventive step resided in the provision of a solution to the 'locked-in' problem afflicting deadlocks.[122] That solution involved a breakthrough in the specification of the interoperable static properties of a lock rather than performative or process-based qualities. That is to say it was more (to use the language of the *Olin v Super Cartridge* majority) a 'revolutionary product' rather than a breakthrough relating to something in the lock-making process. The invention was the product, seemingly even more so than the product claimed in *Lundbeck* itself. Therefore, under the *Biogen-Lundbeck* approach, claim 1 in *Lockwood v Doric* is likely to satisfy the sufficiency standard so long as one method of making such a lock was enabled by the disclosure. That is to say, the result would likely remain unaffected.

VIII A CONCLUDING SUGGESTION

Any coherent patent system must have a comprehensible legal means to deal with an otherwise valid yet unduly broad claim in a granted patent. The Raising the Bar reforms attempt to redress what is perceived as too weak patent validity standards for product claims. The single-embodiment sufficiency rule applied in *Kimberly-Clark* and a textually circular and toothless fair basis rule applied in *Lockwood v Doric* are in the sights of its initiator (IP Australia) armed with Lord Hoffmann's *Biogen* judgment and emboldened by his disparagement of such similar rules in Europe as 'mechanistic and impoverished'. However it is doubtful that what has emerged from *Biogen-Lundbeck* offers a coherent approach that is able to be practically applied by judges.

The problem of undue claim scope is difficult because 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*. Central to *Mullard v Philco* was inventive step. *Biogen* sufficiency on the other hand 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 pure process claims. The coherence of this confinement is dubious.

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 the best key to this area of law. A test along the lines of 'whether the product claim involves the disclosed inventive step in a proximate way' may offer a helpful way to think about whether the description

122 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2007) 235 CLR 173.

'fully' supports any claim in dispute. This moves the consideration to first identifying the inventive step that the claim is said to involve — is it the discovery of static product features that when combined confer interoperable synergies or is it the discovery of a method of making a useful product that was previously unavailable? This seems to shed light on the proper scope of any product claim.

Thinking about testing claim scope by naked recourse to inventive step is not unprecedented. This was essentially what was undertaken in *Mullard v Philco*. There are hints of this style of thinking in other cases. In the course of a discussion on whether certain amendments to a chemical product patent substantially changed the nature of the invention claimed, Lord MacDermott stated that:

> But when the inventor can say that his inventive step is such that each of the various new products which manifest it must have therapeutic value, and that although some of them have never been made, then, as I see the matter, the state of the art will have changed. It will have lost its empirical nature, at least to some extent, and the chemist will have found some law or principle by which he may *predicate* therapeutic effect in advance.[123]

To similar effect is a fair basis test put forward by Graham J in *Olin Mathieson v Biorex*:

> Where, then, is the line to be drawn between a claim which goes beyond the consideration and one which equiparates with it? In my judgment ... it depended upon whether or not it was possible to make a sound prediction. If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so.[124]

These statements get to the heart of the matter; a qualitative assessment of the nature of the inventive step, and a measuring of claim scope against that nature. Does the nature of the inventive step disclosed enable a claim to be drawn of this scope?

By such an approach, one aspect of that assessment might include whether the inventive step has a dynamic performative nature, or a nature better described as the specification of static elements. Such distinctions might assist in analysing the legitimate scope of any product claim. However, this also necessarily involves an assessment of the merit of the inventive step, so as to evaluate that merit as against claim scope. Such an assessment is one that judges in the common law tradition have been loath to undertake, in the same way that they refuse to assess the adequacy of consideration in contract law. Therein lies the paradox of the whole problem of the unduly broad claim. If a mere 'scintilla' of inventiveness will support a claim, the question becomes unduly broad relative to what? Australian law has tested this by requiring a single embodiment and textual conformity to avoid digging deeper into questions of inventive merit for the purposes of sufficiency and fair basis. UK law has signalled a desire to start digging deeper,

123 *May & Baker v Boots Pure Drug Co* (1950) 67 RPC 23, 50 (emphasis added).

124 *Olin Mathieson v Biorex* [1969] FSR 361, 386.

and the Raising the Bar reforms makes manifest that the Australian Parliament wants Australian courts to follow the UK. However, the *Biogen-Lundbeck* approach is a flawed work-in-progress. The only way to deal with the unduly broad claim in the spirit of the Raising the Bar reforms is for courts to roll up their sleeves and begin evaluating within a predictable methodology the inventive step involved in the claim. Only then can the legitimacy of claim scope be properly considered.